PATHWAY TO A VACCINE: EFFORTS TO DEVELOP A SAFE, EFFECTIVE AND ACCESSIBLE COVID-19 VACCINE

VIRTUAL HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

TUESDAY, JULY 21, 2020

Serial No. 116–121

Printed for the use of the Committee on Energy and Commerce
govinfo.gov/committee/house-energy
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE
55–508 PDF WASHINGTON : 2024

COMMITTEE ON ENERGY AND COMMERCE

FRANK PALLONE, JR., New Jersey
Chairman

BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
ELIOT L. ENGEL, New York
DIANA DEGETTE, Colorado
MIKE DOYLE, Pennsylvania
JAN SCHAKOWSKY, Illinois
G. K. BUTTERFIELD, North Carolina
DORIS O. MATSUI, California
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
JERRY MCNERNEY, California
PETER WELCH, Vermont
BEN RAY LUJAN, New Mexico
PAUL TONKO, New York
YVETTE D. CLARKE, New York, *Vice Chair*
DAVID LOEBSACK, Iowa
KURT SCHRADER, Oregon
JOSEPH P. KENNEDY III, Massachusetts
TONY CÁRDENAS, California
RAUL RUIZ, California
SCOTT H. PETERS, California
DEBBIE DINGELL, Michigan
MARC A. VEASEY, Texas
ANN M. KUSTER, New Hampshire
ROBIN L. KELLY, Illinois
NANETTE DIAZ BARRAGÁN, California
A. DONALD MCEACHIN, Virginia
LISA BLUNT ROCHESTER, Delaware
DARREN SOTO, Florida
TOM O'HALLERAN, Arizona

GREG WALDEN, Oregon
Ranking Member
FRED UPTON, Michigan
JOHN SHIMKUS, Illinois
MICHAEL C. BURGESS, Texas
STEVE SCALISE, Louisiana
ROBERT E. LATTA, Ohio
CATHY MCMORRIS RODGERS, Washington
BRETT GUTHRIE, Kentucky
PETE OLSON, Texas
DAVID B. MCKINLEY, West Virginia
ADAM KINZINGER, Illinois
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
BILL JOHNSON, Ohio
BILLY LONG, Missouri
LARRY BUCSHON, Indiana
BILL FLORES, Texas
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
RICHARD HUDSON, North Carolina
TIM WALBERG, Michigan
EARL L. "BUDDY" CARTER, Georgia
JEFF DUNCAN, South Carolina
GREG GIANFORTE, Montana

PROFESSIONAL STAFF

JEFFREY C. CARROLL, *Staff Director*
TIFFANY GUARASCIO, *Deputy Staff Director*
MIKE BLOOMQUIST, *Minority Staff Director*

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

DIANA DEGETTE, Colorado
Chair

JAN SCHAKOWSKY, Illinois
JOSEPH P. KENNEDY III, Massachusetts, *Vice Chair*
RAUL RUIZ, California
ANN M. KUSTER, New Hampshire
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
PAUL TONKO, New York
YVETTE D. CLARKE, New York
SCOTT H. PETERS, California
FRANK PALLONE, JR., New Jersey *(ex officio)*

BRETT GUTHRIE, Kentucky
Ranking Member
MICHAEL C. BURGESS, Texas
DAVID B. MCKINLEY, West Virginia
H. MORGAN GRIFFITH, Virginia
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
JEFF DUNCAN, South Carolina
GREG WALDEN, Oregon *(ex officio)*

C O N T E N T S

[1] The information has been retained in committee files and also is available at https://docs.house.gov/meetings/IF/IF02/20200721/110926/HHRG-116-IF02-20200721-SD004.pdf.

PATHWAY TO A VACCINE: EFFORTS TO DEVELOP A SAFE, EFFECTIVE AND ACCESSIBLE COVID-19 VACCINE

TUESDAY, JULY 21, 2020

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

The subcommittee met, pursuant to call, at 10:00 a.m., via Cisco Webex online video conferencing, Hon. Diana DeGette (chairwoman of the subcommittee) presiding.

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

Also present: Representatives Eshoo, McNerney, Upton, O'Halleran, McMorris Rodgers, Bucshon, and Carter.

Staff Present: Kevin Barstow, Chief Oversight Counsel; Billy Benjamin, Systems Administrator; Jesseca Boyer, Professional Staff Member; Jeffrey C. Carroll, Staff Director; Sharon Davis, Chief Clerk; Austin Flack, Staff Assistant; Waverly Gordon, Deputy Chief Counsel; Zach Kahan, Outreach and Member Services Coordinator; Chris Knauer, Oversight Staff Director; Kevin McAloon, Professional Staff Member; Joe Orlando, Executive Assistant; Kaitlyn Peel, Digital Director; Peter Rechter, Counsel; Tim Robinson, Chief Counsel; Andrew Souvall, Director of Communications, Outreach and Member Services; Benjamin Tabor, Policy Analyst; Kimberlee Trezciak, Chief Health Advisor; Jennifer Barblan, Minority Chief Counsel; Mike Bloomquist, Minority Staff Director; S. K. Bowen, Minority Press Secretary; William Clutterbuck, Minority Staff Assistant; Diane Cutler, Minority Detailee Oversight and Investigations; Theresa Gambo, Minority Human Resources/Office Administrator; Tyler Greenberg, Minority Staff Assistant; Tiffany Haverly, Minority Communications Director; Brittany Havens, Minority Professional Staff, Oversight and Investigations; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; Brannon Rains, Minority Policy Analyst; Alan Slobodin, Minority Chief Investigative Counsel, Oversight and Investigations; Peter Spencer, Minority Senior Professional Staff Member, Environment and Climate Change; and Everett Winnick, Minority Director of Information Technology.

Ms. DEGETTE. Good morning, everybody. The subcommittee on Oversight and Intelligence will now come to order.

Today the committee is holding a hearing entitled "Pathway to a Vaccine; Efforts to Develop a Safe, Effective, and Accessible COVID-19 Vaccine." The purpose of today's hearing is to examine the research, development, and manufacturing of potential COVID-19 vaccines.

And I really want to express my thanks to all of our witnesses for coming today, because this is obviously the area of greatest concern to our constituents right now, one of the areas.

Due to the COVID emergency, today's hearing is being held remotely. All Members and staff will be participating via video conferencing and as part of our proceeding, microphones will be set on mute for the purpose of eliminating inadvertent background noise. Members and witnesses, you will need to unmute your microphone each time you wish to speak.

If at any time during the hearing I'm unable to Chair the hearing, the chairman of the full committee, who I see on my screen here, Frank Pallone, will serve as chair until I'm willing or able to return.

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

And I want to inform all Members and witnesses that we are expected to have a series of hearings on the floor all day today. I expect that what we will do is, we will rotate through, so that—both on the Republican and Democratic side, so that we will be able to continue the hearing as seamlessly as possible. When has to go vote, Mr. Pallone will preside and vice versa.

Mr. Guthrie, I would hope that the Republicans can do the same thing.

The Chair will now recognize herself for the purposes of an opening statement.

Mr. GUTHRIE. My question is, are you muted, Chairwoman?

Ms. DEGETTE. I'm muted because my staff is looking for my opening statement, which was not included in my briefing notebook.

I will make my opening statement in just one moment.

Mr. Pallone, since they're looking for my opening statement, I think I'll recognize you for purposes of an opening statement for 5 minutes.

Mr. PALLONE. Thank you. Thank you, Chairwoman DeGette.

Ms. DEGETTE. Sorry about that.

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

Mr. PALLONE. Today we'll explore the pursuit of vaccines that could help contain the largest public health crisis the Nation has faced in over a century. The extent of this crisis cannot be overstated. In just six months, more than three million people in the United States have been diagnosed with COVID-19, and more than 140,000 Americans have died.

Sadly, these numbers will only continue to increase as new COVID-19 cases are surging all across the Nation, climbing to nearly 80,000 each day. COVID-19 has wreaked havoc on the country's physical, mental, and economic well-being, particularly among communities of color and low-income communities.

Today we'll hear from some of the manufacturing companies who have been working with the Federal Government to develop a safe and effective vaccine, and I'm pleased that you're all with us today so we can hear how Federal investments are being used to find a vaccine.

But I want to extend special thanks to your colleagues and research teams who are working around the clock to develop a vaccine. Ultimately, it will be the collaboration of your efforts, in partnership with the administration and the support of Congress that will make a COVID-19 vaccine possible.

And along those lines, I also appreciate the chance to bring some transparency to the Trump administration's Operation Warp Speed efforts. This transparency will be crucial to securing the American people's trust that a COVID-19 vaccine will be made available only once it's proven to be safe and effective.

Now, Congress has already taken action to support these vital efforts. This spring, Congress provided billions of dollars for COVID-19 vaccine development and manufacturing efforts and other medical countermeasures.

Then two months ago, the House passed the HEROES Act. This comprehensive legislation, which strengthened the Nation's ability to fight the pandemic by bolstering the Strategic National Stockpile and increasing funding for research, development, and manufacturing of vaccines and treatments.

It would also require the Trump administration to submit to Congress a vaccine plan identifying the activities being undertaken to manufacture, distribute, and administer a COVID-19 vaccine safely.

As I said, the House passed the HEROES Act more than two months ago, and yet the Senate has failed to take that up, even as new infection and death rates soar, and this delay is compounded by the fact that so much more could have been done to mitigate the impacts of the disease.

From day one, President Trump has done everything he can to minimize the severity of this pandemic and to undermine his public health experts. The administration still has not developed a national plan to combat the pandemic. It has no national testing strategy, no one in charge of the supply chain, and little effort to invoke the Defense Production Act.

And we're again seeing a resurgence of the same problems that hampered our response efforts this spring, such as testing shortages, PPE, and medical supply shortages and attacks on public health experts.

These problems will likely extend to the development and distribution of a COVID-19 vaccine as long as Trump is President, and we will want a COVID-19 vaccine to be developed as soon as possible, but before a vaccine is distributed, public health experts must ensure that it is safe, effective, and available to all who need it.

My fear is that FDA will be forced by the Trump administration to approve a vaccine that lacks effectiveness. So we must also ensure that our supply chains can safely manufacture the vaccine in the quantities necessary, along with the vials, needed syringes, and other products required needed to administer it.

This committee has a long history supporting efforts related to vaccine development and deployment. I'm hopeful that if we prioritize public health and strategic preparation, and the administration finally learns from its mistakes, that our collective efforts will result in a safe, effective, and accessible COVID-19 vaccine.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today, we will explore the pursuit of vaccines that could help contain the largest public health crisis the nation has faced in over a century.

The extent of this crisis cannot be overstated. In just six months, more than 3.5 million people in the United States have been diagnosed with COVID-19 and more than 140,000 Americans have died.

Sadly, these numbers will only continue to increase as new COVID-19 cases are surging all across the nation—climbing to nearly 80,000 each day. COVID-19 has wreaked havoc on the country's physical, mental, and economic well-being, particularly among communities of color and low-income communities.

Today, we will hear from some of the manufacturing companies who have been working with the Federal Government to develop a safe and effective COVID-19 vaccine. I am pleased that you are all with us today so we can hear how federal investments are being used to find a vaccine.

I want to extend special thanks to your colleagues and research teams who are working around the clock to develop a vaccine. Ultimately it will be the collaboration of your efforts, partnership with the Administration and the support of Congress that will make a COVID-19 vaccine possible.

Along those lines, I also appreciate the chance to bring some transparency to the Trump Administration's Operation Warp Speed efforts. This transparency will be crucial to securing the American people's trust that a COVID-19 vaccine will be made available only once it's proven to be safe and effective.

Congress has already taken action to support these vital efforts. This spring, Congress provided billions of dollars for COVID-19 vaccine development and manufacturing efforts, and other medical countermeasures.

Then two months ago, the House passed the Heroes Act. This comprehensive legislation would strengthen the nation's ability to fight the pandemic by bolstering the Strategic National Stockpile, and increasing funding for research, development, and manufacturing of vaccines and treatments. It would also require the Administration to submit to Congress a vaccine plan identifying the activities being undertaken to manufacture, distribute, and administer a COVID-19 vaccine safely.

As I said, the House passed the Heroes Act more than two months ago, and yet, the Senate has failed to take it up even as new infection and death rates soar.

This delay is compounded by the fact that so much more could have been done to mitigate the impacts of the disease.

From day one, President Trump has done everything he can to minimize the severity of this pandemic and to undermine his public health experts. The Administration still has not developed a national plan to combat the pandemic, it has no national testing strategy, no one in charge of the supply chain and little effort to invoke the Defense Production Act (DPA).

We are again seeing a resurgence of the same problems that hampered our response efforts this spring, such as testing shortages, PPE and medical supply shortages, and attacks on public health experts.

These problems will likely extend to the development and distribution of a COVID-19 vaccine, as long as Trump is President.

We all want a COVID-19 vaccine to be developed as soon as possible, but before a vaccine is distributed, public health experts must ensure that it is safe, effective, and available to all who need it. My fear is that FDA will be forced by the Trump Administration to approve a vaccine that lacks effectiveness. We also must ensure that our supply chains can safely manufacture the vaccine in the quantities necessary, along with the vials, needles, syringes, and other products required to administer it.

This Committee has a long history of supporting efforts related to vaccine development and deployment. I am hopeful that if we prioritize public health and strategic preparation, and the Administration finally learns from its mistakes, that our collective efforts will result in a safe, effective, and accessible COVID-19 vaccine. And with that I would like to yield the remainder of my time, to Representative Eshoo, the chair of our Health Subcommittee.

And I'd like to now yield the remainder of my time to the chairwoman of our Health Subcommittee, Congresswoman Anna Eshoo of California.

Ms. ESHOO. Thank you for yielding, Mr. Pallone, and good morning to my colleagues and to our witnesses.

Each of you represents great hope for Americans and for people around the world. And speaking of hope, we can't help but as we mourn his loss, think of our colleague John Lewis, who always said, keep your eye on the prize.

And I think that's really what we're talking about this morning because all eyes are on your companies to develop a vaccine that will allow us to return to school, to work, to hug our loved ones, and to begin the process of recovering from the COVID-19 pandemic.

But with that opportunity comes great responsibility to ensure that your products are safe, effective, affordable, and accessible. So I look forward to hearing from each of you today how you're going to maintain transparency and accountability for the American taxpayer and the American patient, how you're scaling up domestic manufacturing, your suggestions for a nationwide vaccine distribution plan, and how Congress can tackle the pervasive vaccine hesitancy in our country.

So thank you again to each of you for testifying, to the chairwoman of this subcommittee for holding this hearing.

And I look forward to not only hearing from you but working with you, and I yield back.

[Ms. Eshoo prepared statement appears at the conclusion of the hearing.]

Ms. DEGETTE. The gentle lady yields back. Thank you so much.

The Chair now recognizes the ranking member of the subcommittee, Mr. Guthrie, for 5 minutes.

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

Mr. GUTHRIE. Thank you, Madam Chair. I appreciate you for holding this critical and important hearing. First, we do have three members—I know I don't have to make a unanimous consent request, but just for the record, that Mr. Upton, Mrs. McMorris Rodgers, and Mr. Carter will be sitting in,—waving on to the subcommittee.

Thank you for holding this important hearing. The COVID-19 pandemic has been a tough challenge for our Nation, but the incredible effort to develop safe, effective, and accessible COVID-19 vaccines gives me great hope that we are on a very promising path to solutions.

The unified effort by vaccine manufacturers, the research community, and Federal partners to work with each other is remark-

able, and I am confident that through this unity of purpose, cooperation, focus, expertise, and the tremendous amount of resources, our vaccine efforts will prove successful.

Companies are using their own funds, at their own risk, to conduct research and develop vaccine candidates and create more manufacturing capacity. Some companies are putting up to $1 billion at risk.

The Federal Government has poured billions more dollars into the vaccine effort. The U.S. Government is supporting several initiatives to help accelerate the development of vaccines for COVID-19. Two key initiatives are Operation Warp Speed, and the accelerating COVID-19 therapeutic interventions and vaccines, otherwise known as the ACTIV partnership.

Operation Warp Speed was established to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. The ACTIV public-private partnership also aims to speed vaccines and treatment options.

The testimony today from witnesses of leading COVID-19 vaccine candidates will be of vital interest to the American people. The companies represent a diverse portfolio of vaccine platforms with promising preliminary data.

For example, Moderna's experimental COVID-19 vaccine reportedly provided all 45 of its healthy volunteers with the immune responses to the virus in an ongoing, early-age study, with volunteers who received two doses showing antibody levels exceeding those found in people who have recovered from COVID-19, and were generally well tolerated.

The University of Oxford AstraZeneca candidate might complete human trials by September, and agreements have been lined up to produce two billion doses by 2021. In addition, there reportedly is positive news on the response seen from the antibodies and T-cells.

Last month some vaccine experts expressed concerns that the Trump administration might exert political pressure to put a COVID-19 vaccine on the market before it's ready, and they wanted assurances from the FDA that a vaccine will not be authorized unless there are at least 30,000 people in each phase 3 clinical study. It appears such assurances have been made by the Trump administration.

The leading vaccine candidates, under the auspices of Operation Warp Speed, are required to enroll 30,000 participants in phase 3 trials. As Dr. Fauci, the director of the National Institute of Allergies and Infectious Diseases at the NIH, and Dr. Stephen Hahn, Commissioner of the FDA, testified before the full committee on June 23, there will be no shortcuts on safety and efficacy standards.

The speed is being achieved through the financial risk—the financial risks, I'll repeat that—of manufacturers, not safety or efficacy, in accelerating their capacity to produce millions of doses and not at the expense of safety and efficacy.

Concerns have also been raised about vaccine confidence and whether there will be sufficient vaccination coverage to ensure herd immunity. We need to have a high percentage of American people vaccinated to achieve the protective effect of herd immunity to save American lives.

Regarding supply and manufacturing capacity, we will hear testimony of how these companies are working cooperatively to address potential supply concerns. These companies in the aggregate are committing to manufacture billions of doses.

I look forward to hearing more about how each of these companies before us today are planning to scale up their manufacturing efforts to ensure an adequate supply of an authorized or approved COVID-19 vaccine.

Finally, on access and affordability, many manufacturers have told committee staff that if their vaccine effort is successful, they do not want cost to be a barrier to accessing a COVID-19 vaccine. This is a welcome commitment, and we are eager to discuss it further.

The mission to get a safe and effective vaccine has been a driving force for committee Republicans. At the beginning of this month, Leader Walden and I released the second pillar of its second-wave project, with the recommendations on how to better prepare production and distribution of vaccines and therapeutics.

I welcome all of our witnesses and look forward to their testimony and discussion of these issues.

And Madam Chair, I yield back.

[The prepared statement of Mr. Guthrie follows:]

PREPARED STATEMENT OF HON. BRETT GUTHRIE

Thank you, Chair DeGette, for holding this critically important hearing. I appreciate our bipartisan approach to this hearing and believe this hearing is a great example of how the Energy and Commerce Committee works. We can come together—Republicans and Democrats—to solve vital issues presented by the Coronavirus pandemic.

The COVID-19 pandemic has been a tough challenge for our nation, but the incredible effort to develop safe, effective, and accessible COVID-19 vaccines gives me great hope that we are on a very promising path to solutions. The unified effort by vaccine manufacturers, the research community, and federal partners to work with each other is remarkable, and I am confident that through this unity of purpose, cooperation, focus, expertise, and the tremendous amount of resources, our vaccine efforts will prove successful.

Companies are using their own funds at their own financial risk to conduct research, develop vaccine candidates, and create more manufacturing capacity. Some companies are putting up to $1 billion at risk.

The Federal Government has poured billions more dollars into the vaccine effort. The U.S. government is supporting several initiatives to help accelerate the development of vaccines for COVID-19. Two key initiatives are Operation Warp Speed and the Accelerating COVID-19 Therapeutic Interventions and Vaccines, otherwise known as the ACTIV partnership. Operation Warp Speed was established to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. The ACTIV public-private partnership also aims to speed vaccine and treatment options.

The testimony today from witnesses of leading COVID-19 vaccine candidates will be of vital interest to the American people. The companies represent a diverse portfolio of vaccine platforms with promising preliminary data. For example, Moderna's experimental COVID-19 vaccine reportedly provided all 45 of its healthy volunteers with immune responses to the virus in an ongoing early-stage study, with volunteers who received two doses showing antibody levels exceeding those found in people who have recovered from COVID-19 and were generally well tolerated.

The University of Oxford-AstraZeneca candidate might complete human trials by September and agreements have been lined up to produce two billion doses by 2021. In addition, there reportedly is positive news on the responses seen from the antibodies and T-cells.

Last month, some vaccine experts expressed concerns that President Trump might exert political pressure to put a COVID-19 vaccine on the market before it's ready, and they wanted assurances from the FDA that a vaccine will not be authorized un-

less there are at least 30,000 people in each Phase 3 clinical study. It appears such assurance has been made. The leading vaccine candidates under the auspices of Operation Warp Speed are required to enroll 30,000 participants in Phase 3 trials. As Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, and Dr. Stephen Hahn, the Commissioner of the U.S. Food and Drug Administration,testified before the Full Committee on June 23rd, there will be no shortcuts on safety and efficacy standards. The speed is being achieved through the financial risk of manufacturers accelerating their capacity to produce millions of doses, not at the expense of assuring safety and efficacy.

Concerns have also been raised about vaccine confidence, and whether there will be sufficient vaccination coverage to ensure herd immunity. We need to have a high enough percentage of the American people vaccinated to achieve the protective effect of herd immunity and to save American lives.

Regarding supply and manufacturing capacity, we will hear testimony of how these companies are working cooperatively to address potential supply concerns. These companies in the aggregate are committing to manufacture billions of doses. I look forward to hearing more about how each of the companies before us today are planning to scale up their manufacturing efforts to ensure an adequate supply of an authorized or approved COVID-19 vaccine.

Finally, on access and affordability, many manufacturers have told Committee staff that if their vaccine effort is successful, they do not want cost to be a barrier to accessing a COVID-19 vaccine. This is a welcome commitment, and we are eager to discuss it further.

The mission to get safe and effective vaccines has been a driving focus for Committee Republicans. At the beginning of this month, Leader Walden and I released the second pillar of its Second Wave Project with recommendations on how to better prepare production and distribution of vaccines and therapeutics.

I welcome all of our witnesses and look forward to their testimony and discussion of the issues.

Ms. DEGETTE. I thank the gentleman. The Chair will now give her opening statement.

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

Today's hearing will examine efforts to develop a safe and effective COVID-19 vaccine, and I know I speak for everybody this morning in saying we're all rooting for a safe vaccine to be developed, manufactured, and accessible for all Americans as soon as possible. This committee and Congress have long supported Federal efforts to advance the development and availability of novel vaccines.

This spring we provided billions of dollars in new funding to support vaccine research, development, and manufacturing efforts, funds that are assisting some of the companies testifying today in developing COVID-19 vaccines.

This committee has a responsibility—to conduct oversight of those congressional investments. Today, we'll have the opportunity to hear directly from some of the manufacturers working on potential COVID-19 vaccines, and how the funds Congress has provided are being put to use in these unprecedented times.

I thank the witnesses again for being willing to participate in such a critical hearing at a critical time. We're now six months into this national public health crisis, and COVID-19 case numbers are continuing to climb at a staggering rate.

Today more than 140,000 Americans have lost their lives to this disease. As long as the Trump administration continues to shirk its

responsibility to lead a coordinated national response effort, sicknesses and deaths are going to continue to mount.

It's also clear that we're not going to be able to contain COVID-19 in the United States without a rapid and robust deployment of public health measures and medical countermeasures, including a safe and effective vaccine.

We know that containing the virus as soon as possible is of utmost importance. Millions of Americans face continued unemployment and loss of health insurance. Across the country, parents are making impossibly hard decisions about childcare and school participation, and frontline health workers, essential employees, people of color, seniors, and others most vulnerable to COVID-19 face daily threats to their survival.

Fortunately, there are reasons to be optimistic that the search for a COVID-19 vaccine is headed in the right direction. According to statements from several of the companies testifying today, and based on the speed at which they are progressing through clinical trials, it is possible that a COVID-19 vaccine may become available by the end of this year or early next year. That's a rare bit of good news in this harrowing time.

But while some public health experts are bullish on the development of a vaccine, we must remind ourselves that plenty can still go wrong, and so the anticipated timeline is not guaranteed. Determining a vaccine's safety and efficacy is merely the first of the many challenges that must be addressed if we are to successfully manufacture and distribute a vaccine to Americans and to people around the globe.

While we await the results of clinical trials, the necessary manufacturing capacity and distribution infrastructure must be bolstered so an eventual vaccine is readily available for hundreds of Americans once it is determined to be safe and effective.

Additionally, as the global pursuit of a COVID-19 vaccine speeds forward, we must be prepared not only to produce the vaccine itself but to have the supplies required to administer the vaccine, such as vials and syringes. Last month, the committee heard from governors across the country just how unprepared we were as a Nation to provide basic testing supplies, like swabs and reagents and personal protective equipment.

The lack of these supplies undermined our response effort, and we're still feeling the effects today. I remain concerned that with all of the efforts around the world to develop a vaccine, governments and manufacturers, like with testing supplies and PPE, may be all competing for a limited supply of items such as glass vials and syringes. These supplies are critical in ultimately delivering a vaccine should one prove successful.

Further, critical decisions must be made now across the Federal Government, industry, and public health shareholders, regarding vaccine rollout efforts and public and provider education. This is especially true given the value of any future COVID-19 vaccine lies in the willingness of the American people to get vaccinated and their ability to access and afford it.

Developing and distributing a COVID-19 vaccine requires a national plan, one that the Trump administration has stated is still

being developed, despite this committee urging the administration to adopt such a plan two months ago.

But time is of the essence, and now is the time to prepare for a nationwide vaccine program. If developed, a vaccine will be instrumental in protecting the health and well-being of the Nation. While we are all rooting for all of your collective success, we must make sure it's safe, effective, and ultimately affordable to all Americans who need it.

This committee will continue to conduct oversight to ensure these goals remain the focus of the pursuit for a COVID-19 vaccine.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE

Today, the Energy and Commerce Committee continues its oversight of the nation's response to the COVID-19 pandemic. Today's hearing will examine efforts to develop a safe and effective COVID-19 vaccine. I know I speak for all of us this morning in saying that we are all rooting for a vaccine to be developed, manufactured, and accessible for all Americans as soon as possible.

This Committee and Congress have long-supported federal efforts to advance the development and availability of novel vaccines. This spring, we provided billions of additional dollars in new funding to support vaccine research, development, and manufacturing efforts-funds that are assisting some of the companies testifying today in developing COVID-19 vaccines.

This Committee has a responsibility to conduct oversight of these investments. Today, we'll have the opportunity to hear directly from some of the manufacturers working on potential COVID-19 vaccines and how the funds Congress provided are being put to use in these unprecedented times. I thank the witnesses for being willing to participate in such a critical hearing.

We are now six months into this national public health crisis and COVID-19 case numbers are continuing to climb at a staggering rate. To date, more than 140,000 Americans have lost their lives.

As long as the Trump Administration continues to shirk its responsibility to lead a coordinated, national response effort, sicknesses and deaths will continue to mount.

It is also clear that we will not be able to contain COVID-19 in the United States without a rapid and robust deployment of public health measures and medical countermeasures-including a safe and effective vaccine.

We know that containing the virus as soon as possible is of upmost importance. Millions of Americans face continued unemployment and loss of health insurance. Across the country, parents are making impossibly hard decisions about child care and school participation. And frontline health workers, essential employees, people of color, seniors, and others most vulnerable to COVID-19 face daily threats to their survival.

Fortunately, there are reasons to be optimistic that the search for a COVID-19 vaccine is headed in the right direction.

According to statements from several of the companies testifying today and based on the speed at which they are progressing through clinical trials, it is possible that a COVID-19 vaccine may become available by the end of this year or early next year. That is a rare bit of good news in these harrowing days.

But while some public health experts are bullish on the development of a vaccine, we must remind ourselves that plenty can still go wrong, and any anticipated timeline is not guaranteed.

Determining a vaccine's safety and efficacy is merely the first of many challenges that must be addressed if we are to successfully manufacture and distribute a vaccine to Americans and people around the globe.

While we await the results of clinical trials, the necessary manufacturing capacity and distribution infrastructure must be bolstered so an eventual vaccine is readily available for hundreds of millions of Americans once it is determined to be safe and effective.

Additionally, as the global pursuit of a COVID-19 vaccine speeds forward, we must be prepared, not only to produce the vaccine itself, but also to have the supplies required to administer the vaccine, such as vials and syringes.

Last month, this Committee heard from governors across the country just how unprepared we were as a nation to provide basic testing supplies such as swabs and

reagents and personal protective equipment, or "PPE." The lack of these supplies undermined our response effort and we are still feeling the effect today.

I remain concerned that with all the efforts around the world to develop a vaccine, governments and manufacturers—like with testing supplies and PPE—may all be competing for a limited supply of items such as glass vials and syringes. These supplies are critical in ultimately delivering a vaccine should one prove successful.

Further, critical decisions must be made now across the Federal Government, industry, and public health stakeholders regarding vaccine roll-out efforts and public and provider education. This is especially true given that the value of any future COVID-19 vaccine lies in the willingness of the American people to get vaccinated and their ability to access and afford it.

Developing and distributing a COVID-19 vaccine requires a national plan. One that the Trump Administration has stated is still being developed—despite this Committee urging the Administration to adopt such a plan two months ago. But time is of the essence and now is the time to prepare for a nationwide vaccine program.

If developed, a vaccine will be instrumental in protecting the health and well-being of the nation. While we are all rooting for your collective success, we must make sure that it is safe, effective, and ultimately affordable to all Americans who need it. This Committee will continue to conduct oversight to ensure these goals remain the focus of the pursuit for a COVID-19 vaccine.

And with that, I am pleased to yield 5 minutes to the ranking member of the full committee, Mr. Walden.

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

Mr. WALDEN. Well, thank you very much, Chair DeGette. I want to thank you for holding today's hearing on an incredibly important and timely topic.

I also want to welcome today's witnesses. We know you and your colleagues are hard at work to develop medical countermeasures, including the vaccines that we're here to discuss today. You are literally working to save the world. So we greatly appreciate you taking time to participate in today's hearing.

Energy and Commerce Committee Republicans continue to closely examine current issues related to COVID-19 and how to best prepare for an uptick in cases at the same time as the flu season hits us this fall. Last month, we released a report with recommendations on the first pillar of our work.

I've got those reports here, Madam Chair, which we'd like to have inserted in the record. Earlier this month committee Republicans released a second pillar focusing on vaccines and therapeutics. This report includes a series of important recommendations that officials should consider to better position the country to produce and distribute vaccines and therapeutics.

Ms. DEGETTE. Without objection.

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

As discussed in our report, there are extensive efforts led by the Federal Government, in partnership with the private sector, to develop medical countermeasures for COVID-19 including Operation Warp Speed.

Operation Warp Speed is facilitating, at an unprecedented pace, the development, manufacturing, and distribution of COVID-19 vaccines. One of the many goals of Operation Warp Speed is to have as much as 300 million doses of a safe, effective vaccine for COVID-19 available to Americans by January of 2021.

The speed with which we have been able to identify vaccine candidates and move into critical trials is simply unprecedented. To put it simply, this could not have been done without the private sector, and they have been an integral part of this Herculean effort.

The collaboration we have seen over the past few months, between the Federal Government, the Trump administration, and the private sector, is truly extraordinary, and I commend all those who are involved.

At the committee's June 23 hearing, we heard Dr. Fauci say we are taking financial risks, not risks to safety, no risk to the integrity of the science, but financial risk to be able to be ahead of the game, to make safe and effective vaccines available to the American public.

In addition to hearing today an update on the status of your efforts to develop vaccine candidates, we also want to hear all this unprecedented speed does not mean—does not mean—sacrificing safety or efficacy.

Along those lines, we also need to know how your companies are helping to build vaccine confidence in the U.S. This is a critically important topic that spans COVID-19 and beyond. It is made more urgent by the fact that once a COVID-19 vaccine is proven safe and effective and is authorized by the FDA, we want Americans to feel confident in getting that vaccine.

This is also vital when thinking about the fast approaching fall and the intersection of COVID-19 and the influenza season. We need to ensure not only that the vaccine is available, but also that it is accessible. Rural communities frequently find themselves on the outside looking in. When it comes to COVID-19, no American should be left behind.

As you all continue your work to provide a safe and effective vaccine, I ask that you also take into consideration the need for a robust manufacturing and distribution process, providing this vaccine in a timely manner to all Americans from every walk of life.

We also want to hear about your efforts that are under way to ensure there are sufficient amounts of ancillary supplies such as glass vials, in order to package and distribute vaccines to Americans. This is another issue we need to be taking action on now to ensure the availability of an unauthorized or—excuse me—of an authorized or approved vaccine to Americans as quickly as possible.

So I want to thank you all for being here today. If there are things you need help on from the Congress, we want to hear from you and do our part to be a good partner to provide this vaccine and therapeutics to American citizens who are suffering from COVID or want to make sure they never get it.

With that, Madam Chair, I yield back the balance of my time.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Chair DeGette, I want to thank you for holding today's hearing on an incredibly important and timely topic. I also want to welcome today's witnesses. We know you and your colleagues are hard at work to develop medical countermeasures, including the vaccines that we are here to discuss today. You are literally working to save the world, so we greatly appreciate you making time to participate in today's hearing.

Energy and Commerce Committee Republicans continue to closely examine current issues related to COVID-19 and how to best prepare for an uptick in cases at the same time as flu season hits us. Last month, we released a report with recommendations on the first pillar of our work, focused on COVID-19 testing and surveillance. Earlier this month, Committee Republicans released the second pillar, focusing on vaccines and therapeutics. The report includes a series of important recommendations that officials should consider to better position the country to produce and distribute vaccines and therapeutics.

As discussed in our report there are extensive efforts led by the federal government, in partnership with the private sector, to develop medical countermeasures for COVID-19, including Operation Warp Speed. Operation Warp Speed facilitates, at an unprecedented pace, the development, manufacturing, and distribution of COVID-19 vaccines. One of the many goals of Operation Warp Speed is to have as much as 300 million doses of a safe and effective vaccine for COVID-19 available to Americans by January 2021.

The speed with which we have been able to identify vaccine candidates and move into clinical trials is unprecedented. To put it simply—this could not be done without the private sector and they have been an integral part of this herculean effort. The collaboration we have seen over the past few months between the federal government and the private sector is extraordinary and I commend these efforts.

At the Committee's June 23 hearing, Dr. Fauci stated, "we are taking financial risks, not risks to safety, not risk to the integrity of the science, but financial risks to be able to be ahead of the game" to make safe and effective vaccines available to the American public. In addition to hearing today an update on the status of your efforts to develop vaccine candidates, we also want to hear how this unprecedented speed does not mean sacrificing safety or efficacy.

Along those lines, we also need to know how your companies are helping to build vaccine confidence in this country. This is a critically important topic that spans beyond COVID-19. It is made more urgent by the fact that once a COVID-19 vaccine is proven safe and effective, and is authorized or approved by the FDA, we want Americans to feel confident in getting a vaccine. This is also vital when thinking about the fast-approaching fall and the intersection of COVID-19 and the influenza season.

We need to ensure not only that a vaccine is available, but also that it is accessible. Rural communities frequently find themselves on the outside looking in. When it comes to COVID-19, no one should be left behind. As you all continue your work to provide a safe and effective vaccine, I ask that you also take into consideration the need for a robust manufacturing and distribution process capable of providing this vaccine in a timely manner to all Americans from every walk of life.

We also want to hear about efforts underway to ensure there are a sufficient amount of ancillary supplies, such as glass vials, in order to package and distribute vaccines to Americans. This is another issue we need to be taking action on now to ensure availability of an authorized or approved vaccine to Americans as quickly as possible.

I thank of all of our witnesses for appearing today and I look forward to hearing your testimony.

Ms. DEGETTE. I thank the gentleman, and the Chair asks unanimous consent that Members' written opening statements be made a part of the record.

Without objection, so ordered.

The Chair also announces we have several members of the full committee who will be waving onto this hearing today from the majority—Congresswoman Eshoo, Congressman McNerney, Congressman O'Halleran—and as we heard, from the minority—Congressman Upton, Congresswoman McMorris Rodgers, Congressman Bucshon, and Congressman Carter.

I now want to introduce the witnesses for today's hearing—Dr. Mene Pangalos is the executive vice president, biopharmaceuticals R&D of AstraZeneca. Welcome.

Dr. MacAya Douoguih, the head of clinical development and medical affairs for Janssen vaccines of Johnson & Johnson.

Dr. Julie Gerberding—good to see you, Julie—executive vice president and chief patient officer, Merck.

Dr. Stephen Hoge, president, Moderna.

And Mr. John Young, chief business officer of Pfizer.

Thanks to all of you for appearing today. It's really important to hear what you have to say.

Now, I know all the witnesses are aware that the committee is holding an investigative hearing and when doing so, we have the practice of taking testimony under oath.

Does anyone have any objection to testifying under oath?

Let the record reflect that the witnesses have responded no.

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

Does any of you desire to be accompanied by counsel during your testimony today?

Let the record reflect the witnesses have responded no.

Good news, I'm not going to make you rise, but if you'd please raise your right hand so you may be sworn in.

[Witnesses sworn.]

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

The Chair will now recognize our witnesses for 5-minute written summaries of their written statements. There's a timer on your screen that will count down the time, and it turns red when your 5 minutes has come to an end.

And so first I'm going to recognize for 5 minutes, Dr. Pangalos. You're recognized.

TESTIMONY OF DR. MENELAS PANGALOS, EXECUTIVE VICE PRESIDENT, BIOPHARMACEUTICALS R&D, ASTRAZENECA; DR. MACAYA DOUOGUIH, HEAD OF CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS, JANSSEN VACCINES, JOHNSON & JOHNSON; DR. JULIE L. GERBERDING, EXECUTIVE VICE PRESIDENT AND CHIEF PATIENT OFFICER, MERCK; DR. STEPHEN HOGE, PRESIDENT, MODERNA; AND MR. JOHN YOUNG, CHIEF BUSINESS OFFICER, PFIZER

STATEMENT OF MENE PANGALOS, Ph.D.

Dr. PANGALOS. Thank you very much, Chairwoman DeGette, Ranking Member Guthrie, and members of the subcommittee.

I'm Dr. Menelas Pangalos, and I'm privileged to be responsible for AstraZeneca's research and development activity, from discovery through late-stage development for its biopharmaceuticals therapeutic areas.

I'm here today to convey AstraZeneca's strong commitment to ongoing efforts to develop and manufacture vaccines and therapeutics for the prevention and treatment 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 finding safe and effective solutions for the COVID-19 pandemic for the United States and across the world.

With respect to the COVID-19 vaccine, our strategic approach is focused on partnering with scientists, governments, international organizations, and manufacturers to establish agreements for de-

velopment, supply, and distribution of the vaccine, in an equitable manner around the world, should it prove to be effective and tolerated.

To support our goal of providing broad and equitable access as quickly as possible, we've entered these agreements with the United States and certain other governments and organizations that a supply of hundreds of millions of doses of our vaccine. The cost of the dose of the vaccine under those agreements will be provided at no profit to AstraZeneca.

I would first like to provide some background on AstraZeneca. We're a global, science-led, biopharmaceutical company with our North American headquarters in Wilmington, Delaware, and one of our three global R&D headquarters located in Gaithersburg, in Maryland.

Overall, we have approximately 13,000 employees in the U.S., with 12 operations—operating in 12 States, including in Puerto Rico, and in total, AstraZeneca operates in over a hundred countries, and we're leveraging that global footprint and resources to address this worldwide crisis.

Today I'll focus on three core aspects of AstraZeneca's approach to advancing novel vaccine and therapeutics for COVID-19.

First, AstraZeneca is seeking to develop a novel vaccine for the prevention of COVID-19 and has entered into a license agreement with the University of Oxford for the global development, production, and supply of their COVID-19 vaccine candidate, which we're now calling AZD1222.

In the United States, to avoid any delays that could result in unnecessary loss of life, we're scaling up to manufacture up to 300 million doses of vaccine to be available immediately on approval or emergency use authorization.

Our agreements across the world amount to supply approximately two billion doses, and we're building parallel supply chains with partners to support a broad and equitable global access.

We fully support the mission, as a regulatory agency such as the U.S. FDA, to ensure that our vaccine is determined to be safe and effective, based on sound science and data before receiving any approval or emergency use authorization. Sound science, and patient safety and health, are and will continue to remain our top priority in this effort.

Another vaccine candidate has begun late-stage clinical trials now based on data from both preclinical studies in phase ½ clinical trials in over a thousand healthy volunteers. And just yesterday, we announced some of the data from that phase ½ trial, which showed a robust immune response in all the participants tested. We hope the results from our late-stage trials, planned to involve nearly 50,000 volunteers, will be available by this fall.

Second, we're advancing a combination of monoclonal antibodies against SARS-CoV-2 in collaboration with Vanderbilt University. This program is supported by BARDA and DARPA through a development, and we are aiming to initiate clinical trials in the next few weeks.

Third, we're investigating our approved medicines to see how they could benefit COVID-19 patients, particularly those severely ill patients. For example, our trial with our BTK inhibitor,

Calquence, will assess whether we can reduce the exaggerated immune response, or cytokine storm, associated with a COVID-19 infection.

Our SGLT2 inhibitor, Farxiga, is also being explored to protect against organ damage in patients hospitalized with COVID-19.

In addition to these efforts, we've donated three million masks for healthcare workers across the United States, and addressing this pandemic is an urgent priority for our company. We come to work every day focusing on this goal and that our efforts will save lives and alleviate the devastating humanitarian, social, and economic consequences of the ongoing pandemic throughout the world.

Chairwoman DeGette, Ranking Member Guthrie, and members of the subcommittee, on behalf of AstraZeneca, thank you for the opportunity to participate in today's hearing. We appreciate your interest in these important issues, and I look forward to answering your questions.

[The prepared statement of Dr. Pangalos follows:]

Statement of
Sir Menelas Pangalos, Ph.D.
Executive Vice President
Biopharmaceutical Research & Development
AstraZeneca

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

Pathway to a Vaccine:
Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine

July 21, 2020

Chairwoman DeGette, Ranking Member Guthrie, and Members of the Subcommittee, I am Dr. Menelas Pangalos, Executive Vice President, Biopharmaceuticals Research and Development ("R&D") at AstraZeneca. I have been with AstraZeneca since 2010, and I am responsible for R&D activities from discovery through late-stage development for cardiovascular, renal and metabolism, respiratory, and immunology diseases. I am here today to convey to you AstraZeneca's strong commitment to ongoing efforts to develop and manufacture vaccines and therapeutics for the prevention and treatment 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 finding safe and effective solutions for the COVID-19 pandemic in the U.S. and across the world.

With respect to the COVID-19 vaccine, our strategic approach has focused on partnering with scientists, governments, international organizations, and manufacturers to establish agreements for the development, supply and distribution of the vaccine in an equitable manner across the world, should it prove effective and well-tolerated. *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.*

I would first like to provide some background on AstraZeneca. We are 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 three core aspects of AstraZeneca's approach to advancing novel vaccines and therapeutics for COVID-19:

- *First*, AstraZeneca is seeking to develop a novel vaccine for the prevention of COVID-19. AstraZeneca has entered into an exclusive licensing arrangement with the University of Oxford for the global development, production, and supply of the University's potential COVID-19 vaccine candidate, AZD1222.

  In the U.S., to avoid any delays that could result in the unnecessary loss of life, we are 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. Our agreements so far across the world amount to supply of approximately two billion doses, and we are building a number of parallel supply chains with partners around the world to support broad and equitable global access.

  AstraZeneca's development and manufacturing programs are designed to satisfy all applicable regulatory approval and emergency use authorization standards. We fully support the mission of regulatory agencies, such as the U.S. Food and Drug Administration ("FDA"), to ensure that vaccines and other medical products are determined to be safe and effective based on sound science and data before receiving approval or emergency use authorization. *Sound science and patient safety and health are, and will continue to remain, our top priorities in this effort.*

  We are proud to confirm that our novel vaccine candidate has begun late-stage clinical trials based on data from pre-clinical studies and Phase I/II clinical trials in over 1,000 healthy volunteers. We are rapidly progressing these clinical programs with the hope that results from our late-stage trials, which are currently planned to involve close to 50,000 volunteers collectively, will be available this fall.

- *Second*, through our scientific expertise in infectious disease and proprietary antibody discovery technology, we have rapidly mobilized our research efforts toward discovering novel coronavirus-neutralizing antibodies as a prophylactic and possible treatment approach against COVID-19 disease.

  We are advancing a combination of monoclonal antibodies against the SARS-CoV-2 spike protein through pre-clinical development following a collaboration agreement with Vanderbilt University. This came at the same time that we signed an interagency agreement with the U.S. Biomedical Advanced Research and Development Authority ("BARDA") and the U.S. Defense Advanced Research Projects Agency ("DARPA") to support the Phase I clinical trial and the manufacturing of the investigational product for testing in Phase I.

  The team is currently designing an accelerated development program, working with scientists, governments, multilateral organizations, and manufacturers around the world, with the aim of reaching clinical trials within a matter of weeks.

- *Third*, we have initiated new clinical trials to investigate our new and existing medicines to see how they could protect organs from damage or suppress the body's overactive immune response in severely ill patients. As the SARS-CoV-2 virus is new, the scientific community is constantly learning about the virus and advancing our understanding on how best to tackle and treat this disease.

  For example, a new global clinical trial for our Bruton's tyrosine kinase ("BTK") inhibitor, Calquence®, will assess the potential of the treatment in the exaggerated immune response, or cytokine storm, associated with COVID-19 infection in severely ill patients. Our sodium-glucose cotransporter 2 ("SGLT2") inhibitor, Farxiga®, is being explored as a potential medicine to protect against organ damage in patients hospitalized with COVID-19 and at risk of developing serious complications.

In addition to these efforts on a vaccine and therapeutics, we have donated three million face masks to be distributed to healthcare workers across the United States to aid these brave and dedicated individuals in battling COVID-19.

Addressing the COVID-19 pandemic is an urgent priority for our company. We come to work every day focusing on the goal that our efforts will save lives and alleviate the devastating humanitarian, social, and economic consequences of the ongoing pandemic throughout the world. We thank the support of members of this Subcommittee in our efforts to achieve these goals, and we appreciate the opportunity to testify today.

I. AstraZeneca is Committed to Ending the COVID-19 Pandemic and Saving Lives

AstraZeneca is collaborating with scientists, governments, multilateral organizations and manufacturers around the world to advance a novel vaccine and monoclonal antibody therapy for the prevention and treatment of COVID-19. In addition to our commitment to enable broad and equitable access across the world to approximately two billion doses of AZD1222, the vaccine candidate licensed from the University of Oxford Jenner Institute, we are also planning to advance a monoclonal antibody combination into clinical development. These monoclonal antibodies will be used in combination with each other both to prevent and treat COVID-19. We believe it is imperative to employ a multi-pronged approach -- both with a prophylactic vaccine and with therapeutics -- in tackling COVID-19.

Our immediate goal is to help prevent further loss of life and to put an end to the unprecedented devastation that the COVID-19 pandemic has caused throughout the U.S. and the world. To support our goal of providing broad and equitable access as quickly as possible, we have entered into agreements with the U.S., 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. We are extraordinarily grateful for the support we have received, which has helped make this commitment possible.

Right now, we are intensely focused on helping to overcome the global public health emergency through the development of our candidates. We recognize that we are only one of many companies working on potential vaccines and therapeutics for COVID-19. We hope that

the other companies testifying today are also successful in their pursuits, as their achievements would offer patients and governments more options, which we believe are necessary to effectively combat this pandemic. I know that none of the companies involved in this project view this as a competition against each other -- our sole adversary is COVID-19.

As noted, although we have yet to determine whether the vaccine will satisfy the rigorous safety and efficacy standards necessary for approval, even prior to any approval or emergency use authorization, we are proceeding to manufacture the vaccine with the support of the U.S. and other governments. We made this decision so that, if the vaccine is approved or authorized under an emergency use authorization, it will be ready for immediate distribution and administration. The alternative of waiting until we have greater certainty that the vaccine works -- which would delay the manufacture of the vaccine by several months or years -- was simply not an option.

We have also initiated new clinical trials to investigate our new and existing medicines to see how they could address serious and life-threatening complications from COVID-19 in severely ill patients. We have commenced our CALAVI-US study, a multicenter, randomized, open-label, Phase II clinical trial to evaluate the efficacy and safety of adding Calquence®, our BTK inhibitor, to best supportive care to reduce the need for assisted ventilation or death in patients with life-threatening COVID-19 symptoms. We are conducting this trial in the U.S. and began enrolling patients in May 2020. The trial design for CALAVI-US is based on strong scientific evidence supporting the role of the BTK pathway in the production of inflammatory cytokines derived from a NIH study. The NIH study was led by researchers in the Center for Cancer Research at the National Cancer Institute ("NCI"), in collaboration with researchers from the National Institute of Allergy and Infectious Diseases ("NIAID"), as well as the U.S. Department of Defense's Walter Reed National Military Medical Center and four other hospitals.

In addition, Saint Luke's Mid-America Heart Institution, in collaboration with AstraZeneca, initiated the DARE-19 study, a Phase III, international, multicenter, parallel-group, randomized, double-blind, placebo-controlled, investigator-sponsored trial evaluating the effect of our SGLT2 inhibitor, Farxiga®, in addition to background local standard of care therapy, on the risk of all-cause death or disease progression and clinical complications. This study began enrolling patients in April 2020 and will be conducted in approximately 50 centers in the U.S. and in other countries with a high COVID-19 burden. We are hopeful that these clinical programs will help improve patient outcomes and provide important data for the scientific community to better understand the SARS-CoV-2 virus.

II. AstraZeneca is Collaborating with Academia and Governments to Advance its Vaccine and Monoclonal Antibody Candidates for the Treatment and Prevention of COVID-19

The progress that AstraZeneca has made in identifying and developing the vaccine would not have been possible without significant contributions from academia and government agencies. We have taken a truly global approach to this project. Our collaborations with institutions and government agencies have been essential in expediting the R&D programs for our candidates, and

in ensuring that the cost of the doses of the vaccine to be supplied under our agreements with the U.S., and certain other governments and organizations, will provide no profit for AstraZeneca, if the vaccine is ultimately approved or authorized under an emergency use authorization.

In May 2020, AstraZeneca entered into an exclusive global development and distribution agreement with the Jenner Institute at the University of Oxford and the Oxford Vaccine Group. This agreement gave AstraZeneca a license to develop and potentially to distribute the University's novel recombinant adenovirus vaccine candidate AZD1222, formerly known as ChAdOx1 nCoV-19. We did so because we recognized the extraordinary potential of the ChAdOx1 vaccine platform and the groundbreaking research conducted by Oxford. And, while I cannot speak for Oxford, I believe the team recognized that a partnership with AstraZeneca would facilitate accelerated global clinical development, would allow scaled-up manufacturing to the unprecedented levels required to mitigate the impacts of a global pandemic, and would promote broad and equitable access to the vaccine around the world, assuming it is approved or authorized under an emergency use authorization.

We are also finalizing an agreement for more than $1 billion with BARDA for the development, production, and delivery of 300 million doses of AZD1222 to the U.S. Under this agreement, AstraZeneca's goal is to supply the initial doses beginning in October 2020 and the remaining doses in 2021. The U.S. government will then own the doses of vaccine that we produce and determine how the doses are distributed. The development program under this agreement includes a Phase III clinical trial with 30,000 participants and a pediatric trial. We are very pleased that the government has moved with speed to advance this critically important agreement with AstraZeneca, and I would like to take this opportunity to thank the Administration and Congress for their unwavering commitment and the funding needed to advance this effort.

We are also extremely proud that the vaccines covered by this agreement will be manufactured in the United States. We are now moving forward with activities at our West Chester, Ohio site, related to the formulation, filling, and packaging of the vaccine for the U.S. market. The West Chester site is one of our key U.S. operations centers, and we selected this site for this important initiative because it is an aseptic sterile filling and packaging facility that has the capability to manufacture the vaccine to scale. We have also partnered with other U.S. pharmaceutical manufacturers to manufacture the vaccine at additional domestic sites.

Additionally, in June 2020, we entered into an exclusive license agreement with Vanderbilt University for six of their most promising monoclonal antibodies, isolated from cells in patients who have recovered from COVID-19. We had evaluated more than 1,500 antibodies from different sources in our own laboratories. Our evaluation assessed their ability to bind to and neutralize the SARS-CoV-2 virus. We now plan to advance a combination of these antibodies into clinical development.

An antibody-based treatment could potentially be used both as a prophylactic approach for COVID-19 and as a complement to vaccines. For example, the antibody treatment could be used for patients who may not be eligible for vaccination or as additional protection for patients who are higher-risk. In addition, we plan to evaluate our monoclonal antibody combination candidate as another potential treatment for patients with COVID-19. Like our Oxford partnership, this

collaboration is intended to facilitate expedited development of this potential therapy. To support the monoclonal antibody development program, we entered into a $25.1 million interagency agreement with BARDA and DARPA for a Phase I clinical trial and manufacture of investigational monoclonal antibodies for testing in this trial. We are in discussions with government agencies regarding Phase II/III clinical trials and manufacturing plans in the event that early clinical trials show that our monoclonal antibody combination candidate is effective and well-tolerated.

We have set an ambitious goal to supply the vaccine to as many countries around the world as possible. We are leveraging our own industrial capacity while also working with a number of partners to establish parallel supply chains in record time. In addition to our partnerships with the U.S., we have, or are in the process of negotiating, partnerships with the U.K., Europe's Inclusive Vaccines Alliance, the Coalition for Epidemic Preparedness Innovations, and Gavi.

III. AstraZeneca's Development and Manufacturing Programs Are Designed to Satisfy All Applicable Regulatory Approval and Emergency Use Authorization Standards

The development and full-scale manufacture of a novel vaccine or treatment often can take years. Given global public health imperatives, we are developing and manufacturing the vaccine and our monoclonal antibodies in a matter of months by compressing timelines and working in partnership with academia and regulators from around the world. However, we must also achieve all of this in a manner that complies with the applicable regulatory requirements. Our first priority is to demonstrate the safety and efficacy of the vaccine and monoclonal antibody candidates through sound science and clinical data derived from adequate and well-controlled studies. To that end, we maintain an open dialogue with regulators to obtain feedback and provide data and other updates in real-time, and we have sought input from FDA on key aspects of our protocol and development program.

Existing knowledge and data regarding the safety and effectiveness of the ChAdOx1 vaccine platform used for AZD1222 has also allowed studies to progress rapidly. Vaccines made from the ChAdOx1 platform had previously been administered safely. Specifically, the Jenner Institute at the University of Oxford had demonstrated the promise of this vaccine platform in prior early-stage clinical trials, including in one trial last year against an earlier coronavirus, Middle East Respiratory Syndrome ("MERS"). Because of that earlier work, we have been able to develop the potential COVID-19 vaccine more quickly.

Although we now have a preliminary understanding of the potential safety and effectiveness profile of AZD1222, protecting the safety of the participants in our clinical trials remains of highest importance. The U.K. has used an independent Data and Safety Monitoring Board ("DSMB") for this purpose, and we intend similarly to employ an independent DSMB for our planned Phase III study in the U.S. and our clinical programs for other treatment candidates. The DSMB will provide continuous oversight throughout the study and will monitor for safety and efficacy results, evaluate cumulative safety and other clinical study data at regular intervals, and make appropriate recommendations based on the available data. The DSMB safety analyses will also help to inform the vaccine's and monoclonal antibody combination's overall safety profiles and will provide valuable insights to regulators, such as FDA.

AstraZeneca is fully supportive of FDA's role in assessing vaccine and other treatment candidates against stringent safety, efficacy, and tolerability standards as part of the approval or emergency use authorization process. We were heartened by FDA Commissioner Dr. Stephen Hahn's recent testimony before the Senate Health, Education, Labor & Pensions Committee, in which he emphasized FDA's commitment to expedite this work without cutting corners in its regulatory decision making. We welcome FDA's recently issued guidance on the development and licensure of vaccines to prevent COVID-19, and we applaud FDA's commitment to maintain independence and ensure that decisions regarding COVID-19 vaccines and treatments are based on sound science and data. The American people must be able to trust in any approved or emergency use authorized vaccines and treatments.

IV. Vaccine Development Status

Clinical development of AZD1222 is progressing throughout the world. Pre-clinical data published in different animal models, such as mice, pigs and non-human primates, show that AZD1222 provokes an immune response against the SARS-CoV-2 virus, with increases in both antibodies and T-cells after a single dose. In the pig model, adding a second dose enhanced this immune response.

An ongoing Phase I/II clinical trial of AZD1222 commenced in April in the U.K. to evaluate the safety and immune response of AZD1222 in over 1,000 healthy adult volunteers. We hope to have the full data from this trial in the coming weeks. Review of initial safety and immune response data from this trial by the U.K. DSMB has allowed progression to late-stage trials, including in the U.K. with over 10,000 volunteers.

Late-stage Phase II/III trials are also progressing in Brazil and South Africa with approximately 5,000 volunteers and over 2,000 volunteers, respectively. We are planning a Phase III trial with approximately 30,000 volunteers and pediatric study in the U.S. and additional late-stage trials in other countries. Ensuring diversity in these trials, including in terms of race, ethnicity, gender, age, and other factors, is a priority in our efforts. These late-stage Phase II and III trials will determine how well the vaccine can protect patients from COVID-19 and will measure safety and immune responses in different age ranges and at various doses. We are evaluating one and two-dose strategies in order to maximize the prospects that the vaccine will protect against COVID-19.

We hope to have results from these larger trials in the fall, but the timing of those results will depend on the rate of infection within the clinical trial communities. AstraZeneca will continue to monitor infection rates and will adjust our global clinical trial program as appropriate. We will also continue to evaluate the number of doses of the vaccine that will be required, so that we can achieve the most optimal level of protection against COVID-19.

V. Monoclonal Antibody Development

We are currently in the pre-clinical evaluation stage for our monoclonal antibody combination candidate, and we hope to be in the clinic within weeks as we are making good progress. We plan to move this forward as quickly as possible. A possible future antibody-based

treatment could potentially be used as a prophylactic approach for COVID-19 and could be complementary to vaccines, *e.g.* for people who may not be able to have a vaccination or to provide added protection for high-risk populations. In addition, we plan to evaluate our monoclonal antibody combination candidate as a potential treatment for patients with COVID-19. AstraZeneca is committed to working with regulatory agencies to ensure rapid but safe access to the monoclonal antibody combination, should it prove effective in clinical trials. Based on current data, we are hopeful that an antibody combination approach will be able to neutralize the SARS-CoV-2 virus, to reduce the impact of any escape mutations, and to be prescribed as both a prophylactic and a treatment option for those exposed to the virus. We engineered the monoclonal antibody combination using our proprietary half-life extension technology, and prior experience with this technology suggests the combination could provide meaningful protection against the SARS-CoV-2 virus for as long as 150 days. The additional antibodies we licensed from Vanderbilt could also be important for future research efforts as we learn more about the virus and COVID-19, and we will continue to pursue such research in order to find an effective solution to the global pandemic.

* * *

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

Chairwoman DeGette, Ranking Member Guthrie, 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, Doctor.

Dr. Douoguih, you are now recognized for 5 minutes for your opening statement.

STATEMENT OF MACAYA DOUOGUIH, M.D.

Dr. DOUOGUIH. Thank you and good morning.

Chairwoman DeGette, Ranking Member Guthrie, and members of the subcommittee, thank you for the opportunity to discuss Johnson & Johnson's efforts to develop a vaccine for the virus that causes COVID-19.

Thank you also to Chairman Pallone, Ranking Member Walden, and other members of the full committee for joining this important discussion.

I oversee clinical development of Johnson & Johnson's vaccines portfolio, including the COVID-19 programs. I would like to outline our efforts to develop a safe and effective vaccine and our public commitment to provide more than one billion doses at a not-for-profit price for emergency pandemic use.

Working closely with health authorities, other agencies, and academic partners, Johnson & Johnson is pursuing an accelerated approach to the development of our vaccine, including large-scale manufacturing, which we start in parallel with clinical development, in advance of it actually, to make sure the availability of substantial quantities of vaccine is found to be safe and effective.

We have formed an important partnership with the Biomedical Advanced Research and Development Authority, BARDA, under which Johnson & Johnson will receive approximately $500 million for a COVID-19 vaccine research and development.

That agreement supports vaccine research and development efforts, which include preclinical studies, clinical studies, and the production of clinical trial material.

Our efforts progressed rapidly since they began in January. In March, we announced the selection of our SARS-CoV-2 vaccine candidate, Ad26.COV2.S recombinant.

Next we completed a preclinical study in nonhuman primates and have submitted the results to a peer-reviewed scientific journal. We look forward to the publication of those results in the near future.

We expect to start a first-in-humans phase ½ A trial later this month. This trial conducted in the United States and Belgium will involve more than a thousand healthy adults ages 18 to 55 years and adults age 65 years and older. We are anticipating preliminary results will be available in September.

If those results are positive, we will plan to initiate a phase 3 trial that month. We are using our AdVac technology to develop the vaccine. This is the same technology that we've used to develop our ebola vaccine and vaccine candidates for HIV, RSV, and Zika.

We have extensive safety experience with the technology, having vaccinated more than 75,000 individuals in a wide range of populations, including adults, seniors, infants, children, and pregnant women.

With respect to COVID, we believe that we can both accelerate vaccine development and ensure safety, as we have successfully done with our ebola vaccine.

As you may know, earlier this year, Johnson & Johnson committed to bringing its vaccine to the public on a not-for-profit basis for emergency pandemic use. The not-for-profit price will be based on one cost structure, and it will be validated by an external audit.

Johnson & Johnson is also committed to including diverse populations in our studies. We are still in the process of designing our phase 3 trials and ensuring diversity is a key consideration. For example, we plan to implement focused digital and community outreach, to encourage diverse participation in our clinical trials.

Finally, my written testimony has additional information regarding our extensive efforts to increase production capacity at the same time that we are developing a vaccine so that we can produce more than one billion doses in 2021, at least 400 million of which will be manufactured in the U.S.

Madam Chairwoman, we recognize that this is a critical moment for society. Johnson & Johnson is devoting our experience, energy, and resources to develop a safe and effective vaccine for COVID-19 as quickly and as safely as possible.

Thank you very much for the opportunity to speak with you today, and I would be happy to answer your questions.

[The prepared statement of Dr. Douoguih follows:]

Johnson & Johnson

Testimony of Macaya Douoguih, M.D., M.P.H.
Head of Clinical Development and Medical Affairs, Janssen Vaccines and Prevention
Johnson & Johnson

Submitted to the Oversight & Investigation Subcommittee of
the U.S. House of Representatives Energy & Commerce Committee

July 21, 2020

Chairwoman DeGette, Ranking Member Guthrie and Members of the Subcommittee, thank you for the opportunity to discuss Johnson & Johnson's efforts to research, develop, produce, and distribute a vaccine that will provide and make available safe, durable, and protective immunity against SARS-CoV-2, the virus that causes COVID-19.

I am Dr. Macaya Douoguih, and I am the Head of Clinical Development and Medical Affairs for Vaccines and Prevention for the Janssen Pharmaceutical Companies of Johnson & Johnson. I am speaking to you today from near our research facility, where I oversee clinical development of the company's vaccines portfolio, including the COVID-19 program. I have been engaged in discussions with authorities globally, including several U.S. government agencies, regarding the rigorous development strategy for our COVID-19 vaccine to support emergency use and licensure. The physicians in my organization lead the effort to develop the clinical studies and oversee their implementation.

Johnson & Johnson is the world's largest and most broadly based healthcare company, and we are committed to using our full breadth and depth to improve health outcomes around the world. Throughout our more than 130-year history, our company has supported local and global communities during times of crisis, from hurricane response efforts to our recent efforts to combat Ebola. Consistent with the Johnson & Johnson Credo, crafted by Robert Wood Johnson nearly 80 years ago as a mission statement that guides the company's decision making, the needs of patients come first. Therefore, we have a responsibility to invest in solutions for global public health crises.

Since January 2020, Johnson & Johnson has been working directly with governments, health authorities and other partners around the world to help end this fast-moving COVID-19 pandemic. I would like to outline our efforts to develop a vaccine and our public commitment to provide more than one billion doses of our vaccine at a not-for-profit price for emergency pandemic use. I will highlight the progress and the partnerships, both public and private, we continue to secure to deliver on these commitments.

Developing a Johnson & Johnson Vaccine

Working closely with health authorities, Johnson & Johnson is pursuing an accelerated approach that allows us to progress our program significantly faster than normal development timelines, which typically takes between five and seven years. There are several ways we are accelerating the development of our vaccine candidate given the ongoing health emergency, including conducting Phase 1 and Phase 2 clinical trials simultaneously, and beginning large scale manufacturing to support pivotal efficacy clinical trials and potential wider-scale distribution if authorized by health authorities.

In order to develop and supply a safe and effective vaccine, Johnson & Johnson combines deep scientific expertise and know-how with substantial investment in the technology platform, R&D and manufacturing. We also have formed an important partnership to assist in R&D funding with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services. Under our current contract with BARDA, Johnson & Johnson will receive approximately $500 million for vaccine research and development.

Our agreement with BARDA supports the co-funding of vaccine research and development efforts, including preclinical, clinical development, and the production of clinical trial material.

Early research and manufacturing have progressed at a rapid pace. On March 30, 2020, Johnson & Johnson announced the selection of our SARS-CoV-2 vaccine candidate, Ad26.COV2.S, recombinant, from the constructs our scientists had been working on since January 2020.

We have completed a critical preclinical study of our vaccine candidate in non-human primates, in partnership with Dan Barouch, M.D., Ph.D., Director of the Center for Virology and Vaccine Research at the Beth Israel Deaconess Medical Center at Harvard Medical School and the Ragon Institute, his team and others. We have submitted the results of this study to a peer-reviewed scientific journal and are looking forward to their publication in the near future.

As we continue to move forward at a rapid and responsible pace, I am pleased to share with the Subcommittee that we expect to dose our first participant with Ad26.COV2.S, recombinant, in late July 2020 as we begin our Phase 1/2a "first-in-human" trial. This trial will be conducted in the United States and Belgium, and will involve more than 1,000 healthy adults aged 18 to 55 years, and adults aged 65 years and older. We expect to have preliminary results from this trial in September 2020.

If preliminary results are positive, we then plan to initiate our global Phase 3 randomized, controlled, multi-center trial in September 2020. We will design this study to evaluate the efficacy, safety and durability of protection of our vaccine candidate against COVID-19, the disease caused by SARS-CoV-2. The design of this rigorous, complex trial is ongoing, and we are working with the U.S. Food and Drug Administration (FDA), the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID), BARDA, the U.S. Department of Defense (DoD), the European Medicines Agency and other experts on its design.

As we have seen, it will be a challenge to reliably predict disease incidence rates for the timeframe for which this study is planned. We are using available data sources and, in partnership with the Massachusetts Institute of Technology, have constructed a predictive model to determine where best to set up our trial sites globally so that they are in the areas of highest viral infection when we begin the Phase 3 trials, and to identify whom to enroll in the trials considering occupational, environmental, socioeconomic, and demographic risk factors. We have also incorporated all recommendations from the recent FDA guidance related to the development and licensure of COVID-19 vaccines into our development plan.

The AdVac® Technology Underpinning Our Vaccine

Our AdVac® technology is the foundation of our COVID-19 vaccine candidate. We have employed the same AdVac® technology to develop our Ebola vaccine regimen, which received European Commission authorization for use in adults and children on July 1, 2020, and to construct our vaccine candidates for HIV, respiratory syncytial virus (RSV) and Zika. Clinical experience with our AdVac®-based vaccine and vaccine candidates (with more than 75,000 individuals vaccinated to date, including adults, people over 65 years of age, infants, children, HIV-positive adults, and pregnant women) suggest these could be well-tolerated in studied populations.

To develop our COVID-19 vaccine candidate, we combined DNA that codes for the coronavirus spike protein – the protein that is used by the coronavirus to enter human cells – and our AdVac® technology. The AdVac® technology works by using a non-replicating inactivated

adenovirus, the type of virus that causes respiratory syndromes such as the common cold, as a carrier (also called a vector). This vector cannot cause a cold and the protein it produces cannot cause harm either.

Antigens (or, components of a pathogen, e.g., the spike protein of the coronavirus) are then produced to mimic the pathogen, without causing disease. The resulting combination viral vector-DNA encoding the antigen creates our vaccine candidate, which mimics components of the pathogen to trigger the immune system while not leading to infection. When the body encounters the antigen, the immune system will induce both a humoral and a cellular immune response against the antigen, by producing antibodies and immune cells.

Then, if the body later encounters the actual pathogen that causes COVID-19, the body will be able to respond faster and more effectively, as immune cells and antibodies specific to the pathogen will be rapidly produced in the body to prevent the pathogen from inducing disease.

Safety, Efficacy, and Development

I would like to share with you the steps Johnson & Johnson is taking to generate the necessary safety, immunogenicity, efficacy, and durability data of our vaccine candidate. We believe that we can both accelerate vaccine development and ensure safety. We trust that all those engaged in response to the COVID-19 pandemic are committed to developing solutions as rapidly as possible, and the multiple vaccine technologies being employed allow for varying paces of development at different phases.

At Johnson & Johnson, our fundamental responsibility is to provide patients, consumers and healthcare providers with products that are effective and safe. Guided by Our Credo, we put patient and consumer well-being first and foremost in all of our decision making and actions.

Starting in late July, we will initiate our Phase 1/2a study of Ad26.COV2.S, recombinant, in which the safety of our vaccine will first be assessed in a small cohort (or, sentinel group) of human volunteers. If no safety issues are identified, enrollment will be expanded to larger cohorts to further evaluate safety and immunogenicity of the vaccine. Generation of adequate safety and immunogenicity data on participants in this Phase 1/2a study will support further study of safety and efficacy in a larger population in a Phase 3 trial.

As we progress, we will continue to work with the FDA, NIAID, BARDA, DoD and other global authorities to prepare for our Phase 3 trial. Our goal is to complete the Phase 3 trial and have results in-hand in early 2021. Based upon the safety, efficacy, and immunogenicity data from

this trial and the cumulative data generated from our other trials, we would then enter into discussions with the FDA and other health authorities regarding regulatory authorizations for emergency use and licensure.

Pricing of Johnson & Johnson's COVID-19 Vaccine

Johnson & Johnson is committed to bringing an affordable COVID-19 vaccine to the public on a not-for-profit basis for emergency pandemic use. This is rooted in Our Credo and recognizes our commitment to all our stakeholders. We are committed to one price globally, regardless of country or income tier. The not-for-profit price will be for the emergency pandemic period.

Our not-for-profit framework is consistent with established vaccine costing methodologies. Our price will be determined based on one cost structure, with all appropriate costs included. We are pursuing external validation of our not-for-profit calculation approach and external audit / certification of not-for-profit price.

Ensuring Diversity and Inclusion in Our COVID-19 Clinical Trials

Johnson & Johnson is committed to robust representation of diverse populations in our studies. This is a major initiative within our Janssen Pharmaceutical Companies, and vaccine development is just one of the areas where it is paramount. It's well known that people from different ethnic, age, genders or socio-economic groups can respond differently to vaccines and medications. Understanding these variations is an important part of any clinical development program.

We are still in the process of designing our COVID-19 Phase 3 trials. However, ensuring diversity and inclusion is a key consideration balanced with the need to conduct the trial in areas of highest disease incidence. We face several challenges here, in that pandemic hotspots – and therefore the location of study populations we seek to enroll – change rapidly. As a result, it is difficult today to predict where the rates of viral infection will be later this year. Further, because a number of the companies here today will likely be pursuing Phase 3 trials before or at the same time as Johnson & Johnson, we will plan to enroll the study in different geographic regions, including those outside the United States.

As we seek to enroll our future Phase 3 trials in the United States, we will strive to ensure significant representation of populations have been disproportionately impacted by the pandemic, including Blacks, Hispanic/Latinx and participants over 65 years of age. To achieve recruitment of people from highly affected communities, we plan to implement a focused digital and community outreach plan to provide resources and opportunities to encourage

participation in our clinical trials. We will evaluate ways to reduce operational barriers and participant burden within clinical trial sites, and apply lessons learned from previous efforts with underserved and underrepresented populations.

We recognize the critical need to understand health impacts on diverse populations. Thus, we have created a new partnership with Johns Hopkins Bloomberg School of Public Health to generate deeper, more granular insights to better capture data more effectively and understand how the COVID-19 crisis is affecting different communities in the United States. We also have joined a number of coalition calls directed to congressional leaders for increased and improved COVID-19 demographic collection and dissemination, including funding for the U.S. Centers for Disease Control and Prevention's Surveillance for Emerging Threats to Mothers and Babies program.

On a global scale, our Johnson & Johnson Center for Health Worker Innovation is partnering with national governments and partners – like AMREF (formerly known as the African Medical and Research Foundation, Inc.) and the Aga Khan University in Kenya and Comprehensive Community Based Rehabilitation in Tanzania – to engage community health workers in the prevention, detection, and response efforts and to ensure delivery of primary health services in vulnerable and underserved communities.

Building on our commitment, we would like to take this opportunity to urge further collaboration by government, including bipartisan congressional engagement, industry, academia, and community partners to ensure late-stage clinical trials supporting the development of vaccines and therapeutic biopharmaceuticals include demographically and socio-economically representative participants, specific to the disease areas being studied. These data should be shared appropriately with the scientific and medical community.

Building Global Manufacturing Capacity for the Johnson & Johnson Vaccine Candidate

As a result of our own manufacturing capacity and through new U.S. vaccine manufacturing partnerships, we will have the capability to produce over 1 billion vaccine doses in 2021. At least four hundred million of these doses will be manufactured in the United States. We are in the process of identifying manufacturing capacity for the balance of the promised one billion doses.

We have begun preparations for clinical vaccine production at our campus in Leiden, the Netherlands, to support our Phase 1/2a first-in-human clinical trial. At this same campus, we developed our Ebola vaccine regimen and our HIV, RSV and Zika vaccine candidates.

In order to produce the vaccine necessary for wide-scale distribution, we continue our discussions with the U.S. government and other governments worldwide, other companies, global organizations, and other stakeholders as we establish a supply network able to meet, or exceed, our manufacturing goal. We select manufacturing partners based on critical criteria, including capabilities needed, partner experience, quality and safety, and geographic location. The need to ensure a diverse and resilient supply chain to meet manufacturing needs is always a consideration.

For example, we have established partnerships with Emergent BioSolutions, Inc. and Catalent Biologics. Both Emergent and Catalent will reserve operations capacity to potentially support commercial manufacturing of Ad26.COV2.S, recombinant, leveraging our AdVac® technology, beginning in 2021.

Manufacturing of the active ingredient for our vaccine candidate, otherwise known as drug substance, will be completed at Emergent's Baltimore Bayview facility, one of three Centers for Innovation in Advanced Development and Manufacturing (CIADM) in the United States. These centers have been designated by the U.S. Department of Health and Human Services as being designed for the rapid manufacturing of vaccines and treatments in large quantities during public health emergencies. In addition, Catalent will manufacture drug product and refine that into the final vaccine, including filling and finishing vials for distribution, at its Bloomington, Indiana facility, one of its global manufacturing locations.

We also have entered into an agreement with Vibalogics GmbH and IDT GmbH, a global contract development and manufacturing organization that specializes in the production of virotherapy products, to manufacture additional drug product for Ad26.COV2.S, recombinant.

Availability of Johnson & Johnson's Vaccine Candidate

Johnson & Johnson is committed to providing a safe and effective vaccine to healthcare workers around the world. As we progress with the clinical development of our SARS-CoV-2 vaccine candidate, Ad26.COV2.S, recombinant, we are in active discussions with global partners to support worldwide access.

We will continue to work with local and international health authorities, government organizations, regulators and non-government organizations to help ensure that, if development is successful and products are authorized by health authorities, we will provide broad and timely access to our vaccine.

In Summary

This is a critical moment for society, and we at Johnson & Johnson are devoting our global scale, proven success, experience, energy, and resources to swiftly develop a safe and effective vaccine to prevent COVID-19. We are committed to developing, producing, and making available a vaccine as quickly as possible while staying true to our commitment to safety, efficacy, and scientific integrity.

We are not alone in this effort. Global bodies, national governments, non-governmental organizations, academia and private industry all are devoting unprecedented effort to finding solutions to this pandemic.

At Johnson & Johnson, we believe that industry should engage in a collective effort to save lives. It is our sincere wish that multiple vaccines and treatments are identified and deployed, offering the world's population safety, confidence, efficacy, and security so that COVID-19 suffering and loss are ended and normal life may resume. Johnson & Johnson will continue to advance our vaccine research and development and other COVID-19 efforts rapidly and responsibly, reflecting the values of Our Credo, which places the lives of the patients we serve first.

Thank you for the opportunity to speak with you today and to have this critical and timely dialogue. I look forward to your questions and to providing any additional information you may need.

# # #

Ms. DEGETTE. Thank you so much, Doctor.

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

STATEMENT OF JULIE GERBERDING

Ms. DEGETTE. You need to unmute.

Dr. GERBERDING. Can you hear me now?

Ms. DEGETTE. Yes.

Dr. GERBERDING. OK. Thank you.

Thank you, Chairwoman DeGette, Chairman Pallone, Chairwoman Eshoo, Ranking Member Guthrie, and all the other members of the committee. I really am honored to testify today, and thank you for holding this really important hearing.

I also thank the frontline health workers, including my colleagues at San Francisco General who are, as we speak, putting their own lives at risk while providing care to the ill people with SARS-CoV-2. They really are the true heroes of this pandemic.

In 2003 I was serving at the CDC Director when the SARS virus thankfully lost the first race involving a new coronavirus, due in large part to the heroic containment efforts in hospitals around the world. But unfortunately, SARS-CoV-2 is proving to be a much more formidable foe. The current pandemic has already infected 15 million people and caused the loss of more than 140,000 Americans. And the virus is far from contained.

So the race is on, not against each other but against this virus, and unfortunately today the pandemic is far ahead of us. But we in the biopharmaceutical industry are closing in faster than we ever imagined possible.

According to the BioTracker, in the first six months, from the time we learned about the virus, more than 660 unique compounds are in various stages of development, including 173 vaccine candidates, 196 antivirals, and 292 other treatments.

So I have to compare that to AIDS, when it took more than six years to get the first HIV drug approved and 15 years before we had highly active therapies.

This astonishing progress is the result of a robust biopharmaceutical industry and all the partners throughout academia and the world of investigation. Now, I believe this pandemic won't be the last or even the worst we will face.

So we have to preserve a vibrant, innovative, and economically sustainable, biopharmaceutical business as the frontline of our health protection. Failure to do so will jeopardize today's patients and degrade our future health security.

I think science is on our side as we approach the COVID-19 challenges, but these are still early days, and there's much to be learned about this virus and how to safely combat it. Merck is one of the few companies that has continued to invest in vaccines and anti-infectives for almost our 130-year history.

Given that long experience and expertise, we knew when we saw this pandemic emerge, that we had a special responsibility to help end it. We looked at many possible vaccine candidates, and we looked for three main attributes.

First of all, a candidate that was based on a proven platform, known to achieve safe and effective immunity against other viruses.

Second, we were hoping to find a candidate likely to be effective as a single dose.

And third, we wanted a candidate feasible to scale and distribute on a global basis.

As a result of our search, we are pursuing two promising vaccines, one in partnership with IAVI that is based on rVSV which is the same platform we used for our licensed, single-dose ERBEVO vaccine that has helped contain the recent ebola virus outbreak in the DRC.

And also a second vaccine candidate, one that we acquired from our acquisition of Themis, which is based on a measles virus backbone that has been used to safely immunize billions of children.

As everyone has emphasized, speed is important, but we will not compromise careful, scientific, efficacy, quality, and above all, safety assessments, as we evaluate our candidates, despite the urgency that we all truly feel. There will be no safety shortcuts at Merck.

Finding a safe and effective vaccine is only the first hurdle, and the second is even greater. We have to ensure that vaccines are accessible and affordable on a global scale. No one is safe until everyone is safe. Never in the history of human kind have we been tasked with finding an affordable vaccine for everyone.

To put this into context, consider today we can't even fully immunize the world's birth cohort against vaccine preventible childhood diseases, despite decades of effort, or that despite our long awareness of the threat of an influenza pandemic, the annual global supply of influenza vaccine is far less than two billion doses, and most people in resource-limited areas have no access at all.

Merck does have a long track record of making our vaccines available and affordable to people around the world, and we are committed to ensuring affordable global access to any SARS-CoV-2 medicine or vaccine that we help create. Our goal is to ensure that we can make these vaccines available to whoever needs them, and we'll prioritize that access based on risk and medical need.

At the end of the day, access also requires trust—trust in vaccine safety, trust in the integrity of the vaccinators, trust in the medical experts who assess them, and especially in times of crisis, trust in government.

That's a tall order in most countries, including our own, and we have to prepare now to support people's confidence in safe and effective vaccine.

At Merck, we believe this is a daunting but doable mission——

Ms. DEGETTE. Dr. Gerberding, if you can please wrap up thank you.

Dr. GERBERDING [continue]. Core values and the purpose that motivates us to commit our lives to our profession. Thank you.

[The prepared statement of Dr. Gerberding follows:]

TESTIMONY OF DR. JULIE L. GERBERDING
Before the United States House of Representatives
Energy & Commerce Committee, Oversight & Investigations Subcommittee
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"
July 21, 2020

Chairwoman DeGette, Ranking Member Guthrie, and other members of the Committee, thank you for holding this important discussion and for the opportunity to appear today. The SARS-CoV-2 pandemic has already had an unprecedented impact on humanity, both in terms of lives lost and broader societal impact. While we continue to confront these unprecedented challenges, we are also seeing momentum that is a testament to scientific innovation and the men and women behind the initiatives to develop the effective vaccines and therapies that will be required to ultimately end the pandemic. The speed of these efforts has truly been astounding, as is the level of cooperation across the industry.

Merck is a premier biopharmaceutical company that leverages cutting-edge science to address important unmet medical needs. As such, we are contributing our experience and expertise to help solve the SARS-CoV-2 pandemic in the same way we have responded to past health emergencies like widespread measles outbreaks, the HIV pandemic, and the African Ebola virus outbreaks – and with speed made possible by sustained scientific progress in research and development and investments made at risk.

Experts have predicted for years that a pandemic of this magnitude would occur, and significant progress has been made over the last two decades in increasing our preparedness. Now that we are in the midst of responding to the current crisis, we can clearly see the vulnerabilities in our system that remain. Even as we work to manage the current pandemic, we must strengthen our ability to preempt, detect, contain, and mitigate the broad spectrum of future threats we may face. One of the most important pillars of our preparedness is the development of countermeasures – medicines and vaccines that target these threats. To assure ongoing research and development of these products, we must sustain a robust market for innovation and encourage collaboration, partnership, and strategic investments across the public-private continuum. At Merck, with our track record of innovative antivirals, antibiotics, and vaccines, both in human and animal health, we hope to be able to contribute to that readiness.

As one of the very few companies that have continued to invest in both vaccines and infectious disease medicines, at Merck we know we have a special responsibility to apply our experience and expertise to help advance both vaccine and antiviral therapies as part of our overall SARS-CoV-2 pandemic response. Since the earliest days of the pandemic, we have been contributing to the scientific underpinnings of therapeutic and vaccine approaches, working to understand the nature of the new virus and formulate the best approaches. One initial step we took was to establish a significant research collaboration with the Institute for Systems Biology to probe the basic biology of this virus and how it interacts with the immune system, to help formulate our approaches. Progress is accelerating through these and many other efforts, but there is still much to learn about this virus and how it can cause such a broad range of health effects.

Our long history of developing vital medicines and vaccines has shown us that durable scientific solutions take time, expertise, and experience to discover and deliver to the people and communities who so desperately need them. Our initial focus is on vaccine platforms that have proven track records and where Merck can apply its special capabilities and experience in development, formulation, and manufacturing. If approaches developed by others ultimately are proven superior to those being pursued by Merck, we will work to support those efforts for the benefit of global health during the pandemic.

None of us can do this alone. Merck has been leveraging existing partnerships and building new ones within industry and across sectors toward a common goal: ending this pandemic. Today, we are advancing three programs – two vaccines and one antiviral medicine – with a strong sense of urgency and the necessary investment of effort and resources. The vaccine candidate we are developing with the International AIDS and Vaccine Initiative (IAVI) uses a recombinant vesicular stomatitis virus platform, which is the same approach that was used for our Ebola virus vaccine (ERBEVO). Our vaccine candidate that came through our acquisition of Themis is based on a measles virus platform, the same measles virus that has been used in billions of people. The antiviral we are developing with Ridgeback is orally available – which has obvious potential benefits in terms of ease of administration.

We believe the approaches we have selected are among the most promising, and we intend to pursue a rigorous assessment of their safety and efficacy prior to being administered to a broad population. Speed is important, but we will not compromise scientific efficacy, quality, and above all, safety, despite the sense of urgency we all feel.

Once a vaccine is developed and approved for use, it will need to be produced at a scale never seen before. Under normal circumstances, manufacturing and distributing a vaccine is exceedingly complex, requiring hundreds of steps and thousands of complex tests, all validated to ensure that every single vial has the identical high quality and safety. When we think about what will be needed to address this pandemic, we are talking about orders of magnitude beyond what we as an industry are currently doing.

In order to meet this need, we must all appreciate that the biopharmaceutical collaborators are working at risk. In other words, we are making considerable investments in key elements such as manufacturing capacity before we typically would, before we know whether we even have a successful product – in many cases building a manufacturing facility before we have fully developed the process at a smaller scale. As a result, we must think carefully about how these decisions will impact other development programs and allocation of investments, including considering the inevitable opportunity costs.

This unprecedented experience really underscores the need for ingenuity, partnership, and advanced planning as we consider our manufacturing plans. It's also important that we consider the impact that the product profile will have on manufacturing. As discussed above, we are focusing on approaches using proven platforms such as the rVSV and measles platforms, as well as innovations that give us the potential for a single dose vaccine. A single-dose vaccine allows you to vaccinate twice as many people with the same number of doses – an important consideration given the scale that will be necessary to address the global pandemic.

We all hope the first approved vaccine will be transformational in terms of changing the way we fight this disease. However, it may not be the best or final approved vaccine. Novel vaccines will have different characteristics and may vary in the degree to which they have utility in certain populations and settings. Dosing regimens, storage requirements, and contra-indications are a few of the characteristics that will need to be considered when developing guidelines for use of these vaccines. That's why the work being done under the ACT-Accelerator and by technical advisory groups like the Advisory Committee for Immunization Practices (ACIP) in the United States to develop policies and normative guidance for deployment of SARS-CoV-2 vaccines will be so critical – to ensure that all vaccines doses can be deployed to maximize their public health impact.

Currently, the global vaccine industry is already operating close to full capacity – not only is there not a lot of excess capacity available, but it is not always easily transferable from making one vaccine to another. In order to meet anticipated global demand for SARS-CoV-2 vaccines, the industry will need to approximately double its current manufacturing capacity. At Merck, we are investing billions of dollars in new capacity for our current and pipeline vaccines – and that was before this pandemic. Now we are gearing up for hundreds of millions of doses of our SARS-CoV-2 vaccine candidates. In the short-term, one solution is typically to retrofit existing facilities. In the mid-term, construction of additional capacity for SARS-CoV-2 vaccines is necessary. But there is still a need to ensure long-term capacity for better preparation for future pandemic-response capability.

At the end of the day, whatever vaccines are finally approved will not be helpful unless people can access them – and are willing to do so. Merck has a long track record of making our vaccines and medicines accessible and affordable globally, and we will do that for any eventual SARS-CoV-2 vaccines and medicines as well. Our goal is to ensure that we can make these vaccines available to whomever needs them and to prioritize groups based on risk and medical need.

While we are all working tirelessly to bring new vaccines to people who need them, at Merck we are also deeply concerned that routine pediatric, adolescent, and adult immunization rates have fallen all over the world as patients are visiting their doctors' offices and other health care settings less. It's important that as we work to solve the SARS-CoV-2 pandemic we do not allow other diseases for which we do have vaccines to gain ground and overwhelm the already stressed health care system. We must do everything we can to ensure ongoing access to vaccines across the life-course, especially in hard to reach and traditionally underserved communities.

We urge strengthening of the systems that support routine immunization systems and preparing now to adapt them to mobilize for mass vaccination programs once pandemic vaccines are available. We need to apply the same ingenuity to creating innovative access and delivery mechanisms that we are applying to the development of vaccines. This includes strengthening mechanisms for global cooperation, designing innovative local vaccination campaigns, and identifying creative solutions to facilitate convenient access at the local level.

We also need to start now to build trust in the new vaccines and address escalating levels of misinformation related to the pandemic. We are dismayed by the ongoing dissemination of information that is inaccurate and/or misguided. We have also seen the erosion of trust in governments and the health care workers who will be conducting vaccination programs. Ultimately this misinformation threatens a dangerous reduction in people choosing to receive vaccines, which could extend the duration of this global threat. We are already seeing the result of this here in the U.S. A recent AP-NORC poll reported that 20% of Americans would refuse a SARS-CoV-2 vaccine and 31% were unsure whether they would choose to be vaccinated.[1] That more than half of Americans may not accept a vaccine is a troubling indicator of the impact of this misinformation campaign.

Partnerships have already been critical in establishing the current programs and even greater collaboration will be needed to ensure that vaccines and therapeutics are produced and deployed at scale. We believe a range of medicines and vaccines will be needed to end the pandemic, and we will continue to pursue the science along multiple pathways in collaboration with public and private partners. Merck stands ready to assist governments, organizations, and companies as we work together to solve this public health crisis.

[1] AP-NORC, Expectations for a COVID-19 Vaccine, accessible at https://apnorc.org/projects/expectations-for-a-covid-19-vaccine/.

Ms. DEGETTE. Thank you so much, Doctor. The Chair is pleased to recognize Dr. Hoge for 5 minutes.

STATEMENT OF STEPHEN HOGE, M.D.

Dr. HOGE. Chairwoman DeGette, Ranking Member Guthrie, and distinguished members of the subcommittee and full committee, thank you for the opportunity to appear before you today.

My name is Stephen Hoge, and I serve as the president of Moderna. I attended medical school at the University of California San Francisco and briefly served as a resident physician in a New York City hospital.

My wife is also a doctor, as are several members of my family, and I'm proud to work for a company focused on developing one of the vaccine candidates to stop this devastating COVID-19 pandemic.

The pandemic has harmed millions of people. Our hearts go out to those who have lost loved ones, who have been made sick themselves. Millions of Americans are out of work. All of us have been profoundly touched by this in some way.

We also know that communities of color and the working class have disproportionately borne the burdens of COVID-19. We must do everything we can to stop this pandemic.

I'd like to take this opportunity to provide you with an update on our efforts to develop a safe and effective vaccine against COVID-19.

At Moderna, we seek to improve patients' lives by creating a new kind of medicine based on messenger RNA, or mRNA, a molecule—a kind of molecule that plays a central role in biology, including in human health and disease. We're proud to be an American company with a headquarters and a major manufacturing facility in Massachusetts.

Since our founding in 2010, we have built and invested in our mRNA technology platform. This technology creates synthetic messenger RNA sequences that cells recognize as if they were produced in the body. Unlike traditional approaches to the medicine, which introduce a protein or a chemical to the body, our approach sends tailored mRNA into cells where the mRNA instructs the cells to produce a specific protein.

We believe this approach can improve how we discover, develop, and manufacture medicines across a wide range of disease. Because our mRNA technology is flexible and quickly adaptable, we stepped forward and pursued the rapid development of a COVID-19 vaccine candidate in January.

We leveraged Moderna's technologies and years of research that we had done before any of us had ever heard of COVID-19. We collaborated with the Vaccine Research Center and Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases, which is part of the NIH, to try to accelerate our vaccine candidate.

These efforts started with the COVID-19 virus. We used information from the virus to develop an mRNA sequence that instructs the cells in a patient's body to make the Spike protein of the

coronavirus. The body's immune system then learns to attacks this Spike protein and generate a protective immune response.

We progressed from genetic sequence of the vaccine into human testing in just 63 days, a testament to the 10 years of investment and hard work on our platform.

In March, the phase 1 study of our vaccine, which was led by the NIH, dosed its first participant. Our phase 1 study had positive results, and those findings have been published by the NIH and others in the New England Journal of Medicine.

Earlier this month, we completed enrollment of all 600 subjects in our phase 2 study. And now, just over six months from the sequencing of the virus, Moderna is about to become one of the first U.S. companies to enter a phase 3 trial for a vaccine candidate.

We've also been working to develop and scale our manufacturing and distribution chains, which should allow us to reach an annual production capacity of more than 500 million doses next year.

Throughout this process, we have been focused on developing a vaccine that is as safe and effective as possible, looking to the science and the data to guide our decisions. I'm grateful for the hundreds of scientists and other Moderna employees whose hard work and sacrifice have made our rapid progress possible.

At Moderna, we're also grateful to the many companies around the world, including all of my colleagues here, who are working on vaccines and treatments for COVID-19. We're also blessed to be joined in our efforts by dedicated public health officials and scientists at a host of Federal and State agencies.

I'd also 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 the efforts to combat this pandemic, and we remain committed to collaborating with the U.S. Government as this process continues.

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.

July 21, 2020

Chairwoman DeGette, Ranking Member Guthrie, 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"). I am proud to work for a company that is developing one of the vaccine candidates, mRNA-1273, for the treatment of SARS-CoV-2, the novel strain of coronavirus causing the devastating global COVID-19 pandemic.

We recognize the extraordinary harm the pandemic has done to millions of Americans. Our hearts go out to those who have lost loved ones or have been sick themselves. Millions of Americans are out of work. Others, like my wife and I, work to balance parenting with our professional obligations. My wife is a practicing physician, as are several members of my family, and I have seen how profoundly healthcare providers have been challenged by COVID-19. The pandemic has postponed weddings, cancelled graduations, and kept people away from funerals. All of us have been profoundly touched by this in some way. We also know that communities of color and the working class have disproportionately borne the burdens of COVID-19. We must do everything we can to stop this pandemic.

I understand there is significant interest in the work of Moderna and the companies who have witnesses testifying today. People all over the world want to know when we might be able to return to some sense of normalcy. People want to know how they can best protect their relatives and others. People want to go back to work. Others miss the ability to easily see their friends or family. Parents want their kids to continue their education, and their children want to play with their classmates. People also want to know that the taxpayer funds invested in potential vaccine candidates will pay off. I hope that my testimony today will provide further information about how Moderna—like the other companies testifying today and others not present here—is working as hard as it can to fight the COVID-19 pandemic. This may provide comfort to people in America and around the globe.

I feel fortunate to be in a company that is now working toward a scientific response to this current crisis. I joined Moderna eight years ago to do something like this and meet significant scientific challenges. My background is in medicine. I attended medical school at University of California San Francisco and briefly served as a resident in the emergency medical department at a New York City hospital. A decade later, while consulting for companies in the healthcare sector, I learned about a ten-person start-up pursuing a revolutionary approach to

treating disease: Moderna. If it worked, the vision and technology driving the company could unlock new frontiers for medicine. The chance to pursue that future is why I joined Moderna.

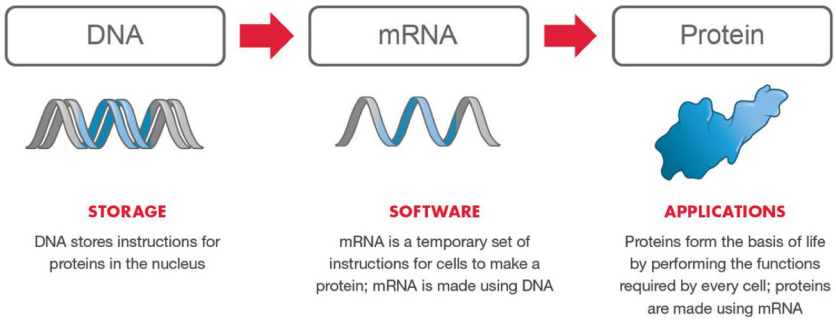
Over the past few months, Moderna has been pleased to collaborate with the U.S. government during the development of our vaccine candidate. This collaboration includes not only working together to test a possible COVID-19 vaccine, but also to build the manufacturing and distribution capacity needed to deliver a safe and effective vaccine to the American people. As we move into Phase 3 of our mRNA-1273 clinical trials, we remain committed to maintaining an ongoing dialogue with key U.S. government agencies to ensure that our work proceeds as quickly and safely as possible.

I'd like to take this opportunity to describe Moderna and our efforts to develop a vaccine that will be effective against COVID-19. *First*, I'll give you a brief overview of our mRNA technology and how it works. *Second*, I'll explain the process we used to develop our COVID-19 vaccine. *Finally*, I'll provide an update on the current status of our efforts. I appreciate deeply 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 800 employees—a far cry from the ten-person startup that I first encountered. 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 messenger RNA, or 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 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.

II. Moderna Has Used its mRNA Platform to Develop a Promising COVID-19 Vaccine

As the spread of COVID-19 across the globe has shown, the virus will not wait for the development of a vaccine. Lives depend on finding multiple safe, effective vaccines as soon as

possible. Because our mRNA technology is flexible and quickly adaptable, we stepped forward and pursued the rapid development of a COVID-19 vaccine candidate named mRNA-1273, focused always on making it as safe and tolerable a candidate as possible. We collaborated with the Vaccine Research Center and Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases ("NIAID"), which is part of the National Institutes of Health ("NIH"), in January 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. That experience, 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 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 mistakenly 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 have been 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 includes our understanding of the safety of our platform and our experience producing over 100 batches of mRNA for use in human clinical trials in just the last two years.

In our prior work on betacoronavirus 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 will instruct 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, which the body's immune system then attacks, 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 coronavirus or one of its components. Instead, we used the information from the virus to teach the cells in a patient's body how to make the virus's spike protein, which then 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. Now, just over six months from the sequencing of the virus, Moderna is about to become one of the first U.S. companies to enter a Phase 3 trial for a vaccine candidate, with 30,000 participants. While we pursue this mission with speed, we have been, and remain committed to, prioritizing safety and effectiveness. I am grateful for the hundreds of scientists and other Moderna employees whose hard work and sacrifice have made our rapid progress possible.

III. Moderna's Progress Toward a Vaccine

I would like to give you an update on the current status of our work. Right now, we are focused on two important tasks: *First*, testing mRNA-1273 in clinical trials to assess its safety and efficacy. *Second*, developing and scaling our manufacturing and distribution capacity for mRNA-1273. I will first describe the status of our clinical trials.

As I noted above, 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, which showed the generation of neutralizing antibody titer levels in all eight initial participants. A fuller set of interim data and results of the Phase I study were recently published by the NIH with other authors in the *New England Journal of Medicine*, which are consistent with and expanded on the interim results disclosed by Moderna on May 18, 2020. The vaccine showed neutralizing antibody titers in all forty-five participants evaluated.

The first participants in our Phase 2 study were dosed on May 29, 2020. We completed enrollment of all 600 subjects in our Phase 2 study on July 8, 2020. The Phase 2 study is ongoing.

We are set to begin our Phase 3 trial this month. 30,000 participants are expected to enroll in a randomized and placebo-controlled study, conducted in collaboration with NIAID. Each participant receiving mRNA-1273 will be dosed at 100 μg, the level Moderna has selected as the optimal dose to maximize the immune response while minimizing adverse reactions. Like the earlier Phase 1 and Phase 2 trials, the Phase 3 is a two-vaccine regimen with the doses delivered 28 days apart. The primary focus of our Phase 3 trial is determining whether mRNA-1273 can prevent symptomatic COVID-19 diseases, along with other secondary considerations, such as whether the vaccine can prevent severe COVID-19 disease.

We, along with the rest of the world, will eagerly await the results from these trials. If our vaccine is proven to be safe and effective, the Food and Drug Administration ("FDA") will be responsible for determining whether, when and under what conditions mRNA-1273 is approved.

We have also been working to develop and scale our manufacturing and distribution chains for mRNA-1273. These efforts have been partially facilitated by a $483 million grant awarded from BARDA, as well as $1.3 billion of recent investment from our shareholders. These have helped to lay the foundation for, if mRNA-1273 is proven safe and effective, the efficient manufacture of the vaccine and transfer into the appropriate distribution channels for the vaccination of Americans. Recognizing the need to have a robust manufacturing capability that can be executed at scale quickly, we announced a long term agreement with Lonza Ltd., a Swiss-based company with manufacturing sites in the U.S. and elsewhere, which should allow us to reach an annual manufacturing capacity of more than 500 million doses for worldwide usage.

* * * * *

As the COVID-19 pandemic spread across the world, Moderna hoped and believed our groundbreaking technology could make a positive difference. With the support of our dedicated team of employees, our Board of Directors, our shareholders, and our collaborators in the U.S. government, we stepped forward to pursue the safe and rapid development and manufacture of our vaccine candidate, mRNA-1273.

This is an unprecedented challenge, and no one has ever done anything like this before—not Moderna, not the NIH, and not any of the other companies working to stop this pandemic. While these are trying times, we are dedicated to creating a safe, effective vaccine that can help bring an end to the global pandemic. We remain committed to collaborating with the U.S. government in this process.

Thank you, and I look forward to your questions.

Ms. DEGETTE. Thank you so much.

Now I'm very pleased to yield Mr. Young 5 minutes for your opening statement.

TESTIMONY OF JOHN YOUNG

Mr. YOUNG. Thank you.

Chairwoman DeGette, Ranking Member Guthrie, and members of the subcommittee, thank you for inviting me to testify today. Like my colleagues, I'm honored to be a part of this panel. My name is John Young, and I'm the chief business officer at Pfizer for whom I've worked for over 30 years.

At Pfizer, our purpose is breakthroughs that change patients' lives. In the face of COVID-19, this need is more urgent now than ever, and we've harnessed the full breadth and depth of our colleagues' expertise to help address this global pandemic.

We know that safe and effective vaccines are pivotal, and we're committed to bringing our deep heritage, our reach in scale, and our financial capital to serve the billions of people around the world impacted by this devastating illness.

While there are still important data on the safety and effectiveness of our potential COVID-19 vaccine still to be generated, if our clinical studies and manufacturing scale-up is successful, we have a path to submit our clinical trial data in a Biologics License Application, or a BLA, to the FDA as early as October this year.

Pfizer's chairman and CEO, Albert Bourla, recognized early that this pandemic was not business as usual. But on March the 13, Albert announced our five-point plan to help address the pandemic: First, sharing tools and insights; second, marshaling our people; third, applying our drug development expertise; fourth, offering our manufacturing capabilities to support others; and lastly, improving future rapid response.

As we pursue a potential vaccine for COVID 19, between funding research and development and scaling up manufacturing capacity at risk, we expect to invest at least $1 billion during 2020. To date, we have not accepted any Federal Government funding for this vaccine program, as we recognize that we are uniquely positioned with the scientific and manufacturing expertise and financial resources to have the potential to deliver a vaccine without funding from the Federal Government.

If our clinical trials progress well and we receive regulatory approval, we hope to be able to manufacture up to 100 million doses by the end of 2020, and potentially more than 1.3 billion doses in 2021 globally, subject to final dose selection for a pivotal study.

We extended our existing partnership with BioNTech to develop an mRNA vaccine for flu, to develop a vaccine for COVID-19, as both companies recognize that this technology has the potential to be successfully applied to this disease.

Diversity in clinical trials is critical for this program, given that COVID-19 disproportionately impacts communities of color in the U.S., and to that end, ensuring that our clinical trials are inclusive of diverse populations is a key priority. On July 13, we announced that two of our four investigational vaccine candidates had received Fast Track designation from the FDA.

We've already shared encouraging but preliminary data from the most advanced of our investigational vaccine candidates, suggesting that this candidate could be administered in a dose that appears well tolerated and generate a dose-dependent immunogenicity.

Yesterday we also released additional data from our German phase ½ clinical trial which further demonstrated encouraging T-cell and cytokine responses. Data from this ongoing phase ½ clinical trial will enable the selection of a single lead candidate and identification of the optimal dose level for a large, global phase 2b/3 safety and efficacy study of up to 30,000 participants. And we currently plan to begin that study later this month subject to FDA approval.

We are working closely with regulatory authorities to accelerate the program while maintaining the highest standards in our development process. In order to reduce the normal time taken for such a development program, we are doing sets in parallel rather than sequentially, which requires more capital to be deployed at risk but is the only way to cut significant time from the development program while maintaining safety as a key priority.

In the event that our clinical development program is successful, we've already begun the work to scale up production for global supply. We've announced that Pfizer facilities in St. Louis, Missouri, Andover, Massachusetts, and Kalamazoo, Michigan, will be the sites in our U.S. supply chain.

And finally our goal remains to bring a safe and effective COVID-19 vaccine to as many people as possible globally as quickly as we can. I have great confidence that our industry can prevail in the ultimate outcome of our battle against COVID-19 and that science will win.

Thank you.

[The prepared statement of Mr. Young follows:]

Testimony of John Young, Chief Business Officer, Pfizer
House Energy and Commerce Oversight and Investigations Subcommittee
July 21, 2020

Chairwoman DeGette, Ranking Member Guthrie and Members of the Subcommittee, thank you for inviting me to testify today and I am honored to be part of this panel. My name is John Young and I am the Chief Business Officer at Pfizer. I completed a Bachelor of Science degree in Biology at the University of Glasgow, followed by post graduate research in Immunology at the University of Strathclyde prior to joining Pfizer, for whom I have worked for over 30 years.

At Pfizer, our purpose is: Breakthroughs that change patients' lives. In the face of COVID-19, we recognize that this need is more urgent than ever, and we have harnessed the full breadth and depth of our colleagues and their expertise from across our organization to help address this global pandemic. We know that safe and effective vaccines are pivotal to defeating this pandemic and providing protection from the threat of infection. We are committed to bringing our deep heritage and experience in vaccine development, which spans more than 130 years, our reach and scale, and our financial capital to serve the billions of people around the world impacted by this devastating illness and its consequences for their lives and livelihoods.

I am extremely proud of how Pfizer colleagues are applying our decades of scientific expertise in pioneering vaccine discovery, development and manufacturing, along with our partners, BioNTech, to respond to this global health crisis.

It is both a great privilege and responsibility for all Pfizer colleagues and we are focused every day knowing we are all working towards a common objective — to defeat this virus.

Pfizer has made decisions during this pandemic based on three clear priorities:

- First, ensuring the safety and well-being of our colleagues.
- Second, ensuring the continued supply of our medicines and vaccines to patients around the world.
- Finally, continuing our commitment to collaborate and play our part in discovering breakthrough therapies and vaccines to fight this crisis.

The COVID-19 global pandemic represents an unparalleled moment in the history of modern science. While there are important data on the safety and effectiveness of our potential COVID-19 vaccine still to be generated, if our studies are successful, and our plans to rapidly scale

manufacturing go according to plan, we have a path to submit our clinical trial data in a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) as early as October. According to recently published FDA guidelines, dependent on the data from our studies on the safety and effectiveness of our potential vaccine, that could allow the agency to consider Emergency Use Authorization if the agency determines that the clinical evidence sufficiently meets its guidelines, while it fully reviews our BLA submission.

On March 13, 2020, Pfizer's Chairman and CEO Albert Bourla announced Pfizer's five-point plan to help scientists and companies across the biotechnology ecosystem bring forward potential therapies and vaccines for COVID-19 and prepare the industry to respond more effectively to future health crises.

First, sharing tools and insights: As the scientific community continues to learn more about the virus, many are working in parallel to develop cell-based assays, viral screening tools, serological assays, and translational models to test potential therapies and vaccines. Pfizer is committed to making the tools and data we generate available on an appropriate open source platform to the broader scientific community and to sharing the data and learnings gained with other companies and academics in real time to help rapidly advance therapies and vaccines to patients.

Second, marshalling our people: Human capital is our most valuable resource. Pfizer has created a rapid response team composed of some of our leading virologists, biologists, chemists, clinicians, epidemiologists, vaccine experts, pharmaceutical scientists and other key experts to focus solely on addressing this pandemic. Pfizer's rapid response team is applying their passion, commitment and expertise to a single focus of accelerating the discovery and development process that will deliver therapies and vaccines to patients as soon as possible.

Third, applying our drug development expertise: Many smaller biotech companies are screening compounds or existing therapies for activity against the virus causing COVID-19, but some lack the experience in late stage development and navigating the complex regulatory requirements. Pfizer is committed to sharing our clinical development and regulatory expertise to support the most promising candidates these companies bring forward.

Fourth, offering our manufacturing capabilities: If a therapy or vaccine is approved it will need to be rapidly scaled and deployed around the world to help put an end to this pandemic. As one of the largest manufacturers of vaccines and therapeutics globally, Pfizer is committed to using excess manufacturing capacity that is not required for other important and life-saving medicines to support other companies to ensure new COVID-19 treatments get to patients as quickly as possible.

And, lastly, improving future rapid response: To address future global health threats, Pfizer is working with federal agencies including the National Institutes of Health, the National Institute of Allergy and Infectious Diseases and the Centers for Disease Control and Prevention to help participate in a rapid response team of scientists, clinicians and technicians that can move into action immediately when future epidemics surface.

These guiding principles have provided a consistent framework for all our subsequent work and elicited around 500 unique enquiries from academic institutions, small and medium sized biotech companies, and some industry peers.

As part of these efforts, we have developed a focused plan to develop both a potential vaccine and antiviral treatments for COVID-19, and we are leveraging expertise from across our organization in trying to rapidly progress these efforts.

As we pursue a potential vaccine for COVID-19, between funding both research and development and scaling up manufacturing capacity at risk to be able to quickly supply a vaccine at scale if we are successful, we expect to invest about $1 billion during 2020. To date, we have not accepted any federal government funding for this vaccine development program as we recognize that we are uniquely positioned with the scientific expertise and experience, manufacturing scale and financial resources to have the potential to deliver a potential vaccine without funding from the federal government. If our clinical trials progress well, and we receive regulatory approval, we hope to be able to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses in 2021 globally, subject to final dose selection from our clinical trial.

Pfizer's Rich History in Vaccines

Vaccines are among the greatest public health advancements of all time. For more than 130 years, Pfizer has played a pivotal role in helping to reduce the threat of deadly infectious diseases by developing and selling novel vaccines based on new delivery systems and technologies. And Pfizer's legacy continues to underscore our deep commitment to safety and efficacy.

- In 1906, the diphtheria antitoxin became the first FDA-licensed product manufactured at the company's Pearl River, New York, facility.

- In 1948, the company introduced a combined vaccine for preventing diphtheria, tetanus and pertussis in young children.

- In 1968, Pfizer was the first to develop a bifurcated needle which subsequently revolutionized delivery of the smallpox vaccine and led to its worldwide eradication.

- In 2000, Pfizer was the first to license a 7-valent pneumococcal conjugate vaccine for infants and young children.

- In 2010-2011, we were the first to license a 13-valent pneumococcal conjugate vaccine (PCV13) for infants and young children and, in 2011, for adults 50 years and older.

This history illustrates Pfizer's legacy in researching, developing and manufacturing safe and effective vaccines to help prevent many devastating diseases.

We operate one of the most sophisticated supply chain systems in the industry with over 40 Pfizer-owned global sites and have approximately 10,000 U.S.-based manufacturing colleagues. Pfizer manufactures 23 billion medication doses per year in-house, including over 200 million vaccine doses, and is one of the largest U.S. sterile injectables suppliers, producing approximately 1 billion sterile units in the U.S. per year.

Collaboration with BioNTech and Our mRNA Vaccines

Pfizer initially partnered with BioNTech in 2018 to research and develop an mRNA vaccine for influenza. Both companies recognized early in the pandemic that this technology had the potential to be successfully applied to COVID-19, and so we extended our partnership with the BNT162 COVID-19 vaccine program.

The vaccine candidates are based on BioNTech's proprietary mRNA vaccine platforms. The collaboration leverages Pfizer's expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network.

mRNA vaccines are a new approach to vaccination and work by conveying genetic instructions (the mRNA) to human cells that then use their cellular machinery to "translate" or make the spike protein antigen specific for the COVID-19 virus that is displayed on the surface of the cell.

The thesis is that the antigen is recognized by the immune system of the vaccinated individual, generating an antibody response to inactivate (neutralize) the SARS-CoV-2 virus and so prevent, or lessen the symptoms of, COVID-19.

The novel design of the clinical trial program has enabled Pfizer and BioNTech to evaluate up to four different potential vaccines with combinations of two different antigens and three different mRNA formats to enable us to select and advance the optimal vaccine candidate efficiently with the goal of identifying a potential COVID-19 vaccine for further evaluation, in a Phase 2b/3 safety and efficacy study that is subject to regulatory approval.

This approach of testing multiple vaccine candidates allows us to collect clinical data on the safety and effectiveness of each potential vaccine at multiple dose levels in each age group (older and younger adults) to inform our decision-making earlier in the development process.

Clinical Trials – Pfizer and BioNTech Development Plan

Pfizer and BioNTech are currently running two trials in parallel with Pfizer leading the U.S. trials and BioNTech leading the EU trials. The clinical trials in the U.S. and EU have been designed to test the same candidates.

The first stage of the U.S. study began in early May and is taking place at four sites across the U.S. These initial sites include: NYU School of Medicine; University of Maryland School of Medicine; University of Rochester School of Medicine; and Cincinnati Children's Hospital.

Diversity in Clinical Trials

Diversity in clinical trials is a priority for Pfizer and is critical given that COVID-19 disproportionately impacts communities of color in the U.S. We understand the importance of developing vaccines and potential treatments that are safe, effective and easily available to people of color. To that end, ensuring that our COVID-19 clinical trials are inclusive of diverse populations is a key priority.

Our COVID-19 clinical trials include understandable patient-focused materials in multiple languages to educate and inform prospective participants about the disease and explain what they can expect when participating in the clinical trial. Our goal is to recruit participants in alignment with the epidemiology data that has been produced by the Centers for Disease Control and Prevention. We know conducting studies in locations with diverse communities will be instrumental in recruiting minority participants and study staff.

We have developed a dashboard with data from Johns Hopkins University and the U.S. Census Bureau by county, including percent distribution of individuals in the population by race, ethnicity and other demographics, along with the incidence of new cases of COVID-19. This dashboard will aid the investigator site identification process and help us identify areas of opportunity for study placement in communities of color and in locations that have seen higher rates of COVID-19 infection.

Early Positive Phase 1/2 U.S. Data

On July 13, 2020, we announced that we have reached another milestone: two of our four investigational vaccine candidates have received fast track designation from the FDA. These two are the most advanced vaccine candidates in the BNT162 program.

Previously, we shared preliminary topline data from the most advanced of our investigational vaccine candidates, known as BNT162b1, from the mRNA-based vaccine program. Overall, the data are encouraging and showed that this candidate could be administered in a dose that was well tolerated, and generated dose-dependent immunogenicity, as measured by RBD-binding IgG concentrations and SARS-CoV-2 neutralizing antibody titers.

Early positive data show that BNT162b1 administered in doses between 10 ug to 30 ug provided neutralizing titers at or above a panel of human convalescent serum as early as 28 days; 7 days after the second dose of the vaccine.

Local reactions and systemic events after immunization with 10 µg and 30 µg of BNT162b1 were dose-dependent, generally mild to moderate, and transient. No serious adverse events were reported.

Data from the ongoing Phase 1/2 clinical trial will enable selection of a single lead candidate and identification of the optimal dose level for a large, global Phase 2b/3 safety and efficacy study of up to 30,000 participants that may begin later this month, subject to FDA approval.

The preliminary clinical data from this ongoing study have been submitted for potential publication in a peer-reviewed journal and we made this immediately available on an online preprint manuscript server.

Timelines for Approval

We are working with closely with regulatory authorities, including the FDA, to accelerate our program while ensuring that safety is our top priority. We are maintaining the highest standards in our development process. However, in order to reduce the normal time taken for such a development program, we are doing steps in parallel rather than sequentially, which requires more financial capital to be deployed at risk but is the only way to cut significant time from the development program while maintaining safety as the key priority.

We are sharing data from our COVID-19 vaccine clinical trials with the FDA in real time so the agency can evaluate at the earliest possible time whether the safety and efficacy threshold has been met that would enable us to continue our development and proceed to the necessary larger Phase 2b/3 clinical trials.

Manufacturing

Pfizer is dedicating its best-in-class global resources to ensure we can respond rapidly to the COVID-19 pandemic, including rapid development of a supply chain for the new potential vaccine while ensuring the necessary standards of quality and safety are achieved.

In the event our clinical development program is successful, we have already begun the work to scale up production for global supply. We have announced that our Pfizer facilities in St. Louis, Missouri; Andover, Massachusetts; and Kalamazoo, Michigan, will be the sites in our U.S. supply chain and we are currently scaling up to prepare for production. In parallel, we are working with our partners BioNTech to develop an EU supply chain. We are investing significant financial capital at risk to procure necessary raw materials, glass, and stoppers as well as making capital investments in new manufacturing suites and processes for this sophisticated new technology.

Volume

mRNA vaccines are an extremely innovative new technology that require the rapid development and scale-up of novel manufacturing technologies. As part of our capacity planning for a COVID-19 vaccine candidate, we identified that producing the volume of doses that we have committed to, in addition to our existing medicines and vaccines, will make significant demands on our current manufacturing network. We are leveraging redundant supply capacity as well as pulling forward production of other important medicines in our network to create capacity for vaccine manufacture to begin in the fall.

Next Steps

Pfizer's manufacturing and supply chain professionals have been taking several steps to accelerate the scale-up and manufacture of the most promising vaccine leads, including:

- Working with internal and external partners to exchange technology and to enable rapid facility, equipment and process design plans.

- Ordering materials and starting to manufacture multiple vaccine variants in parallel with initial clinical trials knowing that only one of the variants will be selected to move forward.

- Hiring and training staff in select sites to give our operations the support and flexibility needed.

- Shouldering the financial risk to do what it will take to bring as many doses of a vaccine forward as quickly as possible. Pfizer anticipates making additional investments over time.

In conclusion, I believe the probability is high that the biopharmaceutical industry will be able to develop one or more safe and effective vaccines, effective antiviral treatments, and targeted immune-modulators that patients and the world at large so desperately need. But we must also remain vigilant and be prepared to respond to potential new strains of the virus or future threats. We should learn from this unprecedented global crisis and ensure that the world has vaccine platforms capable of rapid development and deployment to prevent the human and economic tragedy of COVID-19 from ever happening again.

I have great confidence that our industry can prevail in the ultimate outcome of our battle against COVID-19 — and that Science Will Win.

Ms. DEGETTE. Thank you so much. And it's now time for the questioning. The Chair will recognize herself for 5 minutes.

Everybody knows that time is of the essence in the search for a COVID-19 vaccine, and obviously everybody wants it as quickly as possible, but we need to make sure that it's going to be safe and effective against the virus too.

I want to ask each of you your quick and honest assessment on the likelihood of success of the vaccine candidates and when they would be available to millions of Americans?

I only have a brief amount of time, so brevity is the answer of the day. Dr. Pangalos, yesterday seemingly encouraging results from your early clinical trials were released. You stated that AstraZeneca hopes to have the results of its phase 3 study this fall and is scaling up to manufacture hundreds of millions of doses of the vaccine to be immediately available upon emergency use authorization on approval.

Briefly, what do you think the probability of your vaccine to be proven safe and effective, and do you believe it will be available in the United States at the end of the year?

Dr. PANGALOS. Thank you, Chairwoman. I think it's a great question, a difficult question to answer in terms of probability. I think we're very encouraged by the industry data that we have in the phase ½ study and the probability data we have because we are seeing both an antibody response and a T-cell response. And as you know at the moment, we don't know what the immune correlates of protection are that will ultimately confer protection against this virus.

Ms. DEGETTE. Right. But if it is approved, do you hope it will be available at the end of the year on an emergency basis?

Dr. PANGALOS. Yes, we do. So if we have efficacy data, we hope we will have them any time from September onward.

Ms. DEGETTE. Thank you.

Dr. Hoge, Moderna is set to begin its phase 2—3 study this month, but it's never brought a successful vaccine to market. Do you believe that your vaccine candidate will be successful, and if so, do you think it will be available for distribution by the end of the year?

Dr. HOGE. Chairman DeGette, thank you very much for the question. I think we're optimistic—cautiously optimistic I think is the word others have used—that the vaccine will be successful.

The data we published in the New England Journal of Medicine is the basis for that, as well as other data we've seen in challenge models. So we're quite encouraged by the progress.

Ms. DEGETTE. Yes but——

Dr. HOGE. The phase 3 trial—I'm sorry.

Ms. DEGETTE. Yes.

Dr. HOGE. The phase 3 trial is a little bit beyond our control in terms of timing because it's a case-driven study. But presuming that we are able to accrue cases relatively quickly in that study, we would hope in the fall or towards the end of the year, we'd have data that we could submit to the FDA for them to make a determination on whether to approve.

Ms. DEGETTE. And then——

Dr. HOGE. We would also hope at that point to have millions of doses of vaccine available for disbursement.

Ms. DEGETTE. Thank you.

OK. Mr. Young, Pfizer is developing four vaccine candidates and will also begin a phase 3 study later this month. It expects to manufacture up to a hundred million vaccine doses by the end of the year.

Again, briefly, what's the likelihood that one of your candidates will be successful, and when would it be available to the American public?

Dr. YOUNG. So thank you for your question.

We are very encouraged by the early data that we've seen from our initial phase 1 study in terms of both safety and effectiveness. We aim to complete that study this month and submit those data to the FDA, and subject to their approval, to begin our large phase 3 clinical study, and obviously that study is going to be pivotal in informing the scientific community and regulators, particularly as to the safety and effectiveness profile of the vaccine.

As I mentioned in my statement, we have a line of sight on a clear, critical path, to be able to deliver up to 100 million doses of commercial scale vaccine product in 2020, and up to 1.3 billion doses of our vaccine in 2021.

So encouraging early signs and a lot more work still to do.

Ms. DEGETTE. OK.

Dr. Douoguih, how realistic is it that your timeline, based on the status of your clinical trials and your manufacturing capacity?

Dr. DOUOGUIH. Thank you for the question.

We are very much encouraged by our preclinical results. As I mentioned, we are starting our first clinical trial this month. We will be starting our phase 3 in September. Now, it's very difficult to say whether or not we will be lucky enough to have set up our sights in the right places to be able to get an answer and read-out on efficacy. That's certainly possible, but we're targeting to at least have results by early 2021, as well as a hundred million doses by the end of March.

Ms. DEGETTE. Of 2021?

Dr. DOUOGUIH. Correct.

Ms. DEGETTE. Thank you.

Finally, Dr. Gerberding, as we learned from your testimony, Merck's timeline is a little bit longer than the others we've heard from, but please tell us briefly, are there reasons to be optimistic that all Americans who need a COVID-19 vaccine will have access to one by early 2021, maybe even in January?

Dr. GEBERDING. I certainly hope my colleagues are successful in prosecuting their pipelines. I can really only speak for Merck. We expect to be in clinical trials imminently for both of our products, but we would not expect to have a licensed product until 2021 at the earliest.

Ms. DEGETTE. Thank you. Thanks to all of our witnesses. I really appreciate it.

The Chair will now recognize the ranking member, Mr. Guthrie, for 5 minutes for purposes of his questions.

Mr. GUTHRIE. Thank you very much. I want to answer mine quick because I want all five of you to answer, and I want to be

able to make sure that you have time to answer, so mine's is on the speed and—the speed versus safety and effectiveness. Dr. Fauci and Commissioner Hahn said in testimony last month that it is—we're not risking safety to science. I think it's important the American people hear from each of you on your trials.

And one, could you—so this is the question: Could you explain whether the unprecedented speed with which you are moving means sacrificing safety or efficacy? And what specifically is your company doing to ensure safety and efficacy of your vaccine? And could you tell why you believe it's possible to bring a safe and effective COVID-19 to market in 12 to 18 months when currently the fastest vaccine to be developed was mumps, and that took 4 years.

So I'm just going to call on you, and I'm going to try to manage the time to make sure you all have a chance to answer. You each have about 45 seconds to answer that, but first, Dr. Pangalos.

Dr. PANGALOS. Thank you very much for what's a very important question. So, in short, I do believe we can do this in terms of delivering both a safe and efficacious vaccine. These are unprecedented times in terms of how we're interacting with regulatory authorities all around the world, including the U.S. FDA, but also, how our people are working in terms of 24/7 work. All of our interactions, I think, have been consistent with having to demonstrate a safe and effect vaccine. I don't think any of the regulatory bodies who we interact with are lowering their standards.

And by the end of our pivotal studies, we'll have dosed nearly 50,000 people. So that will be, I think, a very significant number and comparable to any of the vaccines that have been approved in recent times.

Mr. GUTHRIE. Well, thank you.

Dr. Douoguih. Sorry for the quick response. Dr. Douoguih.

Dr. DOUOGUIH. Thank you. We do also believe it's possible to deliver a safe and effective vaccine. We have experience with the accelerated programs, as we have developed the Ebola vaccine. A lot needs to be done in parallel, but it can be done safely and without compromising any of the standards that we usually undertake for any clinical trial. There may be a need to perform post marketing surveillance, and we're working on a plan there to make sure that we continue to monitor safety, not only before licensure, but after for the duration that's deemed appropriate by the regulators. So it will be an effort, and we will continue to monitor safety long term, but it should be feasible to do this.

Mr. GUTHRIE. Thank you.

Dr. Geberding?

Dr. GEBERDING. Thank you. You know, Merck has a long experience, and science is a stern taskmaster in this regard. There is a lot we don't know about this virus, and there are some special safety concerns that really have to be watched for it, including enhancement of the respiratory disease under this kind of immunologic pressure.

So, I think while we are fully prepared to move as quickly as we can through the things we can do in parallel and gearing up for manufacturing now at risk, we do not expect to be able to accelerate the safety assessment. And, in fact, we're quite relieved that the FDA insisted upon applying the same high standards of safety

and efficacy, even under these emergency conditions, that they would apply to any of the vaccines that we've prosecuted in the past.

Mr. GUTHRIE. Thank you very much.

Also, now, Dr. Hoge.

Dr. HOGE. Thank you, Congressman. We—I echo my colleagues' earlier comments. We do believe it's going to be possible to, in a safe way, bring afford an effective vaccine in 12 to 18 months. We have been working around the clock as an industry, as a company, with colleagues outside of our company as well to make sure that we're doing it this an incredibly responsible way all the way through it. So we have a full phase 1, phase 2, phase 3 program. And as has been referenced before, we're following the FDA's guidance to conduct a 30,000-person, full phase 3 program over the course of the fall. We hope that generates a robust body of data, demonstrating the safety of the vaccine that can give the FDA and Americans confidence in its profile.

Mr. GUTHRIE. Thank you very much.

And Dr. Young.

Mr. YOUNG. Thank you for the question. Pfizer is completely committed, as I think you've heard from my colleagues here in the panel, to ensuring the safety and effectiveness of any COVID-19 vaccine.

In answer to your question about how we were able to move quickly, we were actually in a fortunate position. We were able to leverage a couple of years' worth of basic science that we did along with our partners, BioNTech, for seasonal flus and to apply those learnings to our vaccine platform for COVID-19.

I want to underscore something that my colleagues have mentioned, which is, I think the American public should take great confidence in the FDA's guidelines which I think clearly and very transparently lays out standards for both effectiveness, but importantly, for safety, and I think we're very happy to say those clear guidances and the high standards that they're going to expect for all of our companies to demonstrate in our clinical trials in order for any vaccine candidate to be approved.

Mr. GUTHRIE. So, good. So you're all saying there will not be a vaccine on the marketplace that does not meet the high standards of the safe and effectiveness regardless of the timing. So thank you very much. My time has expired, and that's very comforting to hear.

Thank you very much, and I yield back.

Mr. PALLONE. All right. I'm going to recognize myself for 5 minutes next until Diana comes back. Let me say that I heard what some of the previous speakers said, and you know, historically, I've been very confident in the FDA. But now that Trump is President, I still think there's a real possibility that he will pressure the FDA to lower the standards, either by maybe putting out new guidelines that say that they don't have—the standards don't have to be as good. I think right now, they say the vaccine has to be 50 percent effective. But let's say—let me give you a scenario where the FDA changes its guidance and says, Oh, it only has to be 20 percent effective, or 10 percent effective. Or they keep to the guidance, but you know that yours is only 10 or 20 percent effective, and they

approve it anyway, saying, Well, you know, it meets the standards even though you don't.

I guess I'm trying to rely on you as the manufacturers to kind of assume that the FDA will not meet the high standards either by changing the standards, or by saying it's OK when you know it isn't.

What do you—what can you do in those circumstances? I mean, I want to make sure that you will guard against any pressure that comes from the FDA to either lower its standards, or to approve something that you know doesn't meet the standards. How can we—what would you do as manufacturers to help us out in that regard on the assumption that we can't trust the FDA the way you sort of assume?

And let me start with—I guess we could start with Dr. Pangalos. I know that's difficult to answer, but I want you to kind of assume what, unfortunately, shouldn't happen which is, you know that the FDA is approving the drug even though it's only 10 or 20 percent effective. Will you tell us that? Do you feel an obligation to tell us that and give us that information? I'll start with Dr. Pangalos.

Dr. PANGALOS. Thank you very much for, again, a very important question.

What I will say, first of all, all of our interactions with the regulators have given us no evidence that they're lowering the standards or thinking about lowering the standards. Secondly, as a company, we will always think about safety and efficacy, first and foremost, in making is sure that we have an effective medicine. We would not be trying to launch a medicine that is not effective.

Mr. PALLONE. But, Dr. Pangalos, what I would ask is that regardless of what the FDA says or does that we could have some sort of assurance from you and others that you would tell us truth about the effectiveness of the vaccine, that they are not—

Dr. PANGALOS. Absolutely. So all of our data have been pivotal studies that we published, as is true of all of the studies that we run in pivotal trials, but also, remember, this is going to be a vaccine that is going to be used globally, and so every regulatory authority is going to have a view on the efficacy and the safety of our vaccine.

Mr. PALLONE. That's helpful. Now let me ask Dr. Douoguih the same thing. Assuming that, you know, you find out the FDA's going to approve something that you know is not 50 percent effective, that's 10 or 20 percent, can you give us some assurance that you would tell us truth about the effectiveness of it, regardless of FDA approval?

Dr. DOUOGUIH. Thank you for the question. So we have a target product profile, which outlines the minimum characteristics and desired characteristics for the development of our product, and that includes assumptions on minimum vaccine efficacy. If we saw 10 percent, and we would design our trial, actually, to target the efficacy that's outlined in our target product profile, the study would fail if it hit 10 percent. We would make those results available, but we would not feel comfortable bringing forward a product that did not—that was not found to be efficacious according to what we put forth in our protocol.

Mr. PALLONE. Well, I appreciate that. Now, let me ask Dr. Hoge from Moderna. Can you describe how you would report any adverse events that might arise in your clinical trials once it's available for use? I'm trying to get some answers on adverse events reporting, if you would.

Dr. HOGE. Sure. So thank you for the question. Just like we've done recently in our New England Journal publication, any adverse events, we would publish completely that data, and we would expect to do that similarly for the phase 3 results, regardless of whether the trial is successful or not.

It's important also to note, sir, that our vaccine study is being conducted in collaboration with the NIH, and they've actually set up an independent data safety and monitoring board that will be adjudicating and reviewing both the safety and efficacy of our study, which hopefully will provide another level of confidence in the conclusions.

The CHAIRMAN. All right. Thank you all. I appreciate your responses. And I will now yield to the ranking member, Mr. Walden, 5 minutes. If he's not there—maybe he went to vote. I don't know.

Mr. GUTHRIE. Mr. Chair, he did go vote. He was voting on the floor.

The CHAIRMAN. Do we have another Republican that's available? Mr. Griffith? Can we go to you, Morgan? I recognize Mr. Griffith for 5 minutes.

Mr. GRIFFITH. I'm available. Thank you very much, Mr. Chairman. I do appreciate it.

We've heard a lot of comment, and I thought that when you're answering Chairman, or Ranking Member Guthrie's questions, you made it clear that you all felt the FDA guidelines were sufficient. Those guidelines issued in June of this year related to the COVID-19 vaccine, so let's go through that again just so we can eliminate any hypotheticals.

Do you all believe—do your companies believe that the guidance issued by the FDA is sufficient to ensure a safe and effective vaccine, and if not, say why? We can start with you, Dr. Young.

Mr. YOUNG. Thank you for the question. I'd just like to reaffirm what I mentioned in my comments previously. I think the FDA should be commended for publishing clear, transparent, evidence-based guidelines that set an appropriately high standard on both safety and effectiveness for a vaccine. I think—in echoing some of my colleagues here, I think the clinical trial protocol that we are putting together for our phase 3 study will follow those guidelines, and, you know, were a vaccine to demonstrate lower effectiveness, then, frankly, it would fail the study.

So we have great confidence that, actually, in following the FDA's guidelines that the American public and Congress, in fact, should be confident that any vaccine that is approved should meet those standards for safety and effectiveness.

Mr. GRIFFITH. All right. Anyone else want to weigh in on that? I know that you've already answered the question sort of, but I wanted to clear up any confusion.

All right. Let me ask this question, then: What is FDA requiring of your companies to ensure that corners are not being cut during the development process? Are there details that you can give us

that might quell concerns that this process is happening too quickly? And we can start with whoever wishes to start. Dr. Geberding?

Dr. GEBERDING. Thank you. Yes. I think the way to think about this, really, is to understand that the FDA is not loosening any standards, so business as usual. Whatever portfolios or dossiers that we bring to the FDA have to meet these rigorous standards.

And let me just say that when we were prosecuting our Ebola vaccine portfolio, it took five years from the time that we did the phase 3 study until the FDA finally approved our vaccine at the end of 2019, in part, because they maintained a very rigorous standard of safety in the context even of that dreadful outbreak.

So, we are familiar with the expectations, and we're fully prepared to be transparent about any safety signals and fully transparent about the efficacy that we observe.

Mr. GRIFFITH. Dr. Pangalos?

Dr. PANGALOS. I think the guidelines that FDA have issued are absolutely to the normal standards, and I think that if we are able to meet them, we will have a safe and efficacious vaccine. There is nothing that gives me pause that they're lowering their standards in any way.

Mr. GRIFFITH. I appreciate that. Any of the other witnesses want to answer that question?

Dr. DOUOGUIH. It's Macaya Douoguih. Yes. We also agree that the standards are appropriate, and perhaps even more stringent than some of the criteria we've had for some of our other products, so we think that that will ensure that we are developing the appropriate studies and with appropriate follow-up to really evaluate the safety and efficacy of this vaccine.

Dr. HOGE. Congressman, all I would add is, I would also agree that the standards put out by the FDA are really the gold standard, and we appreciate them put out in advance, and we intend to measure ourselves against it.

Mr. GRIFFITH. Thank you very much.

Now, I did speak with Dr. Young earlier about this question, but I'm happy to hear from others as well. I'm just curious if the company has learned anything in the process thus far of working on the COVID vaccine that might help develop future flu vaccines and make that process both more efficient and more effective, and frankly, have a vaccine created more quickly when we know what's coming at us.

Mr. YOUNG. Thank you for that question. Yes. Thank you for the question. I think as I mentioned in my other comments, you know, one of the things that we were able to do is to leverage some of the basic research that we've done with our partners, BioNTech, on mRNA technology which potentially lends itself to having lower and more potent dosage, but also being able to change out the coding of the mRNA in order to be able to develop much more quickly than would normally be the case a vaccine with an antigen for a particular pathogen or infection.

We believe that technology platform potentially lends itself extremely well to having more effective flu vaccines in the future, and we hope to apply the learnings from our COVID program to that going forward.

Mr. GRIFFITH. Now, I don't have enough time to get everybody in, but real quickly, can you tell the folks back home who are watching this or later tonight on C-SPAN what mRNA is, messenger ribonucleic acid?

Mr. YOUNG. It's actually the coding our bodies normally use. It's essentially like a code that our cells use to—naturally to produce proteins in our body, and we can use that same basic technology to produce an antigen that would enable the—potentially enable the development of an immune response to a pathogen such as COVID-19.

Mr. GRIFFITH. Thank you. My time is up.

And thank you, Mr. Chairman. I yield back.

The CHAIRMAN. Thank you, Mr. Griffith.

Next is Ms. Schakowsky recognized for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, or Madam Chairman, wherever she is.

So I want to talk about Pfizer. A recent Gallup poll showed that nearly nine in ten Americans are concerned that drug makers will take advantage of the pandemic to raise prices. From insulin to countless other examples, we've seen drug companies use monopoly control to price gouge patients, and sometimes make it impossible for them to get their medications. Ensuring the safety and efficacy of COVID-19 vaccines, of course, is critical, but it will mean nothing if the price is a barrier to all Americans getting it.

So, to the witnesses. Your trade association, PhRMA, claimed in an advertisement, and I quote, "We've had a number of companies that have already made public a public pledge that if their vaccine is ultimately successful that they will"—"they will produce it essentially at cost, meaning no profit for that company," unquote. Now, Mr. Young from Pfizer has already stated that it will sell its vaccine for a profit.

So for the rest of the witnesses, will you please answer yes or no? Will you sell your vaccine at cost and provide contract transparency so that we can verify you aren't making a profit? So, Dr. Hoge, yes or no?

Dr. HOGE. We will not sell it at cost.

Ms. SCHAKOWSKY. You will what?

Dr. HOGE. We will not sell it at cost. No, ma'am.

Ms. SCHAKOWSKY. You will not sell it at cost. OK.

Dr. Pangalos, yes or no?

Dr. PANGALOS. Under the agreement we have with BARDA for the 300 million doses, we are selling that to the government at no profit.

Ms. SCHAKOWSKY. Thank you.

Dr. Geberding, yes or no?

Dr. GEBERDING. Yes to your question about transparency as we have reported since 2018, transparency in our pricing. We have not raised our prices since the pandemic began. And, no, we will not be selling vaccine at cost, although it's very premature for us, since we're a long way from really understanding the cost basis of what we'll end up with.

Ms. SCHAKOWSKY. A yes and a no.

Dr. Douoguih.

Dr. DOUOGUIH. Yes. We will be providing vaccine at a not-for-profit price during the emergency pandemic.

Ms. SCHAKOWSKY. Thank you.

Taxpayers have provided nearly $10 billion to Operation Warp Speed, but have no knowledge of how these resources are being spent. For the companies receiving taxpayer funding for your vaccines, have any of your contracts or agreements with the Federal Government included provisions to ensure affordability in pricing or vaccines, and affordable pricing of vaccines or treatments? Let me start, again, with Dr. Hoge about the agreements? What's in them?

Dr. HOGE. No. We don't have a supply agreement with the U.S. Government, Congresswoman. We have a research and development agreement, and it doesn't specifically speak to those supply conditions.

Ms. SCHAKOWSKY. That's what I'm asking. OK.

Dr. Pangalos?

Dr. PANGALOS. Yes. Under our agreement with BARDA which is over $1 billion, it's funding our clinical development program which is the 30,000-patient study in adults and children, and it's also funding the 300 million doses that we're going to be providing at no profit for AstraZeneca.

Ms. SCHAKOWSKY. Dr. Geberding.

Dr. GEBERDING. We are not receiving funding from Warp Speed at this time, but we do have just under $40 million for research and development of our vaccine portfolio, but we have no procurement agreements at all.

Ms. SCHAKOWSKY. Dr. Douoguih.

Dr. DOUOGUIH. Our funding covers research and development activities, and we do not have a supply agreement in place.

Ms. SCHAKOWSKY. OK. I'm going to put these—this question out there, and it may have to be answered, then, in writing. Mr. Young from Pfizer, your company has rejected taxpayer funding for your vaccine on concern that you will make this—that you made this decision to be able to price gouge, or at least I'll say that, without question from Congress. Will Pfizer commit to affordable vaccine pricing and full transparency around research and development?

Mr. YOUNG. So thank you for the question. You know, let me just say, as I mentioned in my earlier comments, that we didn't accept the Federal Government funding solely for the reason that we wanted to be able to move as quickly as possible with our vaccine candidate into the clinic.

In regard to your question, let me just say that we recognize that these are extraordinary times, and our pricing will reflect that. And during the time of the pandemic, we'll price our potential vaccine consistent with the urgent global health emergency that we're facing.

And, secondly, we also believe, and critically, that COVID vaccine should be free to the public. A vaccine is meaningless if people are unable to afford it. And I just want to applaud Congress for passing the CARES Act to ensure that many patients who will not face any cost-sharing for future COVID vaccine, and we would certainly commend that stance.

Ms. SCHAKOWSKY. OK. Well, we'll see what that means. I hope you do find a cure.

And I yield back. Thank you.

The CHAIRMAN. Thank you, Ms. Schakowsky.

I'm told by the Republicans that next is Mr. McKinley recognized for 5 minutes.

Mr. MCKINLEY. Thank you, Mr. Chairman, and to the panel. From what we've heard today, a vaccine still could be months away, and that parents have been saying to us that they don't want to send their children back to school without a vaccine. So knowing what you know now, would you send your children, your grandchildren, back to school, yes or no? Each of the five.

Dr. PANGALOS. I can say in the United Kingdom, I will be sending my children back to school in September if the schools are open.

Mr. MCKINLEY. OK.

Dr. HOGE. Congressman, I can say for myself, my wife and I are both physicians. Our local public school has asked us to answer that question, and I honestly don't know the answer yet, even for my three children. We're wrestling with the same challenges parents across the country are trying to figure out the right thing to do.

Mr. MCKINLEY. So have you come to a conclusion?

Dr. HOGE. No, sir. We're talking about that tonight at dinner. I don't know yet.

Mr. MCKINLEY. Just—if you're confused, think about all across America, if they're following the guidelines. I hope it's not perpetuating this problem if we follow the guidelines. So, how about quickly, the other people on the panel? They maybe can step up and do what's right.

Dr. GEBERDING. I can respond to that from my perspective. I had a conversation last night with a mother and two grandchildren in our family, and they are facing a situation where all three children, or the two children and the mother are teaching in three different school districts. They may end up with different policies. So I think there's a great deal of local variability, and we need better science about the role of pediatrics transmission in daycare, schools, and colleges.

Mr. MCKINLEY. Haven't the pediatrics—hasn't the association already said they should be back in school? So I'm not going—I just wanted to get your input because people are looking for you for leadership and what to do with the children, whether we are getting our schools to open up, and you all are waffling on this, given that the Pediatric Association has already advocated.

So let me go to the second question. Given that what we've learned through the difficulties that we've been dealing with with China, would any of the ingredients in your vaccine formula come from China?

Mr. YOUNG. Maybe I can start. Congressman McKinley, thank you for the question. For Pfizer's—Pfizer and BioNTech's potential COVID-19 vaccine, none of the materials, none of the drug substance will involve any part of the China supply chain. So we anticipate for our vaccine candidate that we'll develop our supply chain within the Pfizer network dedicated to the United States.

And the raw materials and drug substances, likewise, would be sourced within the United States.

And in the case of, you know, glass and some other important parts of our supply chain, that would be sourced from Canada, Germany and the United States, so no contribution from China.

Dr. PANGALOS. I can answer. This is a global pandemic, so as a company, we want to resolve this pandemic globally. We have kept our supply chains independent of each other. So for our U.S. supply, all of our U.S.—all of the manufacturing will be done in the United States using our—either our own facilities or contract manufacturers in the United States.

Mr. MCKINLEY. OK. Let me go to the third question that I have. I was hoping it was going to be a yes or no, that we would be able to get through the other one. But on this last, already—Chairman Pallone and DeGette have already brought up this irresponsible allegation that your companies might bring a drug to market before it's been sufficiently tested.

Are you—are your companies insulted by that—an accusation that you could bring a drug to market that's not safe or effective? Is that insulting? Each of the five of you, please.

Dr. PANGALOS. I think people—thank you for the question. I think given the speed at which we're working, it's understandable that people may ask questions about whether anyone is cutting corners. I think what you're hearing from all of us is that despite the speed that we're working at, we're not cutting corners, and regulators are not lowering their standards. So I feel comfortable if there are vaccines that are effective, they will be safe and effective, and that they'll be good to go in terms of then getting regulatory approval.

Mr. MCKINLEY. Any others?

Dr. DOUOGUIH. It's Macaya Douoguih. We are working around the clock to accelerate our developments, but we are not cutting corners on safety. We believe that we will——

Mr. MCKINLEY. Yes. My question was, is that insulting, that you could even be accused—that a company of your stature, that you could be accused of cutting corners?

Dr. DOUOGUIH. We follow science, and we will continue to develop safe and effective products as we always have.

Mr. MCKINLEY. Thank you. Thank you.

I yield back. My time's expired.

The CHAIRMAN. Thank you.

Next, the gentleman from Massachusetts, Mr. Kennedy, is recognized for 5 minutes.

Mr. KENNEDY. Thank you, Mr. Chairman. I'm grateful to you and grateful to Chairwoman DeGette for convening this hearing, and grateful to our witnesses for being here as well. It's an important topic of conversation.

I have no doubt that our country is capable of and committed to developing a vaccine for COVID-19. I'm grateful for all the work that you all are doing to get us there. But what I also want to ensure is that there is sufficient political will and corporate courage to ensure that a vaccine is not only accessible to the patients and communities hit hardest by the coronavirus, but also intentionally distributed to them as well because it has been choices of genera-

tions of elected officials and a healthcare industry that has led to some of the historic disparities that we have seen throughout the course of this pandemic, particularly for communities of color who have been devastated by the spread of this virus.

Back home in Massachusetts, our State government recently designated eight separate cities as hotspots even though—or where the rate of COVID-19 infection is higher, and the rate of testing is lower: Chelsea, Everett, Fall River, Lawrence, Lowell, Lynn, Marlboro, and New Bedford, communities with higher rates of immigrants and higher rates of minorities and communities of color than the rest of our Commonwealth, and there is, I think, well known at this point a direct correlation between them.

Now, the companies represented here today have put forth enormous effort and resources into the development of a vaccine, but obviously, as Ms. Schakowsky pointed out, you haven't been doing it alone. Many of you—well, some of you, anyway, have received the backing of the American people through Federal funds for support, half a billion for Johnson & Johnson, half a billion for Moderna, and up to $1.2 billion for AstraZeneca.

So I believe you all have a responsibility for those investors as well. You have a commitment to the social good and a commitment to righting the wrongs of past decisions that have priced life-saving medicines out of those same communities, and I'd like to start diving in a little bit here about what your plan is.

So I want to begin with Dr. Pangalos. Do you have—have you engaged at all in any plan to ensure that there is, in fact, equitable distribution of a vaccine should you come up with one, and particularly, into front line communities where you—where we have seen rates of infection the highest?

Dr. PANGALOS. Thank you for the question. And we appreciate the impact that this disease is having, the disproportionate impact these disease is having on those core communities, communities of color and of ethnic diversity. And as I said in my testimony, our goal is to provide good and equitable access to all races, and all people in the United States and around the world.

In terms of the agreement that we have with the United States to supply the 300 million doses, clearly we're supportive of making sure that distribution of vaccine is done equitable and fairly.

Mr. KENNEDY. So, sir, I don't mean to rude. I just don't have a ton of time here. So is there a plan that is being put forth to ensure that there is, in fact, equitable—I know you want there to be, but is there—have you actually developed one, and in what state of development is that?

Dr. PANGALOS. No. It would be the administration that is determining the 300 million doses that we provide, how they wish to distribute them across the United States because we're giving out doses to the United States Government.

Mr. KENNEDY. And, Dr. Douoguih, the same circumstance. Is it up to the administration to decide the distribution?

Dr. DOUOGUIH. It is. However, we are prepared to share our equitable—our plan that we are working on which is based on an ethical framework which focuses on the highest risk and highest medical need, and we're happy to provide that and have further discussions on that topic, important topic.

Mr. KENNEDY. I would be grateful.

Dr. Geberding. Is it up to the—the same. Do you have a plan or not? Dr. Geberding?

Dr. GEBERDING. Yes. Thank you. Right now, we don't have a plan because we don't have a product, but we will have a plan. And, in addition, I just want to say very quickly, to count on the ACIP as well as the National Academy of Medicine to really help adjudicate those allocation decisions independent of the administration, per se.

Mr. KENNEDY. And Dr. Hoge?

Dr. HOGE. Congressman, we completely agree that the vaccine should go to place of greatest need, and support that entirely. We will be relying also on the government to advocate and distribute the vaccine to those places.

Mr. KENNEDY. Dr. Young?

Mr. YOUNG. Thank you for that question. Like my colleagues, we believe that in ensuring that, you know, a vaccine, if approved, goes to the patients of greatest need is critical. And I just want to say that we believe the CDC guidelines that were developed a number of years ago that outline specific patient populations and those at greatest risk is very helpful, and we look forward to working with the administration on distribution should we be successful.

Mr. KENNEDY. But just so we're clear, and I've got 20 seconds left on this. Out of the five companies that are most—invested the most resources, including those without government funding, one of you has a plan. All of you are relying on a government that couldn't procure proper PPE for wide swaths of this population, including, still, shortages across this country, and we've got—even with the backing of taxpayer dollars. And we have a pharmaceutical environment here in this country where still 26 percent of people that rely on insulin still can't get access to it. And that's great, you're saying you're distributing it relying on the Federal Government.

Clearly, the Federal Government has failed here multiple times over, and I would—I'm just curious. If you don't think that there's going to be a problem for your companies when communities of color and lower income communities don't have access to this, you're going to be coming back here and have another hearing where we're grilling you on this stuff.

And so, buyer beware on this. If you don't actually make some effort intentionally now, I would urge you to do so because the consequence of not doing this right is going to be dramatic for this country, and this administration I don't trust at all to actually do this right.

I yield back.

Ms. DEGETTE. The gentleman yields back.

The Chair now recognizes Mr. Mullin for 5 minutes.

Mr. MULLIN. Thank you, Madam Chair. And just real quick, I don't think at all that our government has failed. I think we're in a pandemic that we've never experienced before, but we're responding better than any other country out there. We're testing more. We're developing more. And the rest of the world is depending on our country to find a vaccine. And so to say that our government failed is completely—it's completely wrong.

Real quick. Can each of you speak to your manufacturing capacity and how ramping up to meet that demand will be—it will be needed once the vaccine is authorized or approved by FDA, and I don't really care the order. You guys can take it one at a time.

Mr. YOUNG. Thank you for your question. It's John Young from Pfizer. As I mentioned in my testimony, we have a dedicated supply chain that we're establishing for supply to the United States. And parallel with that, we're working with our partners to develop a supply chain for the EU. We'll be looking to leverage our existing Pfizer network in our sites in St. Louis, Missouri, and Andover, Massachusetts, and also Kalamazoo, Michigan, to do the entirety of our drug manufacturing process from drug substance through the drug product. We're very proud of the incredible, heroic work that our Pfizer colleagues have done to really begin the work already before we have completed our phase 3 program to establish our manufacturing and supply network. So we have a lot of work still to do, a lot of work ahead of us, but we're very proud of the work that our colleagues have done so far.

Mr. MULLIN. Thank you.

Dr. PANGALOS. Mr. Mullin, let me go next. So I'm confident about our supply chain. Our operations team has done a phenomenal job vetting facilities in AstraZeneca. But also working with our partners, Emergence and AMRI. We will be supplying 100 million doses this year and then a further 200 million doses in the first half of next year, and we'll continue to build supply as the vaccine is needed, assuming it's efficacious and safe.

Mr. MULLIN. Thank you.

Dr. HOGE. I'll take a stab next. At Moderna, we've been working on a dedicated U.S. supply chain for several years now. In fact, we built a factory in Massachusetts to manufacture mRNA, and we've recently partnered with a large—one of the largest manufacturers of drugs, a company called Lonza, to use their facility in New Hampshire. And through that dedicated supply chain, we're very confident we're going to be able to deliver several hundred million doses next year.

Dr. GEBERDING. And I can speak for Merck. Like the other manufacturers, we are manufacturing at risk, meaning we're preparing now. We expect to have hundreds of millions of doses available beginning in 2021 and are securing the ancillary supplies that we need to be able to support that.

Mr. MULLIN. Thank you.

Dr. DOUOGUIH. I can answer for Johnson & Johnson. We are setting up global supply. We have entered partnerships with Emergent and Catalent so we will be able to produce 400 million doses coming out of those facilities, and we're also setting up in other areas, entering agreements, so that we can supply the rest of the world with the vaccine. We're targeting 100 million doses by early 2021, with the goal of getting to 1 billion by the end of the year.

Mr. MULLIN. Thank you. Can you guys tell me if any of this manufacturing is happening in China? Anybody? Does anybody know?

Dr. DOUOGUIH. It is not. It is not, not for Johnson & Johnson.

Dr. HOGE. Our manufacturing is domestic.

Dr. PANGALOS. We have a U.S. supply chain.

Mr. MULLIN. So would you guys say the majority, or if not all of this, is happening inside the U.S.?

Mr. YOUNG. For Pfizer, 100 percent of our product, if successful, will be supplied from our U.S.-based supply chain.

Mr. MULLIN. Is that the same for everybody else?

Dr. PANGALOS. So we have supply agreements around the world. Our U.S. supply chain will be sourced from the U.S., but other supply chains we have around the world will be supplied from other sources to try and keep supply chains independent and actually not competing and conflicting with each other.

Dr. GEBERDING. I would say Merck had committed to building out our supply chain in the U.S. to the tune of about $9 billion prior to the pandemic, and we're only adding to that now.

Mr. MULLIN. Great.

Dr. DOUOGUIH. For Johnson & Johnson, roughly half of the supply will come out the U.S., and the rest will come from other supply chains distributed around the world.

Mr. MULLIN. So with 20 seconds left, real quick, does the majority, or all of you guys have plans to expand your manufacturing capacity inside the U.S.?

Dr. GEBERDING. Yes.

Dr. DOUOGUIH. Yes.

Dr. HOGE. Yes, we're doing it now.

Mr. MULLIN. Well, thank you, guys.

Madam Chair, thank you so much, and I'll yield back.

Ms. DEGETTE. Thank you very much.

The Chair now recognize Mr. Ruiz for 5 minutes for questions.

Mr. RUIZ. Thank you. Thank you all for being here today. I am cautiously optimistic after hearing the progress you all are making in your efforts to develop an effective and safe vaccine. And while the numbers of the vaccines that you anticipate having in the next year seem promising, I am very concerned about the lack of a health equity plan in the distribution of those vaccines.

The number one step is the science of developing an effective and safe vaccine. Number two step is to produce that vaccine. Number three is to distribute the vaccine. And then four is to administer the vaccine in the front lines. And we should be able to foresee what's coming and develop a distribution plan that's based on public health principles, with the objectives to slow the trend of transmission, and to save as many lives as possible.

When we ask those questions, then we need to ask the question: Where is the highest risk and the highest rate of transmission of coronavirus, and which communities and demographics are dying at higher disproportionate rates of coronavirus? And it is not too difficult to find the answers to those questions.

We know that seniors and seniors in nursing homes are at highest risk of dying, those with underlying conditions. We know that African Americans, Latinos, Native Americans are at the highest risk of getting infected, and also dying from coronavirus. We need public health principles based on public health equity, not politics, not-for-profit going to those who are the highest bidders or objectives that favor the powerful, the prosperous, or the healthy or large corporations who can afford and offer the highest bidding amount in order to keep their healthy workers safe to affect their

bottom line and their profit. We cannot repeat what has happened already in the distribution of testing, in the outreach, and in the treatments of the coronavirus.

I was just called by a previous employee yesterday who told me—or texted who told me that his sister, who works in the front lines as a nurse in COVID-19 units who was recently exposed, couldn't get testing herself. It wasn't offered and couldn't—it wasn't offered in the hospitals. She had to go to an urgent care and pay for it for herself. It was difficult to get testing. Yet, he has a cousin who is in training for the Washington Nats, the professional baseball team, and they get tested every two days.

So my office is hearing the same thing from nurses across my district. This is unconscionable, and we cannot repeat this mistake with the distribution of vaccine.

So having millions of vaccines is a good first step. We also need to be planning now how we get the vaccines into the hands of the people that need this most, and I don't want to look back and then have health equity be an afterthought. It has to be prioritized.

So I want to ask Dr. Geberding from Merck. What is your company doing to ensure that the distribution of these vaccines are getting to the populations that need them the most with the highest transmission and the highest death rate from COVID-19?

Dr. GEBERDING. I think the best way to answer your question is to think through what already works and doesn't work in this regard. It is the CDC's responsibility, the ACIP that makes decisions about allocation. But in this very special case, I have personally, and I think many of us have called for the National Academy of Medicine to create a mechanism to look at health equity, and make sure that the allocation is fair.

Mr. RUIZ. Thank you. Thank you very much. You know, I've heard a lot of, Well, that's the government, that's the government, but not all of you are going to give 100 percent of your vaccines to the government. There is going to be a percentage that you will hold back for the private market as well, and that market should also follow a public health principle so that we can save as many lives, and we can stop the surge in order to improve the public health. Dr. Young from Pfizer, can you answer that question for me, please?

Mr. YOUNG. So a very important question. I want to, you know, support what my colleague, Dr. Geberding, has just said, you know. We believe that actually the CDC has laid out very clear criteria for a pandemic situation as to which patients should actually be prioritized. And we look forward to working with the Federal Government and its agencies in order to ensure that distribution of our vaccine is equitable.

Mr. RUIZ. I'm going to ask every single one of you if you can please mail my office and this committee your distribution priorities, not only that go towards the government, but also that you have within your own private market, sales, and distribution, and what your objectives are during this pandemic. Can you do that please?

Mr. YOUNG. Yes, we will.

Dr. DOUOGUIH. Yes.

Mr. RUIZ. Thank you. Dr. Pangalos, Dr. Hoge, and Dr. Geberding, can you do that? OK. I'll take that as a yes from all of you, and I'll follow up with you as well, and I believe I heard from Johnson & Johnson, Dr. Douoguih, as well. Thank you.

Ms. DEGETTE. The gentleman yields back.

The Chair now recognizes the ranking member of the full committee, Mr. Walden, for 5 minutes.

Mr. WALDEN. Thank you again, Chairwoman. I appreciate this hearing, and I appreciate the testimony of the witnesses. Many of us have had an opportunity to talk before this hearing.

I have a couple of questions. First of all, just real quickly. When we talk about the dosages that will be available before the end of the year, and then into next year, do all of your vaccine candidates require at least two doses to be effective?

Mr. YOUNG. John Young from Pfizer. Thank you for the question. So we anticipate that the protocol that we will study in our pivotal trial will use an initial dose plus a booster, so yes, two doses.

Mr. WALDEN. All right. Is that true for the others? Our witnesses can go on.

Dr. DOUOGUIH. It remains to be seen. I'm sorry. I was just going to say earlier in our development, we may have the possibility to evaluate both, but we don't yet know if it will be one or two.

Mr. WALDEN. All right. All right.

Dr. GEBERDING. Merck selected vaccine candidates that we believe have a reasonable possibility of being single dose vaccines. That's our hope, but that's unproven at this point in time.

Mr. WALDEN. OK. All right.

Dr. PANGALOS. Our data suggests that two doses are giving a stronger immune response than one, but until we understand the immune protection, we don't know ultimately whether one will be enough.

Mr. WALDEN. All right.

Dr. PANGALOS. We'll go with two to be sure, but it could end up becoming one dose.

The CHAIRMAN. Thank you. That's really helpful, I think, for us and for the public to understand that when we talk about having 300 million doses or 30 million doses, we probably should estimate that's half—cut that in half in terms of the number of people that are actually going to be able to get vaccinated, sort of in the worst-case scenario is my take-away of that.

In terms of the supplies you need, and I know many of you have talked about this, the ancillary supplies, such as glass vials and stoppers and packaging and shipping. Is the Federal Government assisting your companies in this endeavor, or do you feel like you have the supply chain locked down to be able to produce package, ship safely, effectively, and efficiently? Is there more work that the administration or we in Congress need to do to assist in that?

Dr. PANGALOS. Congressman Walden, first of all, I would say obviously the funding we're getting from the government, which we're very thankful for, is helping us ensure that we everything we need to enable the supply of the 300 million doses as rapidly as possible. So from our perspective, we have what we need, we think, to build supply as agreed with the government.

Mr. WALDEN. All right. Ms. Geberding?

Dr. GEBERDING. Yes. From the Merck perspective, when we say we are anticipating hundreds of millions of doses going forward, we have secured the necessary surround sound, ancillary supply contracts, et cetera. And we can do that because we are a big company, and we make a lot of vaccines, so we have existing mechanisms for those procurements.

Mr. WALDEN. All right. Others?

Dr. DOUOGUIH. It's Macaya Douoguih. We are working on a global supply chain to be able to provide what is needed in terms of vials and stoppers to provide our vaccine.

Mr. WALDEN. And you're confident you'll be able to achieve that?

Dr. DOUOGUIH. So far, it looks as though that would be the case, yes, but we're monitoring the situation closely. We would certainly appreciate support if it's available.

Mr. WALDEN. All right. Mr. Young?

Mr. YOUNG. We've had very positive engagement with our suppliers, you know, both for raw materials, but also for, you know, glass and stoppers, so we believe we have a path to be able to have all the necessary materials for a vaccine program should we be successful.

Mr. WALDEN. Dr. Hoge?

Dr. HOGE. We also believe we have a path that we've either already procured all the necessary supplies, or we're in the process of doing that. But we do appreciate that the career folks at BARDA and HHS have been very helpful in helping us identify contingency plans if we aren't able to secure those supplies.

Mr. WALDEN. I want to talk about FDA for a bit, just real quickly. Are you all comfortable with the guidance the FDA has issued to protect consumers' safety and ensure the efficacy of the drug? Is there anything there that disturbs you? Are you concerned that somebody's going to try and rush you into production?

Mr. YOUNG. John Young from Pfizer. So I would really commend the FDA for having been extremely proactive, and very transparent by the criteria that they've laid out for both safety and effectiveness. I think those standards are high and I think should give all of us as Americans a lot of confidence, actually, if a vaccine is approved, either as a BLA or under emergency use authorization that the FDA has done so according to stringent guidelines for which they're to be commended.

Mr. WALDEN. And I know my time's running out. Does anybody disagree with that?

Dr. PANGALOS. No.

Dr. HOGE. Agreed.

Mr. WALDEN. Thank you all, and the team you work with, for the work you're doing to try and safeguard the world, frankly, from this pandemic and bring about a vaccine and therapeutics.

I yield back my time.

Ms. DEGETTE. I thank the gentleman.

The Chair now recognizes Ms. Kuster for 5 minutes for questions.

Ms. KUSTER. Thank you very much, Madam Chair, and thank you to all of you for being with us. One point I want to make clear because we know we're talking about confidence of consumers and Americans who have a great deal of stress and anxiety. Could you

articulate briefly, if you can, the notion that, because you are taking a risk on the manufacturing, that is related to speeding up the timeline of the vaccine, but that you are not taking a risk as to the safety and efficacy on the research side? If you could, one by one, and we'll just start with Dr. Pangalos.

Dr. PANGALOS. Yes. It's a very good question, Congresswoman Kuster. So you're absolutely right that what's different is about what we're doing is that we're manufacturing that risk in the hope that we will have a safe and efficacious vaccine, such that when we have that data available, and hopefully, the regulators agree that our vaccine is safe and effective, we will have the doses rates to supply in the U.S. and around the world straightaway. That, I think, is what this funding from BARDA gives us is that ability to——

Ms. KUSTER. How much time do you think that takes off the clock of a typical vaccine production?

Dr. PANGALOS. It's difficult a concept, but a lot. I mean, you wouldn't be making these investments and going into pivotal studies and trying to produce two billion doses around the world before you have any evidence of efficacy, so I think it's a huge help.

Ms. KUSTER. Thank you. I want to focus in on the daunting task of ramping up production to provide doses for over 320 million Americans in a matter of months. This will be an unprecedented task, and our ranking member has pointed out that this may take two doses per person. Recently, I introduced H.R. 7104 which would expand our manufacturing capacity and require the administration to begin this planning now because I believe planning is essential so that we can assure that all Americans have equitable access to the vaccine when one is available, and our communities can reopen fully and safely, including our schools.

This legislation was included in the House version of the HEROES Act, and I'm very anxious for the Senate to move forward without delay.

So, again, Dr. Pangalos, if you will, AstraZeneca has stated it anticipates producing 300 million doses of the vaccine beginning as early as this fall. Does that include the one billion doses it plans to supply around the globe?

Dr. PANGALOS. It does not. The 300 million doses are for the U.S. supply chain only. The other 1.7 billion doses plus that we'll be supplying around the world will be done in independent supply chains all around the world.

Ms. KUSTER. Thank you. And, Mr. Young, Pfizer anticipates producing up to 100 million doses by the end of 2020, and 1.3 globally in 2021. It's my understanding that Pfizer recently had some challenges in manufacturing sterile injectables that resulted in shortages and delays. What steps is Pfizer taking to increase its capacity and mitigate any risk of future shortages or equitable distribution issues?

Mr. YOUNG. Thank you for the question. So since we acquiring Hospira in 2017, we've invested several hundred million dollars, invested in those legacy Hospira sites in order to remediate production difficulties and some quality challenges.

We're very proud of the work that our manufacturing team has done. And, indeed, we're particularly proud that in the COVID-19

pandemic, actually, those sites have been able to respond to incredible increases in the number of really important basic injectable medicines that are used in intensive-care situations, and obviously, we saw a lot of that with COVID-19.

So our plan was that that would be substantially remediated in 2019, and completed by 2020. I am pleased to say that those sites were on track. The sites that will ultimately manufacture the COVID-19 vaccine are actually from our legacy Pfizer network, where we don't have any history of compliance or quality problems.

Ms. KUSTER. All right. My time is coming to a close. I'll do my next question for the record.

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

Ms. DEGETTE. I thank the gentle lady.

The Chair now recognizes Mr. Burgess for 5 minutes.

Mr. BURGESS. I thank the chair. Madam Chair, let me first ask unanimous consent to place into the record the letter from Retractable Technologies about their production of 240 million syringes with the contract they recently received from BARDA. It is significant with us being able to provide the delivery mechanisms that Dr. Ruiz talked about. And along the lines—I'd just like to ask all the panelists along the lines of what Dr. Ruiz was discussing about the availability.

You know, the price of vaccines historically has not really been one of the big obstacles, or a big determinant in vaccination levels. In fact, we've had some hearings in this Oversight Investigation Subcommittee at the very beginning of this Congress on the issue of vaccine hesitancy. I did introduce a bill with Dr. Schrier of Washington State following the measles outbreak up there last year. So do we—and this was a bill designed to increase or decrease vaccine hesitancy.

So I would just ask all of our panelists: Are there additional steps that the administration and/or the Congress could and should take to encourage the American public to receive the vaccine when it's available? And let's see. Why don't we start with AstraZeneca?

Dr. PANGALOS. Thank you, Congressman Burgess, and this is an important question because, ultimately, we know that people need to be vaccinated to be protected from the pathogen. And we recognize the vaccine hesitancy and public distrust in the COVID-19 vaccine, particularly given the speed at which we're developing it. It may be perceived as a problem. However, we're completely supportive of the U.S. Federal agencies to ensure that Americans have vaccines that can be used safely and effectively. And I think the FDA Commissioner, Stephen Hahn, has already committed to showing that the FDA's regulatory review process will uphold the highest standards, and we've talked about those at length during the course of the hearing so far.

Mr. BURGESS. Right.

Dr. PANGALOS. We also support the CDC's efforts as well to develop materials to encourage people to be immunized, particularly in areas and communities that are underimmunized. Thank you.

Mr. BURGESS. I think they actually identified that as a weak point in the hearing that we did a year ago, but I do—I agree that we are going to have to engage the CDC.

Johnson & Johnson, the same question to you.

Dr. DOUOGUIH. Well, I fully agree that vaccine hesitancy is an increasingly bigger challenge over time, and it certainly will be for COVID-19. I think the outreach and discussions and educational materials, all of that needs to happen now. And we would very much support any efforts that really focus on solid educational programs to make sure people understand, can share their concerns, because it's not only about access, it's about people willing to accept the vaccine. And they need to have trust and confidence, not only in the safety and efficacy, but also, have their concerns answered.

Mr. BURGESS. Great.

Dr. Gerberding?

Dr. GERBERDING. Thank you. I couldn't worry about this more. I think that trust is a consequence, both of truth-telling, as well as transparency. And it's not enough to have a government spokesperson or a manufacturing spokesperson. We really need to engage the people that are trusted, and often those are doctors, doctors at the local level.

So we do have to engage the medical community and help people get the information, and then have their own confidence in what we're doing, so that they can translate that at the community level.

Mr. BURGESS. Great.

Dr. Hoge?

Dr. HOGE. Congressman, thank you for the question. I couldn't agree more with the concern, just like the other panelists. We do think it's going to take a broad effort to try and make sure the vaccine is broadly adopted.

I would echo, too, Dr. Gerberding's last comment, there is a trust deficit, and we have to rely on those who have that trust, particularly given the short time horizons we have.

Mr. BURGESS. Great.

And Mr. Young?

Mr. YOUNG. Thank you for the question. I mean, I think vaccine hesitancy is probably one of the greatest challenges for public health that America faces. Until we fully support the work of the CDC——

And I would endorse the comments of my fellow panelists, that actually all of us need to play a role in ensuring that should we be successful in this mission, that actually there is confidence in the safety and the effectiveness of our vaccines, based on data, based on confidence that the FDA will approve a vaccine only if it's proven to be safe and effective.

Mr. BURGESS. Yes, OK.

Mr. YOUNG. And so we certainly support the work of this panel in achieving that end.

Mr. BURGESS. Thank you.

Look, the Federal Government has launched several initiatives aimed at accelerating medical countermeasures, including vaccines. How has your interaction with the Federal Government been through the vaccine development process? Have they been helpful, yes or no?

Let's again start with AstraZeneca.

Dr. PANGALOS. Yes, they have been helpful.

Thank you very much for their support.

Mr. BURGESS. And Johnson & Johnson?

Dr. DOUOGUIH. Yes, they have been extremely helpful and very constructive in this process.

Mr. BURGESS. And Dr. Gerberding?

Dr. GERBERDING. Absolutely helpful. We wouldn't have an ebola vaccine approved and licensed if it wasn't for BARDA.

Mr. BURGESS. Dr. Hoge?

Dr. HOGE. Yes, absolutely, incredibly helpful.

Mr. BURGESS. And Mr. Young?

Mr. YOUNG. Yes. We've maintained very constructive discussions with a whole range of Federal Government agencies.

Mr. BURGESS. Thank you, Madam Chairman. I yield back.

Ms. DEGETTE. I thank the gentleman.

The Chair now recognizes Ms. Castor for 5 minutes.

Ms. CASTOR. Well, thank you, Madam Chair.

Thank you to our witnesses who are here today.

I'd like to continue the discussion about CDC and our public health professionals across the country and how we will distribute vaccines. Because I believe any successful effort to deploy the COVID-19 vaccine will rely on our public health professionals across the country.

They have been on the front lines of the pandemic from day one. We've got to build on that long-standing public health infrastructure that's already in place across America, and while I believe it's been drastically underfunded in past years, the Congress has provided some resources to CDC and our public health departments, and the HEROES Act that we passed in the House months ago would build on that investment.

State and local immunization leaders recently wrote to Operation Warp Speed leaders just a couple weeks ago, and they said our Nation has a decades' long track record of facilitating both public and private infrastructure to successfully deliver life-saving vaccines.

But I'm very concerned because the Trump administration has not relied on our public health experts at a time when we need their guidance the most, and I think this is—you know, their dismissal of a scientist and public health experts has really put folks at risk.

I mean, I represent the State of Florida, and we are in a world of hurt right now. In fact, just this past weekend, it was reported that the Trump administration is trying to block necessary funding for testing, tracing, and the CDC to fight COVID in the next emergency aid package.

So getting a vaccine that is safe and effective is going to be absolutely critical, and I hope the President and those around him will consult our public health professionals.

Dr. Gerberding, you were at CDC, you were a leader there, and in your testimony, you state, we urge strengthening of the systems that support routine immunization systems and preparing now to adapt them to mobilize for mass vaccination programs once the pandemic vaccines are available.

Would you agree that the Centers for Disease Control and the long-standing public health professionals across the country have been critical to our Nation's historical vaccine distribution efforts, and what role do you believe the CDC and our public health partners must play in a national COVID-19 vaccine plan?

Dr. GERBERDING. Thank you so much for your question. I can only believe CDC is a national treasure—I'm getting some echo. I hope you can hear me—and that there is a long track record——

Ms. DEGETTE. If the gentle lady will suspend? Dr. Gerberding?

Dr. GERBERDING [continue]. Of success in immunizing our children, our teenagers, and our adults. We cannot possibly do this without the CDC and the frontline of our State and local health departments.

We need to strengthen their support, we need to strengthen their ranks, and we need to get fully behind them, arming them not only with information but with the resources necessary to really step forward and support a mass vaccination campaign in the context of this pandemic. They are our frontline.

Ms. CASTOR. I concur, and that whole system has been very successful in the past to contain outbreaks. I mean, for H1N1, they delivered over 100 million vaccine doses during that 2009 pandemic.

Mr. Young, why will this existing vaccine distribution network and infrastructure be essential for the COVID-19 vaccine distribution effort?

Mr. YOUNG. Thank you for the question. So I just endorse everything that Dr. Gerberding has just said. Plainly, the challenge that we face, you know, is enormous. In theory, I think Dr. Gerberding, in her testimony, actually already said, none of us are safe until all of us are safe, and that is what is unique about this situation and the importance of a vaccine, that it gets to those who are at greatest risk, but ultimately that everybody is protected.

And so the criticality of public-private partnerships that's represented in this hearing today, but actually the engagement of the government agencies and the full distribution network to be able to get to potentially 330 million Americans and ensure that they're all protected, is going to be absolutely fundamental.

Ms. CASTOR. And Dr. Hoge, is this coordination happening now? To your knowledge, has Operation Warp Speed leadership engaged in this kind of planning with our public health professionals across the country?

Dr. HOGE. So I can't speak to what Operation Warp Speed would be doing outside of our field of vision, but I am aware through our conversations they have brought in obviously colleagues from the NIH and CDC and other public health officials to help us both plan how to execute our study and perhaps to begin to anticipate what happens if we end up with a safe and effective vaccine.

Ms. CASTOR. Thank you, I yield back.

Ms. DEGETTE. I thank the gentle lady.

The Chair now recognizes Mr. Duncan for 5 minutes.

Mr. DUNCAN. Thank you, Madam Chair, and I want to thank the witnesses for being here.

Just some stats in South Carolina for our population of 5,148,714 people. We've had 1,164 deaths. That's a 0.023 percent mortality rate in South Carolina, 89 percent recovery rate from folks that have contracted COVID and have gone on to recover.

I'm glad we're pursuing this vaccine, but I just want to caution us to a few things. When I look up the data for an influenza vaccine—and granted, there are many different strains of influenza, but there's also a fear that COVID-19 could mutate and have dif-

ferent strains, but when I look up something we've been dealing with a long time, and that's influenza, we have to guess every year what strain will be there.

And if you look at the effectiveness, in 2019, it had an estimated 45 percent effectiveness; in 2018, a 29 percent effectiveness; 2017 was 38 percent; 2016 was 40 percent; 2015 was 48; 2014 was 19 percent effective, for a vaccine that was created to deal with influenza and a virus that we've been dealing with a long time.

Now we've got a novel coronavirus, known as COVID-19, and we're trying to create a vaccine for it. Hopefully it won't mutate, hopefully the vaccine will work, but when I think about influenza, I think about the fact that it affects a very similar population more so than others. And that population being the older population, 60-plus, especially if there's comorbidities involved.

Influenza affects the same age group. When you look at the data of influenza to use as a comparison, the vaccinations are effective, most higher percentage wise, healthy adults, age 18 to 46. That's about a 70 percent effective rate. Healthy children, age 6 to 24 months, 66 percent effective rate. Influenza vaccine also appear to protect against other infractions with a benefit of 15 to 45 percent.

Where it's not effective is that population 60 and above, especially when comorbidities are involved.

So let's shift to COVID-19. We're trying to create a vaccine for COVID-19, and my question for every company is, how will you create a vaccine that is effective for the most vulnerable population, and that is the 60-plus population, especially when there's comorbidities?

Comparing to the influenza vaccine, it's not very effective for that demographic as well. So how are you going to target the most vulnerable population, if you look at the fatalities of COVID-19? Answer that.

And then how are you going to deliver it to those? That's another question. But let's talk about how you're going to target that vulnerable population.

Ms. Gerberding?

Dr. GERBERDING. Thank you. It's a really important question, and I think at the very beginning of vaccine development, we tend to study vaccines in the people who have the greatest likelihood of responding to the vaccine, but we do need to understand what will happen with these vaccines in older people. That's one of the reasons why I think we're going to ultimately end up with more than one vaccine.

The first vaccine might not be the best vaccine for seniors or for children. So we need to have additional studies to really define the value in the highest risk populations, and the safety in those Populations.

Mr. DUNCAN. OK. Mr. Pangalos?

Dr. PANGALOS. It's, again, a very important question, and during our studies, we'll be treating a variety of age groups and vulnerabilities, from five years old to 70-plus. And so we'll be able to generate data that gives us an indication of who is best responding to the vaccine.

As we said previously, the regulators have said they want to see a 50 percent efficacy level in the broadest population, but it may

be that a younger population responds better than an older population. We don't know yet.

What we do know with our vaccine is that we do see good immune responses in the elderly, in other diseases that the Oxford Group have tried to treat. So we are optimistic that it will work in older adults as well.

But we also have additional therapies, like our monoclonal antibody programs that will be independent of generating an immune response. And so if you have, let's say, an immune compromised individual, or a person that doesn't respond to the vaccine, we'll be able to treat them with an antibody instead, and then we'll be helping them—basically giving them their immune response without therapy.

Mr. DUNCAN. My time is about out. Let's go to MacAya.

Dr. DOUOGUIH. Yes. So I fully share your perspective that the elderly are an important population, and that's why we are planning to evaluate them in our very first study, so that we can understand what the immune responses are, what does the safety profile look like, and select the appropriate dose and/or schedule such that we can evaluate them in our efficacy study as well, because we believe they should be some of the first people to get access to the vaccine.

We do have experience with our platform in another respiratory virus, RSV. We have a program targeting the elderly, and we're encouraged by some of the data that we have now been seeing in terms of the immune response looking comparable to what we see in younger adults. So there is a good possibility that we may have a viable vaccine for that population.

Mr. DUNCAN. Stephen?

Dr. HOGE. Thank you for the question. It's an important question. Two quick answers because I know we're running out of time.

Ms. DEGETTE. You're out of time——

Dr. HOGE. Sorry.

Ms. DEGETTE [continue]. So answer fast.

Dr. HOGE. We've already evaluated our vaccine in elderly populations. That data is ongoing both in the phase ½ study. We look to publish that the future. And in our phase 3 study, we have actually stratified the study to be ready for 25 to 40 percent of folks who are over the age of 65 or have comorbidities, specifically to evaluate the efficacy of the vaccine in that population.

Mr. DUNCAN. That's important.

Thank you, Madam Chair.

Ms. DEGETTE [continue]. Your time is expired.

Mr. Sarbanes is recognized for 5 minutes.

Mr. SARBANES. Thank you, Madam Chair. Can you hear me?

Ms. DEGETTE. Yes.

Mr. SARBANES. Excellent.

I want to thank the panel for all your work and obviously for your testimony today. I wanted to drill down a little bit more on this tension between safety and speed that you've spoken about a number of times. Of course, all of you have testified that you don't have to sacrifice safety to achieve the speed that you've undertaken right now.

But it sort of begs the question, what happens in normal times? Because I know, for example, that you would have said to investors

that were leaning on you to move more quickly with getting a vaccine produced, or some other product, that you have to go deliberately for safety reasons.

So can you, maybe, Dr. Gerberding, or Dr. Young, just to take two of you from the panel, tell me exactly why it is that you're able to move fast without sacrificing safety, when we lay that against what the normal procedures would be?

Is it that you are now putting staff on this literally 24 hours a day, whereas normally you'd be working a 12-hour shift? Is it that you've got resources coming behind you from the government that you don't normally have that allows you to move faster? What are the actual logistical dimensions of what it means to go fast but stay safe?

Dr. GERBERDING. I can start. You've mentioned some of the categories. I think the biggest time-saver is the fact that we're already investing in building the manufacturing capacity, literally the plants that will be manufacturing the vaccine. Because as we said earlier, normally that doesn't happen until we've proven that the vaccine works. So that takes a huge chunk of time out of the preparation.

But in addition, the collaborative efforts such as the NIH is creating, bringing together industry leaders along with scientists to try to define what are the leading candidates, so we don't waste time and resources prosecuting a portfolio that isn't going to go anywhere, we concentrate on the most promising opportunities.

Then I think the FDA is doing a lot to make sure that the portfolios are reviewed in an expeditious manner. Even putting the guidelines out is a great help to us because it creates more regulatory certainty about what we need to come forward with, with a portfolio. We know we need six months of safety data, for example.

So all of these things added together begin to chunk out pieces of the normal, very extended timeline. That all assumes that things will go exactly as we planned, and I think those of us who are experienced with vaccines know that that isn't always the case, so we don't want to over-promise on the timeline. And that is one of the reasons why Merck is cautious about that.

Mr. SARBANES. Well, let me jump in and ask another question.

I'm going to pivot a little bit here, but it's related—and let me just say to the points that you made, I think you're describing how this pandemic may be completely changing up the way vaccines are produced and approved and tested and so forth, for life after the pandemic.

Obviously this is a unprecedented situation, but it's forcing a changing in kind of the modeling and design in how we do this, which will be relevant on the other side of it. And I think it's interesting, in the moment even, to step back and consider what that means.

But let me pick up on your point about expanding the manufacturing capacity in a sense, ahead of whether you know that you're going to need it, because that is going to be a time-saver. And maybe—I know that a Pfizer executive recently indicated that even if their company's vaccine is not successful, Pfizer will pivot and dedicate whatever capacity it's building to help produce what is successful.

So maybe, Dr. Douoguih and Dr. Pangalos, you could speak to whether Johnson & Johnson and AstraZeneca has a similar posture on this, that you're going to step up and be part of a manufacturing capacity solution, regardless of what happens with your own vaccine pursuit?

Dr. DOUOGUIH. That's a very good question, and I think we can make ourselves available for those types of discussion if our vaccine were not to be successful. We would have the capabilities to produce. It's something that we would entertain a discussion on, absolutely.

Mr. SARBANES. Dr. Pangalos?

Dr. PANGALOS. And I can say we've been having conversations with the administration around our overall manufacturing capacity. I know we're already a hundred percent full, which is why we're also using contract manufacturers to help us actually provide the 300 million doses.

Mr. SARBANES. Thank you. I yield back.

Ms. DEGETTE. I thank the gentleman.

The Chair now recognizes Mrs. Brooks for 5 minutes.

Mrs. BROOKS. Thank you, Madam Chairwoman, and thank you for holding this incredibly important hearing. I wish that all of America could actually be listening in, and that's part of what I want to ask everyone, and thank you all so very much for your work.

Dr. Burgess already brought up the fact that this committee has looked at the issue of vaccine hesitancy and vaccine competence, and a recent poll showed that as few as 50 percent of people in the United States are committing to receiving one of your vaccines with another quarter wavering.

And so I continue to be really concerned about what we all are doing relative to vaccine hesitancy, and so I'm really curious what your specific companies' approaches are, whether it's how you market it, how you communicate it, how you educate the doctors, and the public health professionals about the efficacy and safety of your vaccine, because as you can see, there's been a lot of questions about that.

And I'll start with my friend and fellow—the chair of the CSIS commission, Dr. Gerberding, if you could share with us what Merck is doing. I know you talked about truth-telling and so forth, but what is it the companies are doing specifically to help educate the American people? And I'd love to hear from everyone.

Dr. Gerberding?

Dr. GERBERDING. Thank you.

And thank you for mentioning the commission. We really appreciate your support in that regard and in all of your efforts on behalf of our health security. You know, it's a long answer, and perhaps I should bring some of this back to you for the record, but the short answer is that it really does have to do with grassroots, as much as it does top-down, and that means getting out in the communities. For example, dealing with the health disparities of COVID means we go to the frontline. We're actually supporting, through various local NGOs, the opportunities to bring information to people to encourage them to seek care, to try to catch up with the missed vaccinations that have occurred and the consequence of the

pandemic so far, where we're now at risk for a measles pandemic, because of the under-immunization.

So it's the grassroots on the ground, supporting the medical providers and supporting community leaders on their terms, bringing them information. As chief patient officer, I have roundtables with various patient advocacy groups, just listening to what they know, what their concerns are, and how can we broker better information exchange. And then of course social media is also a big help.

Mrs. BROOKS. OK, thank you. And if there are other things—Dr. Pangalos, anything with AstraZeneca? Anything different?

Dr. PANGALOS. I would just add, too, I think the other piece that we need to be doing is being incredibly transparent about the data that we're generating with the vaccine and the studies that we're running. We'll be following up our patients for 2 years post vaccination.

Making sure that data is visible for all the different ethnic diversities in our trial population, different age groups, I think will give more confidence to the population at large that the vaccines are safe as well as effective.

Mrs. BROOKS. Thank you.

Dr. Douoguih?

Dr. DOUOGUIH. Yes. I think the efforts need to start now in terms of education and outreach. I mean, of course, we have to develop a safe and efficacious vaccine and be confident that the data that we are presenting are shared in an understandable and digestible way so that people feel comfortable in accepting vaccination.

But I do think that the communities that are disproportionately affected might require more engagement, and that is the long process that really needs to start now such that they could even consider participating in clinical trials.

I think that diverse participation also gives credibility to the safety and the efficacy of the vaccine and forms the foundation for the work that has to come after that.

Mrs. BROOKS. Thank you.

Dr. Hoge, want to make sure that everyone is able to say what your company is doing.

Dr. HOGE. So I would echo the comments about transparency of the data we are working to generate. We need to create information that allows trusted advisers to make these recommendations to patients. And for us, our focus right now is making sure that we're enrolling populations in our phase 3 study that are representative of the diversity of America and representative of the burden of disease.

And we are partnering with a number of different groups nationally, the National Black Church but also the NIH and others, trying outreach to those communities, to leverage those trusted advisers to try and communicate with those populations.

Mrs. BROOKS. Thank you.

And Mr. Young, Pfizer?

Mr. YOUNG. Thank you for your question. It's a critical question. I would endorse the comments that my fellow panelists have made. I would just add that for Pfizer, data transparency is really important.

One of the commitments that we made early on in this pandemic was to publish transparently our clinical data as we generate it, which we have sought to do. We think that will continue to be important.

We, like some of the other companies here, are also looking to ensure that our pivotal study is representative of the burden of disease for COVID-19. So recruitment of minorities, of women, of older patients into the study is going to be really important.

And that's critical so that when that trial completes and when we follow-up those patients, that physicians, that the scientific community, and then I think to all the comments that were made, the grassroots, you know, of America can be confident that a vaccine that is approved is going to be safe and effective for patients.

Mrs. BROOKS. Thank you all very much.

I would just remind you all, most of us are not physicians or in the medical community, and so to the extent that you can educate us all, in, you know, the best language possible, is most appreciated.

Thank you all for your work and good luck. I yield back.

Ms. DEGETTE. The gentlelady—and the Chair now recognizes Mr. Peters for 5 minutes.

Mr. PETERS. Thank you, Madam Chair, and thanks to the witnesses for being here. I'm sort of at the end, so I have a long list of questions, most of them have been answered.

I want to say thank you very much for the good work that you're doing in developing this vaccine, and of course, we wish you the best of luck.

A couple things I didn't hear that I wanted to ask about were about interactions with the flu vaccine. Will patients, in the ordinary course, be able to get this vaccine at the same time as the flu vaccine? And when will we know if there's dangerous interactions between the vaccine and other medication?

Anybody?

Dr. PANGALOS. I think during the course of our clinical studies around the world, we'll be looking at all of the appropriate drug interactions, interactions with comorbidity, et cetera, that you would need to publish,—you know, that one would then need regulatory filing, and you would need to be aware of that, and obviously a regulator would look at that as a consequence, label you appropriately. I think that will be discovered during the clinical studies that we're running.

Mr. PETERS. And also you've spoken, and I think people have spoken at length, about the elderly, and I guess the question I had is whether the very young kids are going to be able to get or use this vaccine. Are you testing that vulnerable population as well as older folks as part of the phase 3 trial?

Dr. PANGALOS. I can go again.

We have a pediatric study that will be ongoing in the United States in addition to the broader population of 18-year-olds to 70-pluses.

Dr. DOUOGUIH. Yes, we are planning to initiate our pediatric program once there's evidence of efficacy in the adult population.

Mr. PETERS. And I think that the vaccine is available later for those populations than for other folks, or will that be affected by it—will that affect the schedule at all?

Dr. DOUOGUIH. Well, we'll need to understand what the schedule is and the immune response, but you don't necessarily need an efficacy study in that population to be able to just generating the appropriate safety and immune response data.

Mr. PETERS. OK. And just in the couple minutes I have left, one of the issues that's come up as a result of us, our country not being prepared for this, is the availability onshore of the materials we need.

Obviously, PPE was a big topic of conversation, ventilators. But I wanted to ask about basic pharma. A lot of the basic pharma that has not been available, has already become generics. It's not the ones that you're involved with the United States in terms of domestic production, that most of that is produced overseas in India.

I ask each of you for your thoughts on how the United States should strategize around making sure that those drugs, those pharmaceuticals, are available onshore when we need them in the case of a second wave or the next pandemic.

Maybe start with Mr. Young.

Mr. YOUNG. Thank you for your question. I think the question of availability of high quality, essential medicines is a critical one for every healthcare system around the world, and that's something certainly that we've tried to play our part and are very committed to.

I mentioned earlier in the response to the previous question, that actually our manufacturing network in the United States has seen a significant surge in a number of those injectable medicines that are off patent, they're basic, but absolutely vital to essential care, particularly in an intensive care situation.

We've seen volume spikes of 10- or 15-fold for some of those medicines, you know, given what we've seen in intensive care units. We believe it's absolutely critical. Certainly we are committed to our United States supply network. We have 12 sites in the United States across ten States and Puerto Rico, 11,000 colleagues in our manufacturing network based in the U.S. It's something we are very committed to in trying to honor the spirit of your question.

Mr. PETERS. Let me ask the representative of Johnson & Johnson, maybe more specifically, how would you suggest that we, as a committee and as a Congress, strategize getting those basic drugs, many of which are generic, onshore for the next pandemic?

Dr. DOUOGUIH. I'm not sure I'm the best placed to answer that. My focus is indeed on vaccines. What I can say is that we are committed to providing our products and making sure that the people who are already on those medications have access to those first and foremost, and then those who are at risk are next in line for that.

And so far we're monitoring our supply and making sure that we are able to continue to provide the pharmaceuticals that we've marketed.

Mr. PETERS. Thank you.

It's probably a topic for future hearings, but I really appreciate your thoughts.

And Madam Chair, I yield back.

Ms. DEGETTE. Thank you.

Seeing no members of the subcommittee present at this time, I'm going to go to the Members who are not on the subcommittee.

And thank you all for joining us, and I will start with Congressman Upton, if you're ready, for 5 minutes.

Mr. UPTON. Well, thank you. It is a delight to be here. Thanks for the opportunity for this hearing. It's so important.

Ms. DEGETTE. Fred, can you put your camera on, please?

Mr. UPTON. Yes. I thought I had. There. Should be on, right?

Ms. DEGETTE. No.

There you go. We see you.

Mr. UPTON. OK, good.

Well, thank you. I really appreciate the opportunity for the hearing and thank our witnesses for coming today to certainly discuss all that they're doing to quickly develop a safe and effective vaccine and thus a treatment for COVID.

I want to especially thank John Young from Pfizer for coming to talk about the great work that they are doing. Of course earlier this week, we got the great news that two vaccine candidates that Pfizer is working on, with BioNTech got the Fast Track designation from the FDA.

Actually, last week, Thursday, I had the chance to visit Pfizer's manufacturing facility in my district, where they're, in fact, already gearing up to make their vaccine.

It's amazing how quickly you've been able to mobilize on something so huge in a short period of time. And as I talk to folks there, they had received the message from the higher-ups at Pfizer to spend whatever it takes to get this done.

So just a quick question for Dr. Young. You know, we're so excited, can you take us through the whole manufacturing process, and particularly—I know you reference this in your testimony—the idea that we would have the supply chain, in essence, done, made in America from start to finish, at least for these first 40 million doses that you're planning to produce there and assemble there before the end of the year? Can you just walk us through that manufacturing stage for me?

Mr. YOUNG. Thank you for your question. We are extremely proud of the role that our Kalamazoo facility in your district is going to play potentially in the manufacture of our COVID-19 vaccine.

So the manufacturing supply chain for an mRNA vaccine is quite unique. The three sites that we have in the United States that will form our United States supply chain each have a distinct role to play.

So our site in St. Louis specifically will be responsible for the development of what we call a DNA template, which essentially is just that, it's a template for the antigen which is the protein that we hope will elicit an immune response ultimately.

That DNA template is then passed to our site in Andover where it's used to create the mRNA, and the mRNA in turn is combined with lipid nanoparticles, so you have a very small piece of mRNA inside this literally microscopic droplet that is specifically been designed to be taken up by the body cells.

And then that drug substance is just taken to Kalamazoo in Michigan where it will be put into the vials that a healthcare professional or a patient might normally see, and that site in turn—these are questions that have been asked by other panelists—will then be—that drug product will then be taken into the supply chain and enable it to be distributed to hospitals and clinics all around the United States of America.

So we're very proud of the work that's been done to date, but to underscore, I think, the comments of my fellow colleagues, we know we have a lot of hard work still ahead of us, but thank you very much for your question.

Mr. UPTON. So just a quick question, because I want to ask something else.

So I know that the next trial is going to start literally in the next week. As many as 30,000 Americans and others will be in that trial. What is the earliest that you might think, assuming that everything goes well, that there's not a glitch, safety standards remain the same, when is it the earliest that you think that you might be able to see an EUA, an emergency use authorization, that would then allow the unleashing of the—produce tens of millions of vaccines to the American public?

Mr. YOUNG. Thank you for your question. So if all goes well, we hope to be able to provide our dossier of clinical data from our large phase 2b/3 study to the FDA in October.

Obviously, the FDA will then review that data, and they will determine whether our data set meets the requirement they have already laid out ahead of time for what would determine an emergency use authorization.

So they won't be able to make that decision and to review our data for our vaccine, but potentially for the other vaccines represented here.

So you know, sometime in the fourth quarter of this year, potentially they would have the data to enable them to make that decision, and that's why we've invested early in our supply chain, in order to be able to deliver up to a hundred million commercial doses of vaccine in 2020 globally and up to 1.3 billion doses of vaccine in 2021.

Mr. UPTON. Well, I think in the remaining time, let me just say this.

So the Chair of the subcommittee, Diana DeGette and myself, of course, we were the two leaders on passing the 21st Century Cures through the Congress. Can you tell me how helpful this was, as it leads to your actual production now of the vaccine?

Mr. YOUNG. Thank you.

And you know, again, we just support the work that you and Chairwoman DeGette have done in 21st Century Cures. I think it really helped to inform, Producer 6 which as you know is the funding mechanism for the FDA. It helped to lay the ground work for many of the regulatory innovations that have been applied during COVID.

For instance, the recent pilot program guidance on innovative clinical trial designs, the FDA's familiarity with real-world evidence, have all been underpinned by some of the measures that the 21st Century Cures really helped to establish.

And I believe that we should continue to build upon 21st Century Cures and these advancements as the committee begins to contemplate Cures 2.0 and also Producer 7.

So thank you very much to this committee for your support, and thank you for your leadership.

Mr. UPTON. Well, thank you. I yield back the balance of my time.

The CHAIRMAN. [Presiding.] Hi, next we have Congresswoman Eshoo for 5 minutes.

Ms. ESHOO. Thank you, Mr. Chairman, and I'd like to thank all of the witnesses. I've listened highly attentively with the exception of going over to the Capitol to vote.

So thank you for your work, as the Speaker of the House says on a regular basis, that science will be and is the answer to our prayers.

So what you are doing is one of the most important undertakings relative to public health, I think, in a century, so thank you.

Dr. Pangalos, AstraZeneca has operations in the United States, but it's a British company. The U.K. standards are different—or they differ from the FDA. How are you going to meet this challenge?

Dr. PANGALOS. As a global, multinational company, we get our medicines approved throughout the world on a regular basis. That's how our business and how our medicines reach patients around the world.

The standards that we're working to in the U.S. are set by the U.S. FDA, both from a manufacturing and development perspective, and we're also working with other regulators around the world——

Ms. ESHOO. Excuse me. Would there be a time difference between what's approved in the U.K. and what you would seek to have approved in the U.S.?

Dr. PANGALOS. That will depend on the data that each of the countries uses to get its approval.

So we have ongoing studies in the United Kingdom——

Ms. ESHOO. OK.

Dr. PANGALOS [continue]. Where the infection rate is lower. We also have studies going on in South Africa and Brazil that will be part of the U.K. fob, but I think all the regulatory authorities are working as fast as they can with us, and ultimately it will be the data from all of our studies, more than likely, that gives us approval around the world.

Ms. ESHOO. Good. Thank you very much.

I know that the ranking member of the full committee, Mr. Walden, asked a question about dosages, whether there would be one or two, and I want to follow-up on that.

If there are two, how far apart would they be? Now, most reports that I've read have 55 and older in their trial. But in order to—there's something about the dosage here.

If you're dosing for 55 and older, it's like the influenza shot, you need the super-duper one to be effective. And yet for younger patients, for children, young adults, you don't need that higher dosage.

How are you all going to handle this? I can't remember who said they thought they were doing—would have to do two doses, so maybe the two-dose companies can answer that.

Dr. PANGALOS. Well, I can speak for AstraZeneca because I said that we are veering towards——

Ms. ESHOO. I don't have a lot of time, so do it quickly.

Dr. PANGALOS [continue]. That we are veering towards two doses, and you're absolutely right, the different populations may require different schedules.

Our first priority is to demonstrate efficacy, and the best way of demonstrating efficacy is maximizing the dose.

So we'll almost definitely goes with two doses but can then work from that to reduce doses if, for example, the 18- to 55-year-olds need a single dose.

But we will start with two, almost definitely.

Ms. ESHOO. Are you the only ones that are anticipating two doses, or is there any——

Mr. YOUNG. John Young from Pfizer. We also anticipate that we will take two doses into our pivotal trial. The second dose would be administered 21 days after the first dose. That's when the booster would take place. That's what we've studied in our phase 1 trials to date.

And we're going to look to try and find the optimal candidate to take into our phase 3 study so that we end up with a single construct in dosage for both older and younger patients.

And our data will obviously inform the decision about safety and effectiveness across all those age groups.

Ms. ESHOO. Well, I thank you for that. And while I know you're not a scientist by reputation, you are a humanitarian, so I'm going to salute you for that.

Why did Pfizer choose not to take any government money and take it all on yourselves as well as the risk?

Mr. YOUNG. Great question. And you know, our focus, as I mentioned in my oral testimony, was on speed. We recognize that the world is in a completely unique situation.

We also recognize that, you know, both given the experience that we have as a company, as a vaccine development company, but also given the financial strength of Pfizer, that we were maybe uniquely placed to be able to put our own capital at risk, in order to be able to move as quickly as we possibly could.

And so speed has been our priority, while making sure that we obviously maintain a focus on safety, and that really underpinned our decision not to seek government funding for our program.

Ms. ESHOO. I thank you.

And I thank the chairwoman and the chairman of the full committee, all of the witnesses. Let me put it this way—God speed.

I yield back.

The CHAIRMAN. Thank you. So we have to—we go to members of the subcommittee first. So Mr. Tonko has returned, so he's next.

I yield to the gentleman for 5 minutes.

Mr. TONKO. OK. Mr. Chair, can you hear me?

The CHAIRMAN. Yes.

Mr. TONKO. OK. Well, thank you, and thank you to the subcommittee for arranging this hearing and to our witnesses for your participation.

This committee has held many pandemic preparedness hearings over the years. And we have consistently heard that the manufacturing of enough ancillary supplies needed to go with vaccines, such as vials and syringes and other materials, is an essential component for administering a vaccine.

We all remember what happened this spring as States and hospitals scrambled and competed for basic, yet critical, supplies like N95 masks. So now as we look toward an unprecedented effort to manufacture a vaccine for the entire globe, there are increasing concerns about the availability of all those ancillary supplies needed for a vaccine.

With so much riding on a vaccine, we cannot find ourselves in another situation of widespread shortages of critical supplies when it comes to vaccinating people around the world.

So Mr. Young, if a vaccine is approved, we may need enough ancillary supplies to administer hundreds of millions of doses in a compressed timeframe in this country alone. What steps are you taking now to ensure that you will have those sufficient supplies?

Mr. YOUNG. So thank you for your question.

So as I mentioned in my testimony, we've engaged early to deploy capital and to put contracts in place, at risk, with our suppliers. So we've engaged with the suppliers of glass, of stoppers.

We're also, you know, doing a lot of work to invest in the development of that supply chain that's going to be critical to get those vials from our manufacturing site to clinics. And all of that work is requiring capital, which we are deploying at risk.

And so really the thing that we've done is to engage early and to invest early in that supply chain.

Mr. TONKO. Thank you very much.

And Dr. Pangalos, presumably every company in the world working on a vaccine will be competing for these scarce vaccine supplies. But you state in your testimony, and I quote, "none of the companies involved in this project view this as a competition against each other. Our sole adversary is COVID-19."

So my question is, is AstraZeneca coordinating with other companies on this production and procurement of vital supplies, or will you be competing against each other for them?

Dr. PANGALOS. So thank you for the question, Congressman Tonko. So I think, first of all, we're all using five different technologies, which means we're not necessarily competing for the same raw materials, and so I think that is a benefit.

What I would say from an AstraZeneca perspective is, we have created our supply chains in a way that they are not competing with each other. So we have a supply chain for the United States, a supply chain for the U.K., supply chain for Europe, and a supply chain for international regions.

As a consequence, they're protected from one another, and we're ensuring that each one is robust in its own right. So our supply chain in the United States, to provide the 300 million doses under our agreement with BARDA, is working both in our own facilities

but also with contract manufacturers based in the U.S., such as Emergent and AMRI.

So we feel confident in the quality and the strength of our supply chain in the United States.

Mr. TONKO. Thank you.

And as I mentioned, this past spring it was chaos as States and hospitals scrambled to outbid each other for scarce PPE. And as we heard from governors who testified before our committee, the Federal Government did not effectively coordinate PPE distribution at the national level. And in some cases made it much worse.

So Dr. Hoge, Moderna received $53 million, I'm told, from BARDA, specifically to expand its manufacturing capacity. What guidance or coordination is your company receiving from the Federal Government regarding the production and availability of vaccine ancillary supplies, and is that going to be, again, a situation where every company is going out there for itself?

Dr. HOGE. Thank you for the question, Congressman.

We, like other companies on the panel, have been working with suppliers to specifically purchase all the necessary ancillary supplies that you've mentioned, including glass and stoppers and the like.

But we have been working with BARDA directly under the auspice of the grant you just mentioned and providing transparency to them on those purchasers of those contracts and what we're doing.

The purpose of that is twofold. I think it both gives them confidence that we've got redundancy in that supply and that we do have what we need, but it also gives transparency to the U.S. Government on where we're purchasing those supplies.

And certainly if the unfortunate circumstance arose that our vaccine was not successful, I would imagine all of those would be made available to other vaccines if they were successful.

Mr. TONKO. Thank you very much.

Well, I thank all of our participants.

The availability of the ancillary supplies necessary to administer a successful vaccine will require coordination, and I'm pleased to hear that some efforts are under way, but past supply failures by this administration makes me very wary.

So with that, Mr. Chair, I yield back, and thank you.

The CHAIRMAN. Thank you, Mr. Tonko. Next is—Mr. Carter is recognized for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman, and thank all of you for being here, and thank you for your efforts. These are extremely important, and I don't need to tell you that. You understand how important this is, and we appreciate all of the efforts that are being made here.

You know, I've always said that I think there's a difference in knowing something and realizing something. We've known for quite a while now that we're too dependent on other countries for our medical supplies, but during this pandemic I think we've realized it.

And one of the things that we've realized is that 72 percent of all the active pharmaceutical ingredients in the U.S. supply chain are manufactured in different countries, in fact, in more than 150 countries, and 13 percent of it comes from China alone.

We witnessed this as well in March when India even withheld 26 drugs from exportation. This is a serious issue, and I think we should do everything we can to increase domestic manufacturing.

In fact, I've got legislation, the Made Act, that will incentivize pharmaceutical manufacturers to bring their manufacturing back to America.

But I want to talk specifically about the vaccines, and I wanted to ask each of you, specific to your vaccine, how much of the material that's used in your individual vaccine, in your product, comes from overseas. A.

And I'll start with you, Sir Pangalos.

Dr. PANGALOS. Thank you very much.

So for our U.S. supplies, all of our U.S. supply chain will be coming from the United States.

Mr. CARTER. All of it?

Dr. PANGALOS. Yes.

Mr. CARTER. What about vials? What about the other things that are used such as vials or other delivery methods, anything and all, even packaging?

Dr. PANGALOS. To the best of my knowledge, all of the materials that we're using for our U.S. supply are coming from the United States, but I can check that and confirm it for you.

Mr. CARTER. And are you manufacturing the vaccine in the United States, is that your intention?

Dr. PANGALOS. Yes, we are.

Mr. CARTER. OK.

OK. Dr. Douoguih?

Dr. DOUOGUIH. Yes.

So 99 percent of our materials come from either the U.S. or Europe, and so we actually, we have very little coming from—out of China. And in terms of how much manufacturing we have in the U.S., it's roughly half of our supply will be produced on U.S. soil.

Mr. CARTER. And then the other half will be produced in Europe?

Dr. DOUOGUIH. Well, there will probably be a number of facilities in order to best support a global supply of our materials.

Mr. CARTER. Any in China?

Dr. DOUOGUIH. As far as I know, I'm not aware of that, but these discussions are ongoing.

Mr. CARTER. OK.

Dr. Gerberding?

Dr. GERBERDING. Thank you.

I'm going to have to get back to you for the record on this. We're prosecuting two vaccines, and while, generally speaking, Merck's vaccine—and we have several—are very much localized to the United States and a couple of places in Europe.

I need to verify the entirety of the supply chain to make sure that I'm——

Mr. CARTER. OK. If you could get back to us in writing, I'd appreciate it.

Dr. GERBERDING. Absolutely.

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

Mr. CARTER. Dr. Hoge?

Dr. HOGE. So our manufacturing domestically is at two facilities in the United States. The vaccine is made entirely in the United

States. Our supply chain includes a number of raw materials, some of which have been sourced internationally, but we've worked to secure that supply and bring it into depots in advance of needing it for manufacturing to specific——

Mr. CARTER. OK. Can you define internationally? Does that include China?

Dr. HOGE. I do not believe so, sir, but I think there is a lot from Europe.

Mr. CARTER. I'm sorry. Does that include China internationally?

Dr. HOGE. It may include for some of the raw materials, sir, but I don't believe it's a major component. Most of what I was describing was Europe.

Mr. CARTER. OK.

Mr. Young, finally you?

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

As I mentioned in my testimony, we will have a dedicated supply chain for a vaccine, if successful, for the United States. The raw materials for our vaccine drug substance are procured, manufactured in the United States.

Our drug substance is made within our Pfizer network, as is the final drug product, the vials that will go to healthcare professionals.

Mr. CARTER. OK, good.

Dr. Young, while I have you here, the FDA has released the guidelines outlining the conditions for approving a COVID-19 vaccine.

Do you believe these guidelines are fair, and are they achievable, particularly given the time frame that we're working in now and the development of these vaccines?

Mr. YOUNG. Oh, thank you again for your question which I believe is absolutely critical ultimately to addressing the confidence issue that I think we've talked about previously.

And I think the FDA are to be commended for very proactively releasing guidelines that are evidence-based. They are very clear and transparent around the standards of data that they are going to look to expect for both safety and effectiveness.

I think they should give a lot of confidence to every American that a vaccine, if approved, is going to meet high standards for safety and effectiveness.

Mr. CARTER. Good. Thank you for that. And just out of curiosity, does anyone disagree with that?

Dr. PANGALOS. No.

Dr. GEBERDING. No.

Dr. DOUOGUIH. No.

Dr. HOGE. No.

Mr. CARTER. Good. Well, I'm out of time, Mr. Chairman. Thank you very much.

And I'll yield back.

Ms. DEGETTE [presiding]. I thank the gentleman.

The Chair now recognizes Mr. O'Halleran for 5 minutes.

Mr. O'HALLERAN. Thank you.

Thank you, Madam Chairwoman, and I thank the witnesses for doing so much to educate the American public about the potential for a vaccine in the coming months.

Six months ago today, the CDC reported the first case of COVID-19 in the United States. In the months that have followed, American life has been up-ended as we face an unprecedented health crisis in this country.

Lack of PPE is still plaguing our healthcare system. And with no clearly defined coordinated strategy, the administration on testing and contact tracing, the virus is continuing to spread throughout the country.

Congress has allocated money for testing and contact tracing. Yet without a coordinated national strategy, significant lapses continue.

Obviously, while not directly related, it is important for Congress to ensure that similar distribution and accessibility problems do not occur when a vaccine is deemed safe and effective to provide some level of immunity to COVID-19.

I am encouraged by some of the early trials from these vaccines, and I'm hopeful that the later phase trials will prove that a vaccine is safe and effective for mass production and distribution.

However, the accessibility of this vaccine to Americans from all walks of life is critical, and that is where I want to focus my question.

Cases have surged across Arizona, across America, and some of the earliest hotspots occurred on Tribal lands in my district, including Navajo Nation and the White Mountain Apache. It took far too long for the government to respond to our Tribal Nations and ensure that they had the proper PPE and other equipment.

My question is to the entire panel—and we'll go right to left—I know you all are currently in first stages of testing vaccines. As you are planning for later-stage trials with more people, what is your company doing to ensure that there is broad representation across racial and ethnic groups among participants?

Are there any difficulties that Congress needs to be aware of as this next COVID-19 package is being negotiated? And when I say across racial and ethnic lines, I'd like to understand a little bit from each of you what the complexities of that mean.

Thank you.

Dr. PANGALOS. So I will start and thank you for the question.

We absolutely support making sure that our vaccine, during the clinical trials, is tested in as diverse a community as possible to ensure that we have data that gives us confidence that it will be effective, and the community represents all of the populations around the world.

It's why we're running studies in the United Kingdom, in South Africa, in South America, and in the United States to begin with. And we're also considering going into other regions as well such as Japan, China, and elsewhere.

But as we——

Mr. O'HALLERAN. Excuse me. The United States?

Dr. PANGALOS. Yes. So—but ultimately we need to make sure that we're in the United States also. We have diversity in terms of the communities and the populations that we're testing, and in our 30,000-patient study working with NIAID and the NIH, we'll make sure that we do have a diverse population that represent both ethnic diversity as well as age diversity.

Mr. O'HALLERAN. Thank you. Next, please.

Dr. DOUOGUIH. This is Macaya Douoguih. I can go next.

So we're still in the planning stages of our phase 3 study, but we do plan to include a diverse population, not only from an age perspective, but many of the communities that you have mentioned. To do that, we are launching a community outreach program that will involve digital platforms, but also are leveraging some of our existing networks and connections in the context of some of our other programs.

For example, we've had a very long history of doing HIV vaccine trial work with the NIH and their networks, and they have a very strong community engagement of a group that is very active in the communities that you've mentioned. We want to work and partner and leverage the experience we already have because those populations are also disproportionately affected by COVID to make sure that they have information about the disease and the vaccine trials that we're planning and ample opportunity to determine whether or not they want to participate. So it's the past experience that we will use to hopefully help improve the diversity in our trials.

Mr. O'HALLERAN. Madam Chairwoman, I think I'm going to run too long, so thank you. I yield.

Ms. DEGETTE. I thank the gentleman for yielding. Do we have any other members who I'm not seeing on my screen who have not had the opportunity to ask questions?

Seeing none, I want to thank all of our witnesses for their participation in this very important hearing today, and I think I speak for all of my colleagues on both sides of the aisle when we say we wish you well. We wish Godspeed. We wish the development of not just one, but more than one safe and effective vaccines that we can have, we hope, by the end of this year or next year. And then, of course, the challenge will be producing it, distributing it, and convincing everybody to take it.

I want to remind Members that pursuant to the committee rules, they have ten business days to submit additional questions for the record to be answered by witnesses who have appeared before the subcommittee, and I would ask all of our witnesses to please agree to respond quickly and promptly to any questions that you may receive.

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

I'd ask unanimous consent to insert in the record the following documents: A report from the Republican staff On Vaccines and Therapeutics dated July 1, 2020, and a letter from Retractable Technologies to Representative Burgess dated July 4th, 2020. Without objection, so ordered.

Ms. DEGETTE. And with that, again, thanks to all of our witnesses and the members. Thank you for being—thanks to Mr. Pallone for filling in when we all had to go vote. And with that, the subcommittee's adjourned.

[Whereupon, at 12:58 p.m., the subcommittee was adjourned.]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Each of you represents great hope for Americans and for the world.

All eyes are on your companies to develop a vaccine that will allow us to return to school and work, hug our loved ones, and begin the process of recovering from the COVID-19 pandemic.

But with that opportunity comes great responsibility to ensure that your products are safe, effective, affordable and accessible.

I look forward to hearing from you today about how you will maintain transparency and accountability to the American taxpayer and American patient, how you are scaling up domestic manufacturing, your suggestions for a nationwide vaccine distribution plan, and how Congress can tackle the pervasive vaccine hesitancy in this country.

In the meantime, I call on every American to continue to do their part by wearing a mask and maintaining social distancing as much as possible. Together, we can stem the tide of this horrible disease.

RETRACTABLE TECHNOLOGIES, INC.
www.retractable.com - rti@vanishpoint.com
P.O. Box 9, 511 Lobo Lane, Little Elm, Texas 75068-0009
Tel: (972) 294-1010 - Fax: (972) 294-4400 - Toll Free: (888)806-2626

July 14, 2020

The Honorable Michael Burgess, MD
U.S. House of Representatives
Washington, DC 20515

Via electronic mail: Elizabeth.Allen@mail.house.gov

Dear Dr. Burgess:

I wanted to provide this letter as an update on our efforts to support the U.S. Government during the COVID-19 pandemic. On May 1st of this year, Retractable Technologies, Inc. (RTI) received a purchase order for 240 million syringes from BARDA. This was the third (3rd) purchase order made on our existing contract vehicle, but the largest so far. RTI immediately began ramping up production and we are now operating, three shifts at full capacity. We have delivered over 9 Million units so far, and are ahead of our projected delivery schedule.

Throughout our discussions with BARDA, we have offered strategies on how to increase availability of our innovative safety injection devices for use in an immunization campaign. This included a proposal to develop an additional four (4) assembly lines, dramatically increasing our U.S. manufacturing capacity. To that end, we are also pleased to announce that, on July 1st, BARDA and the DOD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) announced a Technology Investment Agreement to expand RTI's manufacturing capacity.

As you know, once a COVID-19 vaccine is developed there will be an urgency to ensure that the Strategic National Stockpile is well equipped to provide delivery of this life saving solution to the public. RTI is honored to play such a critical role in this endeavor. Our team stands by to provide further information upon request.

Once it is advisable to do so, we would welcome a visit from you or your staff to see our facility and meet our dedicated workforce. Thank you once again for your public service and leadership during this challenging time in our national history.

Sincerely,

Lillian Salerno
Director of External Affairs

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"

July 21, 2020

Dr. Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca

The Honorable Brett Guthrie (R-KY):

- **Experts from across AstraZeneca have joined forces with our industry colleagues, as well as international health authorities, governments, and academia to accelerate the development of medicines to prevent or treat COVID-19. We do not consider this a competition, but rather a collaboration to release the grip this virus has on the world. Scientists around the world, including ours, are sharing data and research findings in unprecedented ways.**

1. Through Operation Warp Speed and the efforts of your companies and many more, we are seeing an unprecedented effort to quickly develop a safe and effective vaccine. What lessons or changes from this process should we consider making permanent in an effort to fundamentally change the traditional, years-long process for vaccine development going forward?

   We are collaborating with the FDA and NIH on key aspects of our protocol and development program, including study design, study population, endpoints, and requirements for licensure. In addition to the FDA and NIH, AstraZeneca is working closely with other U.S. government agencies as part of Operation Warp Speed, including the CDC and BARDA at HHS.

   While we are working on expedited timeframes, we are conducting our development and manufacturing programs in accordance with all applicable regulatory requirements. Similar to other vaccine developers, we are accelerating our global clinical development program by compressing the timelines, working in partnership with University of Oxford and regulators and sharing data on a real-time basis.

   The process has helped us see where improvements could be made in order to continue to foster and grow innovation. For example, manufacturers could have improved access to FDA. This current process has demonstrated that having open and transparent discussions, and decision making by all parties is critical. Additionally, coordination between health authorities could be of tremendous help to vaccine developers. The FDA, in coordination with other U.S. agencies, could also create guidance for the industry for rapid development of a vaccine in a pandemic setting. This could help speed up development in the future.

2. How did investments into platform technology help speed up the vaccine development process?

The ChAdOx1 vector system, developed by Oxford University, is an AstraZeneca licensed vaccine platform. This platform utilizes disposable manufacturing systems, transferable analytical tools and a manufacturing process that enables us to rapidly scale up and supply global COVID-19 vaccination programs. In the future, these technologies and principles can be applied to address new pandemics and investments in these platform technologies can help with rapid manufacturing and development, should the need arise.

We have also made investments in developing our manufacturing platforms that have been essential in our rapid vaccine development. For example, our investment internally in end-to-end manufacturing capability has been essential to move product from a cell bank vial to drug product in timelines never seen before.

Digital and technology solutions have played a pivotal role in our response to the COVID-19 pandemic, helping us accelerate the evaluation of potential COVID-19 treatments while maintaining delivery of our innovative pipeline.

At AstraZeneca, we have been investing in digital technologies over the past few years, and this has enabled us to quickly adapt during the pandemic to deliver our clinical trials and maintain a smooth trial experience for patients. This has also been important for vaccine development. Upgrading to a cloud-based system has enabled vaccine supply to sites and monitoring of global stocks in days versus months. In addition, by using data and analytics to model rate of infection across the globe, we have been able to select sites where the rates of infection remain high. We have also expedited the launch of eConsent, a new digital tool that enables remote sharing and review capabilities of the informed consent with patients. This has helped get new trials underway safely and at speed. Finally, through the use of new digital and technology solutions, we are using remote data collection from home wherever possible to safeguard the wellbeing of patients.

3. Do any of your companies have recommendations about how to further innovate clinical trials?

The COVID-19 pandemic has challenged the way that the healthcare industry, including the pharmaceutical industry, delivers care to patients. Traditional methods for conducting clinical trials have been disrupted in unprecedented ways. This disruption has forced regulators and industry to think progressively about how to enable and execute new methods for delivering care to patients. Innovative thinking and modified regulatory policy have allowed for the implementation of continuity solutions to accommodate the ongoing conduct of clinical trials, while maintaining patient safety and data integrity.

The use of digital and technology solutions are key to furthering innovative clinical trials. This includes developing digital solutions to enhance the delivery of medicines, reduce inefficiencies, and support patients in engaging with their own health; redefining the clinical trial experience through the use of digital tools and technologies to improve patient safety and outcomes; and harnessing data science and artificial intelligence to transform the way we discover and develop new medicines. Our drive towards integrated care is dependent on building interoperable and trusted health data frameworks to unlock the full potential of scientific data for patients and healthcare systems.

The implementation of clinical trial continuity solutions has impacted all stakeholders (e.g., sponsors, investigators, patients) involved in clinical research. As a result, there is a rich opportunity to understand the numerous lessons learned from both challenges and successes. These learnings can inform future ways of working for industry as well future policy by regulators. The Modernizing Clinical Trial Conduct Initiative will use data and experience to develop practical guidance and solutions to further enable the successes implemented during COVID-19. This initiative, of which AstraZeneca is supportive, seeks to collaboratively engage other major stakeholders including regulators, patients, sites, and industry groups.

4. COVID-19 has been with us for about seven months. There is still much we don't know about the antibody response and how long it lasts. Is there anything from the last seven months that has been learned that provides any insights into immune responses, and why it might suggest that our vaccine enterprise is on the right track?

As the SARS-CoV-2 virus is new, it is not known what kind and level of immune response is needed to prevent people from becoming ill with COVID-19. While high levels of neutralizing antibodies have been demonstrated in individuals who have recovered from SARS-CoV-2 infection, emerging data suggest that a T-cell response could play a role in mitigation of the disease. In some individuals who have been infected by the virus but remained asymptomatic, they have developed a robust T-cell response with the absence of antibodies. Rapid induction of antibodies and T-cells against SARS-CoV-2 may be important in protection against COVID-19.

We are conducting a comprehensive, global clinical trial development to assess safety, efficacy, and immune response of AZD1222. We have late-stage clinical trials ongoing in the US, UK, Brazil and South Africa, and trials are planned to start in Japan and Russia. These trials will enroll up to 50,000 participants globally (30,000 in the U.S), assessing at different dose levels and regimens, and will include diverse racial, ethnic and geographic groups who are healthy or have stable underlying medical conditions, including those living with HIV, and those at increased risk of infection from the SARS-CoV-2 virus e.g. frontline healthcare workers. Trial participants will also be followed over two years to study immune response in detail. Data from these trials will confirm if this approach provides the best potential to protect against COVID-19 disease. Results from the late-stage trials are anticipated later this year, depending on the rate of infection within the clinical trial communities.

5. Do you have plans to have human challenge studies where you will take healthy individuals, immunize them with your vaccine candidate, and then challenge them with an infectious dose of COVID-19?

   To date, challenge trials have not been necessary. We believe it is too early to consider deliberately exposing trial participants to the pathogen, but it may become an option if found necessary to proceed with the research. Of course, we would work closely with FDA and other regulators and institutional review boards, to review and implement the protocols and subject protections in any such trials.

   a. If yes, how is this ethical, and will your human challenge studies include participants over 55 years of age?

      N/A

   b. If nobody under 55 will be enrolled, will there be a gap in our knowledge about vaccine effectiveness in the 55 years and older age group?

      N/A

6. Could your vaccine candidate(s) be used with an adjuvant? If so, how many additional doses could be generated from the use of an adjuvant.

   An adjuvant is not currently being considered for use with AZD1222.

   a. If not, are there other ways your vaccine could be boosted to strengthen the immune response in patients?

      Based on accumulating preclinical and clinical data for AZD1222, we are proceeding with a two-dose strategy, which is being implemented in all ongoing clinical trials. Results will determine if this approach provides the best potential to protect against COVID-19 disease.

The Honorable David B. McKinley (R-WV):

1. When H.R. 3, the Lowering Drug Costs Now Act, was being considered in the House, members of this Committee raised concerns about what such legislation could do to innovation and drug development in the U.S., and Dr. Gerberding mentioned in her testimony how a robust biopharmaceutical research network has contributed to the accelerated development of a vaccine. H.R. 3 would undermine the important role of private-sector R&D in the U.S., as countries with price controls have suffered a decline in pharmaceutical R&D.

Do you all have concerns about impacts on your research and development efforts, should such legislation become law in the U.S.? Why or why not?

We are concerned that H.R. 3 could limit or delay access to innovative medicines and reduce investment in future treatments. Research has shown that when countries intervene to set a cap on drug prices, research and innovation suffer and that it is "simply not true that government can impose significant price controls without damaging the chances for future cures[1]."

According to a PhRMA analysis, H.R. 3 could cost the biopharmaceutical industry as much as $1 trillion over 10 years – 4 times total annual U.S. net revenues earned by the industry. This drastic cut would jeopardize the almost $100 billion biopharmaceutical companies invest annually in R&D. This plan would erode incentives that are critical to support investment into the risky and uncertain R&D process for complex diseases.

We believe the current health care system needs to evolve, and we are committed to working with Congress and the Administration to address patient access and affordability while continuing to support scientific innovation.

2. Most of you have accepted awards from the U.S. Department of Health and Human Services (HHS) to assist with the development and manufacturing of a COVID-19 vaccine?

    a. Are each of you on schedule and on budget?

Phase 3 trials are underway and we are moving forward with manufacturing to meet our commitments under our initial agreement with the U.S. government. We continue to finalize our agreement with the U.S. government as negotiations continue to move ahead.

    b. If you are behind schedule, do you plan to invest your own capital if the government grant runs out before you are finished with development?

Funding under the terms of our agreement with the U.S. government is reimbursement for AstraZeneca's costs reasonably incurred in performing the contracted work. The provision does not put AstraZeneca in a position to profit from its work with the U.S. government.

If you are ahead of schedule and you have grant money left over, what are your plans for those funds?

We do not anticipate that the contract will reimburse us more dollars than we actually spend.

[1] Information Technology & Innovation Foundation. "The Link Between Drug Prices and Research on the Next Generation of Cures." September 2019. https://itif.org/sites/default/files/2019-drug-prices-cures.pdf

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"

July 21, 2020

Dr. Macaya Douoguih, Head of Clinical Development and Medical Affairs, Janssen Vaccines

The Honorable Frank Pallone, Jr. (D-NJ):

1. The clinical trial work for Johnson & Johnson's vaccine candidate is on a different timetable than the other manufacturers we heard from at the hearing. As you even noted in your testimony, Johnson & Johnson will likely begin its Phase III trials after other companies have already begun large trials in the United States.

    a. What steps is Johnson & Johnson taking to ensure the company is able to recruit the tens of thousands of healthy participants needed for a Phase III clinical trial?

    Our pivotal Phase III clinical trial will be initiated once adequate safety and immunogenicity data are obtained in the current Phase I/IIa first-in-human trial, subject to all appropriate regulatory and health authority consultations. We are working to ensure that we have adequate numbers of sites for our Phase III clinical trial in areas where the incidence of COVID-19 is predicted to be high, both within the U.S. and in several other countries around the world. We are assessing a site's capacity to enroll participants as part of site selection, and we expect to have more sites selected and ready than will be utilized in the study, given that site activation will be guided by current and predicted epidemiology. The company is conducting outreach efforts to raise awareness of our Phase III clinical trial in local communities, particularly in diverse populations that are disproportionately affected by COVID-19. The overall timing of recruitment for our Phase III clinical trial will depend on the timing of approvals related to the Phase III clinical trial from the FDA and other health authorities and endorsement of the Phase I/IIa first-in-human trial data that support its start.

    b. How many participants do you anticipate recruiting?

    We anticipate that our Phase III clinical trial will include up to 60,000 people. The final number will be based on predictions of epidemiology and endorsement by the U.S. government.

The Honorable Brett Guthrie (R-KY):

1. Through Operation Warp Speed and the efforts of your companies and many more, we are seeing an unprecedented effort to quickly develop a safe and effective vaccine. What lessons or changes from this process should we consider making permanent in an effort to fundamentally change the traditional, years-long process for vaccine development going forward?

   Efforts to develop safe, effective, high-quality COVID-19 vaccines have accelerated clinical trial recruitment, and public dialogue around these trials has significantly raised awareness of clinical research within the general population. This acceleration is further enhanced by the investments we are making in several specific community engagement initiatives to build trust and raise interest in study participation, particularly in Black and Hispanic/Latinx communities that are disproportionally affected by the COVID-19 pandemic. In addition, Janssen has established partnerships that facilitate connection with potential trial candidates within specific high-risk populations who already have expressed their interest in participation to a COVID-19 vaccine trial. Finally, our partnership with the U.S. government has opened up opportunities for conducting clinical research in broader geographic locations outside of the traditional large cities. These include the deployment of mobile clinical research capabilities, partnerships with local community organizations, and connections with companies that employ large numbers of individuals at high risk of COVID-19. This geographic expansion enables us to respond to the changing disease incidence in a more rapid and patient-focused way. We believe these learnings will enable us to shorten time needed to identify and recruit volunteers for future clinical research programs.

2. How did investments into platform technology help speed up the vaccine development process?

   Platform technologies and modalities, like our proprietary AdVac® platform, allow for the development and application of experience and deep scientific and technical insights across different products. Janssen Vaccines has invested in developing the AdVac® platform and applying it to develop vaccine candidates for diseases like Zika, HIV, respiratory syncytial virus, and Ebola (the Ebola vaccine was recently licensed in Europe).

   When Johnson & Johnson joined the global fight against the COVID-19 pandemic in early January, we applied the understanding of our platform and the knowledge of the genome of SARS-CoV-2 to design our COVID-19 vaccine candidate. Utilizing our knowledge of the platform enabled us to move quickly by leveraging our prior investment and knowledge, while maintaining rigorous scientific standards.

3. Do any of your companies have recommendations about how to further innovate clinical trials?

   First, we recommend exploring direct-to-participant trial models. We are building the internal infrastructure necessary to launch a direct-to-participant trial model that brings clinical trials into people's everyday lives. We continue to invest in remote clinical trial

capabilities and expand innovative approaches to clinical trial conduct and research by exploring initiatives such as home healthcare nurse visits, telemedicine, direct medication shipment and bringing trial participation into community locations like pharmacies.

Second, we recommend developments in data science and digital health. Janssen seeks to improve participation and retention of clinical trial participants through use of technology for increased engagement and improved clinical trial access. Examples of our digital efforts include wearable devices and voice/chat-enabled software platforms that are designed to expand participants' ability to provide feedback in an alternative and more convenient platform.

4. COVID-19 has been with us for about seven months. There is still much we don't know about the antibody response and how long it lasts. Is there anything from the last seven months that has been learned that provides any insights into immune responses, and why it might suggest that our vaccine enterprise is on the right track?

   Preclinical studies with vaccine candidates from different developers have shown that animals can be protected against a SARS-CoV-2 challenge, supporting the idea that vaccines can induce the type of responses that prevent infection or prevent disease. Neutralizing antibodies have been shown to correlate with protection in animals, and several of the vaccine candidates already in the clinic have been shown to induce such neutralizing antibodies.

5. Do you have plans to have human challenge studies where you will take healthy individuals, immunize them with your vaccine candidate, and then challenge them with an infectious dose of COVID-19?

   We have not yet made a decision about whether to conduct human challenge studies.

   a. If yes, how is this ethical, and will your human challenge studies include participants over 55 years of age?

   b. If nobody under 55 will be enrolled, will there be a gap in our knowledge about vaccine effectiveness in the 55 years and older age group?

   The design of any study (or studies) would be subject to health authority consultations and approvals and would take into account the age of the study population.

6. Could your vaccine candidate(s) be used with an adjuvant? If so, how many additional doses could be generated from the use of an adjuvant.

   a. If not, are there other ways your vaccine could be boosted to strengthen the immune response in patients?

   Adenoviral vectors have an adjuvant activity on their own. As such, our vaccine candidate will not be used in combination with an adjuvant. We are evaluating multiple

dose levels and schedules to be able to determine the optimal and minimum effective dose of our vaccine candidate.

The Honorable David B. McKinley (R-WV):

1. When H.R. 3, the Lowering Drug Costs Now Act, was being considered in the House, members of this Committee raised concerns about what such legislation could do to innovation and drug development in the U.S., and Dr. Gerberding mentioned in her testimony how a robust biopharmaceutical research network has contributed to the accelerated development of a vaccine. H.R. 3 would undermine the important role of private-sector R&D in the U.S., as countries with price controls have suffered a decline in pharmaceutical R&D.

   Do you all have concerns about impacts on your research and development efforts, should such legislation become law in the U.S.? Why or why not?

   We believe that H.R. 3 would have a significant negative impact on drug development. This view aligns with analyses from Vital Transformations (http://vitaltransformation.com/wp-content/uploads/2020/01/Vital-Trans-HR3-Exec-Summ-11-22-2019-30JAN20.pdf), the Congressional Budget Office (https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf) and the Council of Economic Advisors (https://www.whitehouse.gov/articles/house-drug-pricing-bill-keep-100-lifesaving-drugs-american-patients/).

2. Most of you have accepted awards from the U.S. Department of Health and Human Services (HHS) to assist with the development and manufacturing of a COVID-19 vaccine?

   a. Are each of you on schedule and on budget?

      Janssen is on schedule.

   b. If you are behind schedule, do you plan to invest your own capital if the government grant runs out before you are finished with development?

      N/A.

   c. If you are ahead of schedule and you have grant money left over, what are your plans for those funds?

      N/A.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"

July 21, 2020

Dr. Julie Gerberding, Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health, Merck

The Honorable Frank Pallone, Jr. (D-NJ):

1. Completion of Phase III clinical trials will be critical to ensuring the safety and efficacy of any future COVID-19 vaccine. The U.S. Food and Drug Administration's guidance suggests that a Phase III clinical trial must enroll thousands of individuals in order to generate robust data to support an authorization or approval. Historically experts have suggested Phase III trials enroll upwards of 60,000 patients. How many patients does Merck intend to enroll in Phase III trials for a COVID-19 vaccine, and how will the company work to ensure that this goal is achievable given other competing trials?

   Historically Phase III vaccine studies have been designed to provide sufficient information to test stringent efficacy or safety hypotheses. For example, the Phase III efficacy study for our product Gardasil 9® enrolled approximately 14,000 subjects, the Phase III efficacy study for Zostavax® enrolled approximately 38,000 subjects, and the Phase III safety and efficacy study for RotaTeq® enrolled approximately 70,000 subjects. Merck is currently considering the appropriate trial design for its two SARS-CoV-2 investigational vaccines, V590 (VSV platform used for the licensed Ebola vaccine, Ervebo) and V591 (measles platform vaccine used for investigational vaccines for MERS and Chikungunya).

   Current assumptions regarding the incidence of SARS-CoV-2 disease and infection and the approach to hypothesis testing suggest that approximately 31,000 subjects will need to be enrolled to accrue the number of COVID-19 cases needed to provide sufficient power to test a stringent primary efficacy hypothesis. In order to enroll such a large number of subjects in a short period of time – approximately 3 months – Merck is making investments in these large clinical trials at risk, before obtaining the results of early stage studies. Merck plans to use its large global network of experienced clinical trial sites and has already begun collecting information on study site interest and capacity for these trials.

2. You stated in your testimony that, "Under normal circumstances, manufacturing and distributing a vaccine is exceedingly complex … When we think about what will be needed to address this pandemic, we are talking about orders of magnitude beyond what we as an industry are currently doing."

a. What challenges remain to be able to drastically ramp up manufacturing capacity for a COVID-19 vaccine?

b. What steps is Merck taking now to achieve this goal?

As announced in 2018, Merck was already investing significantly to expand our vaccine production capacity. In fact, to meet growing demand for Merck's medicines and vaccines and enable Merck to invest in R&D, Merck had already planned to invest $20 billion in capital projects from 2019 to 2023.

For SARS-CoV-2 specifically, we are already working to scale up manufacturing capacity to produce hundreds of millions of vaccine doses. This involves refitting or repurposing our global manufacturing network, which includes technology appropriate manufacturing sites in the U.S. and Europe, while also identifying additional opportunities to supplement this network.

We are focusing substantial resources on getting our vaccines and therapeutics, if successful, to market as fast as possible.

The Honorable Brett Guthrie (R-KY):

1. Through Operation Warp Speed and the efforts of your companies and many more, we are seeing an unprecedented effort to quickly develop a safe and effective vaccine. What lessons or changes from this process should we consider making permanent in an effort to fundamentally change the traditional, years-long process for vaccine development going forward?

   The SARS-CoV-2 vaccine programs have been enabled by pre-investment in vaccine platform processes that allowed existing pre-clinical safety and manufacturing knowledge to be leveraged for rapid construction of vaccine candidates with antigens selected through the emerging scientific understanding of SARS-CoV-2. In addition, the establishment of effective public-private partnerships based on complementary capabilities and aligned goals have encouraged access to critical reagents and knowledge sharing that has furthered the development of critical research tools such as animal models and laboratory tests. Frequent and expedient engagement with regulatory agencies, resulting in rapid alignment on endpoint definitions and laboratory testing standards, are expected to decrease the cycle time for protocol planning while assuring that the different vaccine candidates undergo consistent stringent scientific assessments.

   Through cooperative efforts, many vaccine programs have proceeded at unprecedented speed while still assuring rigorous safety and efficacy testing. Cooperative aligned efforts will be needed in the future to ensure successful vaccines will reach the public. For example, innovative regulatory review processes and global regulatory agency harmonization that acknowledges the importance of equitable access and the dependence of vaccines on global supply chains will be required for broad approval in the U.S. and around the globe. These and additional steps are critical to allow for broad access while preserving healthy market

dynamics that drive incremental, value-added improvements to vaccine product characteristics, as well as investments toward increased capability to address future infectious disease risks.

Specific to V590 which uses the VSV virus backbone, the flexibility and co-operation of the U.S. Department of Commerce was essential to enable rapid development of this vaccine candidate, as clinical development and manufacturing of this nature requires international co-operation. The VSV virus backbone itself is a controlled technology subject to Bureau of Industry and Security (BIS) license for export outside of the U.S. Normally, this would mean that a new license application would have been required for every third party outside of the U.S., including Merck sites. This is a major limiting factor for a vaccine we intend to be licensed, manufactured, and distributed globally. However, the U.S. Department of Commerce granted a general exemption for the purposes of developing a vaccine.

The development of future vaccines against currently known as well as unforeseen infectious threats will benefit greatly from continued investments in vaccine technologies that can be rapidly applied to new problems, further strengthening of collaborative partnerships, and enhanced regulatory science and alignment between countries.

2. How did investments into platform technology help speed up the vaccine development process?

   Investment in platform technologies allows for the rapid production of clinical material with minimal process development time. As a result of our experience with Ervebo, our licensed vaccine for Zaire Ebola virus infection, materials for our SARS-CoV-2 vaccine candidate V590 (using the VSV platform) were generated within a quarter once the vaccine construct was finalized. Experience with Ervebo allowed V590 to undergo focused pre-clinical assessment. In addition, the initial Phase I formulation and subsequent improvement were informed based on prior experience with the VSV platform.

   For our vaccine candidate V591 (using the measles platform), the fact that the Coalition for Epidemic Preparedness Innovations (CEPI) had already funded a MERS coronavirus vaccine using the measles platform allowed for the rapid pivoting of the program to SARS-CoV-2. Again, this permitted clinical material to be generated within a few months and streamlined the pre-clinical program.

   Unfortunately, these platform technologies take many years to develop, so continual investment is critical to assure availability of promising technologies in the future.

3. Do any of your companies have recommendations about how to further innovate clinical trials?

   We are optimistic that future vaccine trials will build on the innovations that we are seeing with respect to SARS-CoV-2, which will enhance public interest in and ability to participate in clinical trials. These types of innovations include greater utilization of remote monitoring and data collection for trial subjects.

4. COVID-19 has been with us for about seven months. There is still much we don't know about the antibody response and how long it lasts. Is there anything from the last seven months that has been learned that provides any insights into immune responses, and why it might suggest that our vaccine enterprise is on the right track?

   Over the last several months the scientific understanding of the immune response to SARS-CoV-2, the various modes of transmission, and risk factors for severe disease manifestations have evolved. Moving forward, additional knowledge will inform important modeling and simulation exercises to better understand whether immune responses are likely to translate into clinical protection, as well as how population immunity might impact the epidemic.

   To apply these principles to the Merck SARS-CoV-2 vaccine candidates, ongoing and planned pre-clinical studies will assess the ability of these candidates to protect animals from SARS-CoV-2 infections as well as the immune response associated with protection in these animal models. Our planned clinical studies will assess the candidates' ability to elicit robust neutralizing antibodies and T-cell immunity among clinical study participants. Immunogenicity observed following administration of these vaccine candidates will be assessed in light of observations among COVID-19 survivors to determine if late stage clinical trials are warranted. In the absence of established immune correlates of protection, efficacy will be confirmed in large Phase III clinical efficacy trials. These studies will also be sufficiently large to confirm that the safety and reactogenicity profile are suitable for use in large healthy populations.

5. Do you have plans to have human challenge studies where you will take healthy individuals, immunize them with your vaccine candidate, and then challenge them with an infectious dose of COVID-19?

   a. If yes, how is this ethical, and will your human challenge studies include participants over 55 years of age?

   b. If nobody under 55 will be enrolled, will there be a gap in our knowledge about vaccine effectiveness in the 55 years and older age group?

   No, Merck is currently not planning human challenge studies of its SARS-CoV-2 vaccine candidates.

6. Could your vaccine candidate(s) be used with an adjuvant? If so, how many additional doses could be generated from the use of an adjuvant.

   a. If not, are there other ways your vaccine could be boosted to strengthen the immune response in patients?

   Both Merck SARS-CoV-2 vaccine candidates, V590 and V591, are replicating virus constructs and are currently not designed to be used with an adjuvant.

With additional time and resources, other methods of delivery, such as microarray nano-patches, could potentially provide for dose sparing, though this would need to be investigated further. This delivery technology offers the advantages of rapid dissemination of an approved product. In addition, investment into new formulation technologies focused on end-to-end processing can improve dose targeting and thus reduce overage requirements per dose, increasing the total amount of doses available.

The Honorable David B. McKinley (R-WV):

1. When H.R. 3, the Lowering Drug Costs Now Act, was being considered in the House, members of this Committee raised concerns about what such legislation could do to innovation and drug development in the U.S., and Dr. Gerberding mentioned in her testimony how a robust biopharmaceutical research network has contributed to the accelerated development of a vaccine. H.R. 3 would undermine the important role of private-sector R&D in the U.S., as countries with price controls have suffered a decline in pharmaceutical R&D.

   Do you all have concerns about impacts on your research and development efforts, should such legislation become law in the U.S.? Why or why not?

   We believe that H.R. 3 is the wrong approach to address patient affordability. Patients deserve common-sense solutions that will lower their out-of-pocket costs while maintaining access to innovative medicines. Instead of making these types of practical changes, H.R. 3 upends the current competition-based system in favor of government price setting that will have a devastating impact on innovation and limit access to the newest and most innovative medicines. We agree that we must address patient affordability and the misaligned incentives in our current health care system, but H.R. 3 would not achieve these objectives. We will continue to work on solutions to help patients with their drug costs while still supporting the innovation ecosystem to produce the medical advancements that Americans need and desire.

2. Most of you have accepted awards from the U.S. Department of Health and Human Services (HHS) to assist with the development and manufacturing of a COVID-19 vaccine?

   a. Are each of you on schedule and on budget?

   b. If you are behind schedule, do you plan to invest your own capital if the government grant runs out before you are finished with development?

   c. If you are ahead of schedule and you have grant money left over, what are your plans for those funds?

   For our vaccine candidate V590 (our rVSV vaccine being developed in collaboration with the International AIDS Vaccine Initiative (IAVI)), Merck has signed an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health

and Human Services, to provide initial funding support for this effort. These efforts are on schedule and the resources provided by BARDA are only a small fraction of the investment Merck is making to pursue development of this vaccine candidate.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"

July 21, 2020

Dr. Stephen Hoge, President, Moderna

The Honorable Brett Guthrie (R-KY):

1. **Through Operation Warp Speed and the efforts of your companies and many more, we are seeing an unprecedented effort to quickly develop a safe and effective vaccine. What lessons or changes from this process should we consider making permanent in an effort to fundamentally change the traditional, years-long process for vaccine development going forward?**

   At Moderna, we are currently focused on bringing a safe and effective vaccine for COVID-19 to patients as rapidly as possible. Once we have addressed this pressing challenge, Moderna would support an assessment of whether the traditional process for vaccine development should be reformed, either generally or for specific "fast-track" vaccine candidates.

2. **How did investments into platform technology help speed up the vaccine development process?**

   Moderna would not have been able to rapidly develop mRNA-1273 without our mRNA platform and the investment that supported it. 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. At Moderna our "platform" refers to our accumulated knowledge and capabilities in basic and applied sciences across mRNA, the delivery of mRNA to target tissues, and the manufacturing processes for making potential mRNA medicines. We invest in basic science to discover foundational mechanistic insights, and we invest in applied sciences to invent technology that harnesses those insights. We use our platform to identify and develop new mRNA medicines. Our prior research and clinical trials taught us valuable lessons about designing vaccines—particularly how to manufacture mRNA that can be safely injected into people and induce an appropriate immune response. Without the benefit of this prior foundational work, we would not have been able to develop mRNA-1273 on the current timeline in order to meet this pandemic. That work on our platform was made possible by approximately $5.0 billion of investments from investors and partners.

3. **Do any of your companies have recommendations about how to further innovate clinical trials?**

At Moderna, we are currently focused on bringing a safe and effective vaccine for COVID-19 to patients as rapidly as possible. We are grateful to our government partners and their role in our clinical trials. Once we have all addressed this pressing challenge, Moderna would support an assessment of the clinical trial process and whether lessons learned from responding to this pandemic may be useful in innovating future trials.

4. **COVID-19 has been with us for about seven months. There is still much we don't know about the antibody response and how long it lasts. Is there anything from the last seven months that has been learned that provides any insights into immune responses, and why it might suggest that our vaccine enterprise is on the right track?**

   Since January, Moderna has worked tirelessly to understand COVID-19 and design a vaccine to combat it. We are continuing to collect data and evaluate the efficacy of the vaccine, and we are encouraged by the preliminary data. For instance, in August 2020, we announced that our vaccine generated a promising immune response in elderly patients. The study included 10 individuals between the ages of 56 and 70 and 10 individuals age 71 and older. Each participant received two 100 microgram doses of the vaccine 28 days apart. The study found that the participants produced neutralizing antibodies and T-cells and had a higher level of antibodies than seen in individuals who recovered from COVID-19. We at Moderna remain cautiously optimistic and hopeful that we are on track to create a vaccine that can help bring this global pandemic to an end.

5. **Do you have plans to have human challenge studies where you will take healthy individuals, immunize them with your vaccine candidate, and then challenge them with an infectious dose of COVID-19?**

   a. **If yes, how is this ethical, and will your human challenge studies include participants over 55 years of age?**

   b. **If nobody under 55 will be enrolled, will there be a gap in our knowledge about vaccine effectiveness in the 55 years and older age group?**

   We have no current plans for human challenge studies.

6. **Could your vaccine candidate(s) be used with an adjuvant? If so, how many additional doses could be generated from the use of an adjuvant.**

   a. **If not, are there other ways your vaccine could be boosted to strengthen the immune response in patients?**

   We have no current plans to use an adjuvant with our mRNA-1273 COVID vaccine. Future modifications to our vaccine to strengthen the immune response would only be considered after the current vaccine is approved for use.

The Honorable David B. McKinley (R-WV):

1. **When H.R. 3, the Lowering Drug Costs Now Act, was being considered in the House, members of this Committee raised concerns about what such legislation could do to innovation and drug development in the U.S., and Dr. Gerberding mentioned in her testimony how a robust biopharmaceutical research network has contributed to the accelerated development of a vaccine. H.R. 3 would undermine the important role of private-sector R&D in the U.S., as countries with price controls have suffered a decline in pharmaceutical R&D.**

   Do you all have concerns about impacts on your research and development efforts, should such legislation become law in the U.S.? Why or why not?

   We recognize the robust debate in this country regarding access to affordable drugs and other healthcare services. It is an important, complicated topic.

   As a relatively young biotechnology company, our goal is to develop a novel platform for designing and manufacturing a new class of mRNA-based vaccines. Over the past ten years, Moderna has invested over $5.0 billion in creating and developing our mRNA platform, which we believe offers an innovative new technique for discovering, developing, and manufacturing medicines. It is our hope that our platform could potentially help address not only the current COVID-19 pandemic, but other diseases that threaten lives and health around the world, including some for which there are currently no vaccines. Those diseases include Cytomegalovirus ("CMV"), Zika, and Respiratory syncytial virus ("RSV"), and are part of a pipeline of over 23 programs, of which 17 have entered clinical studies. Given the urgency of the pandemic, we have prioritized mRNA-1273, our vaccine candidate for SARS-CoV-2, over other development projects.

   We recognize and support the goal of improving access to life-saving drugs, and we are aware, as is this Committee, of many potential avenues to help achieve that goal. However, at this moment, we are focused on delivering our first product—a safe and effective pandemic vaccine—as quickly as possible. As we enter the commercial phase with an anticipated global launch of mRNA-1273 we will continue to study ways to bolster research and development while also increasing access to affordable drugs, and are happy to continue this conversation as the Committee considers H.R. 3 or similar legislation.

2. **Most of you have accepted awards from the U.S. Department of Health and Human Services (HHS) to assist with the development and manufacturing of a COVID-19 vaccine?**

   a. **Are each of you on schedule and on budget?**

   We are currently in Phase 3 of the Coronavirus Efficacy ("COVE") study of mRNA-1273, which is being conducted in collaboration with the National Institute of Allergy and

Infectious Diseases ("NIAID"), part of the National Institutes of Health ("NIH"), and the Biomedical Advanced Research and Development Authority ("BARDA"). Phase 3 began on July 27, 2020, and enrollment is on track to be completed in September 2020. Our expenditures for this Phase 3 study are consistent with the budgets of our current contracts for this study.

b. **If you are behind schedule, do you plan to invest your own capital if the government grant runs out before you are finished with development**?

When the threat posed by COVID-19 became apparent, Moderna rapidly focused on developing a COVID-19 vaccine. Moderna proceeded at-risk and without government funding. We are grateful to our government partners for their investment and support as we continued this work. So long as our vaccine candidate continues to show promising results, in the event that funds for manufacturing, clinical trials, or other developments were needed, we would continue to secure partners and manufacturing capabilities with our own resources. We would communicate with the government to discuss whether additional support would enable Moderna to bring a safe and effective vaccine to market as quickly as possible.

c. **If you are ahead of schedule and you have grant money left over, what are your plans for those funds?**

Moderna's BARDA awards represent a commitment to reimburse Moderna for allowable costs under our contracts. To the extent that we are able to fulfill our BARDA agreements under budget, the unused funds would remain with the federal government.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"

July 21, 2020

John Young, Chief Business Officer, Pfizer

The Honorable Frank Pallone, Jr. (D-NJ):

1. **During the hearing, you indicated that Pfizer was putting together its clinical trial protocol for its Phase III study and would follow the U.S. Food and Drug Administration's (FDA) guidelines that suggest enrollment of up to 30,000 patients.**

    a. **What is the minimum number of patients Pfizer will seek to enroll in its Phase III trial, and how did the company arrive at this range?**

    Response: The Phase 2/3 part of the study initially seeks to enroll approximately 29,300 participants. This number was based upon the FDA Guidance for Industry on Development and Licensure of Vaccines to Prevent COVID-19.

    b. **What makes your company confident this will be a large enough pool of participants to adequately assess the safety and efficacy of any of its vaccine candidates?**

    Response: The number of participants in the study was determined on the basis of the FDA Guidance for Industry on Development and Licensure of Vaccines to Prevent COVID-19. Per the guidance, we currently project that the planned number will allow for adequate assessment of both safety and efficacy, however we will continue to monitor this closely.

2. **As we heard at the hearing, there are many companies racing to begin and complete the Phase III clinical trials that will be necessary to support an authorization or approval by FDA. What steps is Pfizer taking to ensure the company is able to recruit the tens of thousands of healthy participants needed for a Phase III clinical trial?**

    Response: The more than 120 investigative sites across the U.S. are raising awareness of the trial and recruiting individuals based on their own practices to meet the unique needs of their respective communities. In addition, we are complementing this effort with additional awareness building efforts and referrals to sites, including: a study website, social media and local newspaper and radio communications. We are also partnering with community, government and local advocacy groups to raise awareness of the importance of participation

with their constituents from racial and ethnically diverse communities that have been disproportionately impacted by COVID-19.

3. **Ensuring quality manufacturing of a future vaccine is critical to ensuring rapid access for patients, as well as preventing any potential disruptions that could limit such access. At the hearing you noted that Pfizer's previous manufacturing quality issues associated with sterile injectables were attributable to facilities associated with Hospira that was acquired by the company in 2017. You noted that your remediation for those sites was to be completed by 2020 and that those sites "were on track." While I understand you intend to manufacture a future COVID-19 vaccine candidate in your legacy Pfizer network, what are the lessons learned for Pfizer in the remediation of the sterile injectable facilities you acquired, and what steps is the company taking now to mitigate against any potential quality or compliance issues in your legacy facilities to ensure uninterrupted access to a future vaccine?**

   Response: Pfizer has effectively integrated sterile injectable manufacturing facilities acquired over the years and ensured improvements were made through application of Pfizer's quality standards and necessary capital investments. Pfizer is committed to the delivery of safe and effective products to patients. Pfizer operates a Quality Management System (QMS) within and across relevant functions and departments, and maintains a quality-focused culture to ensure the highest priority is placed on the safety, efficacy and quality of our products, the safety of our patients, and the quality of data supporting regulatory submissions. Pfizer has established a Corporate Quality Policy that describes overall intentions and direction of the company related to quality including key quality expectations and responsibilities for all Pfizer colleagues and contingent workers. The potential COVID-19 vaccine is being developed within the Pfizer QMS in an accelerated fashion taking appropriate steps to identify and mitigate any potential risks. The vaccine supply chain includes Pfizer manufacturing sites operating in accordance with current Good Manufacturing Practices under Pfizer's QMS following our well-established quality standards.

The Honorable Brett Guthrie (R-KY):

1. **Through Operation Warp Speed and the efforts of your companies and many more, we are seeing an unprecedented effort to quickly develop a safe and effective vaccine. What lessons or changes from this process should we consider making permanent in an effort to fundamentally change the traditional, years-long process for vaccine development going forward?**

   Response: The development of a novel vaccine is a complex and lengthy process that generally takes 10 to 15 years. Given the current global scale of the COVID-19 pandemic, Pfizer is working at an unprecedented speed to develop a potential vaccine in a safe and responsible way, collaborating closely with regulatory and health authorities around the world – compressing stages that have taken years into months, and those that have taken months into weeks. We are doing so with an unwavering commitment to scientific rigor, clinical trial quality, and participant safety.

We normally do all vaccine development and manufacturing work sequentially. In light of the urgency of the pandemic, we are now doing the development and manufacturing processes in parallel and we're investing significant capital at risk to help compress the timelines to meet this global challenge. With our partner BioNTech, we selected the most promising version and dose among four potential vaccine candidates, based on Phase 1 clinical studies conducted in the U.S. and Germany. These data and our recommendation for our final vaccine candidate were shared with the FDA and other global regulators who approved our planned Phase 3 study in only a few days. We then rapidly moved into large-scale, randomized testing in 30,000 volunteers that will tell us if the vaccine is both safe and effective.

We've seen the benefit of embracing novel clinical trial designs including seamless adaptive trial designs and platform approaches to test multiple assets in the clinic simultaneously. These mechanisms are not new and should be leveraged routinely, particularly for other serious and life-threatening diseases where similar benefit/ risk considerations apply.

2. How did investments into platform technology help speed up the vaccine development process?

Response: Fortunately, we have been able to leverage several years of ongoing research on the mRNA platform for potential influenza vaccines with our partner BioNTech, dating back to 2018. This is an important foundation for the work in our COVID-19 vaccine program, including preclinical and manufacturing data to support the safety of the underlying mRNA technology. This early work allowed Pfizer and BioNTech to accelerate entry into clinical testing, while preserving high standards for safety and not cutting any corners.

Additionally, the mRNA vaccine platform allows for precise genetic profiling of the viral protein and rapid manufacturing scale-up (millions of doses by the end of 2020 and hundreds of millions in 2021). These unique platform attributes could also be deployed to address future pandemics and pathogens.

From a policy perspective, there is tremendous potential to further leverage a wide variety of genomic platform technologies, for example in vaccines, gene therapies, and small-molecule targeted therapies in the future by leveraging prior knowledge of the platform performance characteristics. The Committee set the stage for this approach through passage of the 21st Century Cures Act, which established a program - Targeted Therapies for Rare Diseases (§3012) - to help streamline the life-cycle submission and review of genetically targeted drugs and variant protein targeted drugs. We encourage the Committee to consider further expanding this program to promote broader FDA utilization of the program across additional genomic platform technologies and therapeutic areas.

3. **Do any of your companies have recommendations about how to further innovate clinical trials?**

   Response: The COVID-19 pandemic has pressure tested regulatory systems as never before. And most will agree that the biomedical research ecosystem will never be quite the same again. The durable lessons learned can help prepare us for future pandemics and accelerate the development of therapies for other debilitating and life-threatening conditions. We see the opportunity in several areas:

   First is building a digitally resilient clinical trials system. We learned that digital tools could be used to great effect to ensure that patients can continue to safely participate in research during the pandemic. Decentralized trials, adaptive designs, master protocols, and real-world evidence are not new, but the mutual experience gained during the pandemic can help ensure that they become routine elements of a modern regulatory toolkit.

   Second, is the value of robust, interactive scientific dialogue between FDA and sponsors during development and throughout the review process. In the usual drug development journey, the process of preparing regulatory data packages to submit to the FDA and then waiting to hear back is typically iterative and time consuming, often taking months. With all hands-on-deck in the fight against COVID-19 across the globe, regulators are responding to data very quickly, often in real time, to help keep trials running as quickly as possible. Additional FDA resourcing may be required to help sustain this type of interaction for COVID-19 and other areas of unmet medical need.

   Finally, the breadth and depth of the collaboration needed between regulators, researchers, and industry in the global pandemic has highlighted the need for enhanced secure data platforms for information exchange. This helps to facilitate real-time or rolling review for COVID-19 vaccines and therapeutics and accommodate large data sets and new tools, including computational models, real-world evidence, and "big data."

   We believe industry and regulators will emerge stronger than before by applying the lessons learned from this crisis to create a more efficient and patient-centric "new normal." We look forward to engaging with the committee on these concepts as it considers 21st Century Cures 2.0 and PDUFA 7 legislation.

   We enclose for the committee's information a paper recently published in Nature that outlines areas that we believe lend themselves to continued innovation.

4. **COVID-19 has been with us for about seven months. There is still much we don't know about the antibody response and how long it lasts. Is there anything from the last seven months that has been learned that provides any insights into immune responses, and why it might suggest that our vaccine enterprise is on the right track?**

   Response: Our studies to date have provided data that shows our investigational COVID-19 vaccine stimulates a strong response from both parts of the immune system, both antibodies and T cells. These are critical to providing protection against a virus such as SARS-CoV-2

and provide encouragement that the vaccine will be able to protect against COVID-19. That is what we now seek to demonstrate in the large-scale part of the study that is ongoing now.

5. **Do you have plans to have human challenge studies where you will take healthy individuals, immunize them with your vaccine candidate, and then challenge them with an infectious dose of COVID-19?**

    a. **If yes, how is this ethical, and will your human challenge studies include participants over 55 years of age?**

    b. **If nobody under 55 will be enrolled, will there be a gap in our knowledge about vaccine effectiveness in the 55 years and older age group?**

Response: We have no plans to perform human challenge studies. However we believe the placebo arm of our Phase 3 study may provide an indication of the degree of protection conferred by our vaccine.

6. **Could your vaccine candidate(s) be used with an adjuvant? If so, how many additional doses could be generated from the use of an adjuvant.**

Response: Because of the inherent immunogenicity of RNA-based vaccines, there is no need for an adjuvant for any specific populations.

    a. **If not, are there other ways your vaccine could be boosted to strengthen the immune response in patients?**

Response: Adjuvants are not necessarily the optimal approach for every type of vaccine. With our partner BioNTech we will continue to explore further opportunities for the mRNA vaccine platform.

The Honorable David B. McKinley (R-WV):

1. **When H.R. 3, the Lowering Drug Costs Now Act, was being considered in the House, members of this Committee raised concerns about what such legislation could do to innovation and drug development in the U.S., and Dr. Gerberding mentioned in her testimony how a robust biopharmaceutical research network has contributed to the accelerated development of a vaccine. H.R. 3 would undermine the important role of private-sector R&D in the U.S., as countries with price controls have suffered a decline in pharmaceutical R&D.**

    Do you all have concerns about impacts on your research and development efforts, should such legislation become law in the U.S.? Why or why not?

Response: Many economists have raised concerns with referencing international prices to U.S. prices and the impact on incentives for innovation. We share those concerns. The Council of Economic Advisors warned in a 2018 report that lowering reimbursement for

medicines in the United States "makes better health costlier in the future by curtailing innovation." In fact, evidence shows that every $1-2 billion reduction in research and development investment leads to development of one fewer new medicine per year; an updated Council of Economic Advisors analysis specific to H.R. 3 forecasted as many as 100 fewer drugs entering the U.S. market over the next decade. The U.S. Department of Commerce found that international reference pricing and other price controls in foreign countries already suppress worldwide private research and development investment by 11-16 percent annually, and international reference pricing here in the U.S. would only compound that problem.

2. **Most of you have accepted awards from the U.S. Department of Health and Human Services (HHS) to assist with the development and manufacturing of a COVID-19 vaccine?**

    a. **Are each of you on schedule and on budget?**

    b. **If you are behind schedule, do you plan to invest your own capital if the government grant runs out before you are finished with development?**

    c. **If you are ahead of schedule and you have grant money left over, what are your plans for those funds?**

Response: To date, we (Pfizer and BioNTech) have not accepted any U.S. government funding for our COVID vaccine research and development efforts. We are on track with our progress at this time.

nature reviews drug discovery

COMMENT · 03 SEPTEMBER 2020

COVID-19 must catalyse changes to clinical development

The response to the COVID-19 pandemic has shown that exceptional efforts can dramatically accelerate the clinical development of vaccines. We propose that it is time to also take immediate actions to improve clinical trials in other areas to better serve all patients.

Rod MacKenzie , **Peter Honig**, **Judy Sewards**, **Robert Goodwin** & **Marie-Pierre Hellio**

In the few months since the emergence of COVID-19, multiple organizations have engaged with the urgent challenge to rapidly develop a safe and effective vaccine. As one of those organizations, working with our partner BioNTech, we are doing things very differently. And if we succeed, we will develop a COVID-19 vaccine in less than a year, compared with the typical timeframe of 10 or more years for vaccine development[1].

So what, one might say. Extraordinary times deserve extraordinary actions. But how can we take such exceptional action for COVID-19, but not cancer, life-limiting autoimmune conditions or a myriad of other major medical needs? Are these patients somehow less deserving? Of course not.

So what will it take to emerge from the COVID-19 pandemic with a clinical trials ecosystem that better serves patients? Here, we propose actions in two crucial areas: equity in access to clinical trials and awareness of the options available for patients; and speed, efficiency and innovation in clinical development.

Equity in access and awareness

Racial and ethnic disparities in clinical trial populations remain unacceptably abundant, and trust in the health-care system among those who suffer racial injustice is low. It is difficult to find a trial and the requirements for participants are often burdensome, contributing to unacceptably high dropout rates.

It is time to stop the expediency and pragmatism that prevails in patient recruitment and perpetuates inequities, and to find common solutions that build trust and address the socioeconomic barriers to clinical trial participation. We propose commitments to improve access and build trust, and to improve awareness.

Improve access and build trust. We believe that clinical trial populations should reflect the demographics of the countries in which the trials are being conducted, and that no-one should be excluded from a clinical trial by socioeconomic disadvantage alone. Neither of these aims is being achieved today, and things will not change until trust in the system is improved and the systemic barriers to participation are reduced.

We call for a concerted and urgent commitment by sponsors, regulators and policy-makers to reduce the inequities of access to clinical trials that today exclude too many people in need. Actions could include ensuring that people who are under-insured have the opportunity to participate. In addition, to help build trust in racially and ethnically disadvantaged communities, the number of clinical investigators and research site staff from these communities should be increased.

Improve awareness. Patients want to know all potential trials available to them, to make informed decisions and easily connect with study sites. We must create a better solution than we have today. Sponsors should work together with regulators to

provide a simple, plain language, easily searchable and accessible website or app for anyone to find trials that are recruiting and how to take the next steps.

Speed, efficiency and innovation

Sponsors and regulators have been galvanized by the COVID-19 pandemic. Flexibility, boldness in capital deployment, responsiveness, parallel processing and speed in decision-making have been the hallmarks of the work to date. However, the pandemic has also highlighted outdated technical infrastructure, especially the lack of contemporary digital capabilities, slowness of interactions, sequential processes and patchy acceptance of new approaches that have existed for too long at the interface of sponsors and regulators.

We list below four proposals that, if implemented by sponsors and regulators, would benefit all patients.

Sponsors expand adoption of parallel processing at risk. The speed of the COVID-19 vaccine programmes has necessitated massive parallel processing of activities that are usually done sequentially. To give a sense of how radical this is, production capacity of billions of doses must be procured and developed, and commercial procurement contracts and launch plans must be put in place while preclinical and early clinical testing is still in progress and pivotal clinical study designs are being finalized with regulators. Operational decision-making is daily, sometimes hourly.

All of this is only possible through bold deployment of capital with no guarantee of success. But this is what is needed if the goal is to 'do the impossible' and match the speed and quality of drug development to the needs of society. This will redefine the expectations that patients with life-threatening conditions and few if any options will place on sponsors.

Sharing knowledge among sponsors. This has been a welcome feature of the COVID-19 response, but remains limited in scope and poorly coordinated in other areas. Sponsors generally view much of their clinical development activities as competitive information to be carefully stewarded. Yet, if such information was shared, drug development could be accelerated by enabling

sponsors to build on prior and emerging knowledge from others. Competition between sponsors would still exist, but it would be properly focused on the relative benefit/risk to patients of the therapeutic molecules and vaccines themselves.

It is time for sponsors to commit to a new interpretation of what is competitive information and share more. We anticipate that established consortia such as TransCelerate BioPharma will be important in implementing such commitments.

Speed up interactions between sponsors and regulators and fully embrace digital tools. The overnight review of COVID-19 protocols, the waiver of the 30-day investigational new drug (IND) application waiting period and analogous clinical trial application (CTA) provisions, the delivery of scientific advice almost in real time and virtual meetings between sponsors and regulators have all enabled rapid decision-making in response to COVID-19. Unfortunately, this is not true for other diseases where interactions between sponsors and regulators are measured in weeks and months. Regulatory review times are often up to a year.

The timelines being achieved for COVID-19 should be retained for other life-threatening diseases for which available treatment options are few or none. We recognize this will require additional health authority funding to achieve. It should be provided.

Fully embracing digital technology is crucial to enhance access, speed, quality and the patient experience. Examples include wearables and electronic diaries for real-time data capture, image collection by smartphone, telemedicine engagements, remote quality and safety monitoring informed by advanced analytics, and electronic health records as the single source of data to reduce onsite data review and verification.

Regulatory inspections of sites and sponsors can be conducted using secure video and data sharing technologies that allow inspectors to interview personnel, review standard operation procedures and validate source documents and data while assuring compliance with privacy laws.

A single shared cloud-based system for data submitted to regulators could accelerate drug development, enhance transparency and speed-up decision-making[2].

Routine communication can take place by secure email. Dedicated portals, digital vaults and video/audio calls can replace hard-copy mail. For submissions and labelling, regulators can stop requiring original hard copies of documents with wet signatures, notarizations or apostilles that no longer serve a purpose but slow development and can introduce the risk of some prescribers relying on outdated information.

A broad and urgent commitment to digital tools is overdue by sponsors and regulators. We need to let go of familiar but outmoded ways of working, and broadly implement common digital solutions.

Increase collaboration, flexibility, mutual recognition and reliance among regulators. Formal collaboration between regulators should be expanded. For example, simultaneous collaborative review by multiple regulators would not only bring breakthroughs to patients more quickly, but would also help regulators in decision-making by learning from each other.

Greater flexibility is also long overdue. There are many examples, but we list three here. First, sponsors should be able to ship investigational materials before protocol review. Second, rolling IND/CTA submissions should be allowed to facilitate earlier medical reviewer familiarity with the R&D strategy and data. Third, changes in quality systems before regulatory approval should be introduced to allow faster responses to supply challenges and reduce the number of drug shortages. More generally, the existing blanket application of regulatory requirements should be replaced with a fit-for-purpose approach that better serves patients.

Acts of will

Progress is being made in many of the areas we discuss above, but progress without substantive real-world impact is not sufficient. COVID-19 will ultimately deliver many lessons, but the response has already taught us what we are capable of when

the chips are truly down. And yet there are so many patients in dire need from other serious diseases; their conditions are no less deserving, nor their needs less urgent. Put simply, COVID-19 is redefining what our response must be.

We intend to play our full part. We commit that the participants in our clinical trials will reflect the racial demographics of the countries and communities in which we conduct our studies. We commit to expand awareness and access to our clinical trials and to improve the experience of our participants. We commit to share our knowledge more broadly. We commit to fully embrace digital tools for speed and quality.

We encourage other sponsors and global regulators to share their own thoughts and commitments. We should seize this moment, before our conventions re-solidify to the old ways of doing things, to embed the improvements made during the COVID-19 pandemic and accelerate others, on behalf of all patients. If not now, when?

doi: 10.1038/d41573-020-00149-2

Acknowledgements

The authors are grateful to M. S. Ringel, C. Liu, A. Goldberg, K. Natarajan, B. Corrigan and S. Anderson for their input and support.

References

Le, T. T. et al. The COVID-19 vaccine development landscape. *Nat. Rev. Drug Discov.* **19**, 305–306 (2020).