PRELIMINARY TRANSCRIPT

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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, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., via Webex, Hon. Diana DeGette [chairwoman of the subcommittee] presiding.

Present: Representatives DeGette, Schakowsky, Kennedy, Ruiz, Kuster, Castor, Sarbanes, Tonko, Clarke, Peters, Pallone (ex officio), Guthrie, 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; Jessica Boyer, Professional Staff Member; Jeff 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, Staff 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 O&I; Theresa Gambo, Minority Human Resources/Office Administrator; Tyler Greenberg, Minority Staff Assistant; Tiffany Haverly, Minority Communications Director; Brittany Havens, Minority Professional Staff, O&I; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; Brannon Rains, Minority Policy Analyst; Alan Slobodin, Minority Chief Investigative Counsel, O&I; Peter Spencer, Minority Senior Professional Staff Member, Environment & 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 the chair 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.

The Chairman. Thank you. Thank you, Chairwoman DeGette.

Ms. DeGette. Sorry about that.

The Chairman. 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 6 months, more than 3 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 reeked 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 2 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 2 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.

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

[The prepared statement of The Chairman follows:]

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

Ms. Eshoo. Thank you for yielding, Mr. Chairman, 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.

[The prepared statement of Ms. Eshoo follows:]

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

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.

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 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 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 2 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.

PRELIMINARY TRANSCRIPT

[The prepared statement of Mr. Guthrie follows:]

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

Ms. DeGette. I thank the gentleman. The chair will now give her opening statement.

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 6 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 2 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.

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

[The prepared statement of Ms. DeGette follows:]

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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 --

Ms. DeGette. Without objection.

[The information follows:]

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

Mr. Walden. -- 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.

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 [inaudible] 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:]

PRELIMINARY TRANSCRIPT

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

TESTIMONY OF DR. MENE PANGALOS

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 development, 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 1/2 clinical trials in over a thousand healthy volunteers. And just yesterday, we announced some of the data from that phase 1/2 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:]

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Ms. DeGette. Thank you so much, Doctor.

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

TESTIMONY OF DR. MACAYA DOUOGUIH

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 1/2A 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:]

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Ms. DeGette. Thank you so much, Doctor.

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

TESTIMONY OF DR. JULIE GERBERDING

Ms. DeGette. You need to unmute.

Dr. Gerberding. Can you hear me now?

Ms. DeGette. Yes.

Dr. Gerberding. Okay. 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 6 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 6 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. -- core values and the purpose that motivates us to commit our lives to our profession. Thank you.

[The prepared statement of Dr. Gerberding follows:]

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

TESTIMONY OF DR. STEPHEN HOGE

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 6 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:]

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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 1/2 clinical trial which further demonstrated encouraging T-cell and cytokine responses. Data from this ongoing phase 1/2 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:]

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

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 1/2 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. Uh-huh.

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.

Okay. 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. Okay.

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?

RPTR MERTENS

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[10:57 a.m.]

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.

The Chairman. 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 okay 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.

The Chairman. 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.

The Chairman. 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.

The Chairman. 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. Yeah. 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 5 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. Yeah. 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 10 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. Okay.

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. Okay.

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. Okay. 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. Okay. 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. Okay.

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 substance, 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. Okay. 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. Yeah. 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 generations 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 2 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 [inaudible].

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? Okay. 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. Okay. 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. Yeah. 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 2 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 1 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 gentlelady.

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.

RPTR MOLNAR

EDTR HUMKE

[11:56 a.m.]

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. Yeah, okay.

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 [inaudible.] I 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. -- 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 different 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 [inaudible] populations.

Mr. Duncan. Okay. 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 5 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. -- so answer fast.

Dr. Hoge. We've already evaluated our vaccine in elderly populations. That data is ongoing both in the phase 1/2 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. -- 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 6 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. Okay, 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 gentle lady -- 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. Yeah, 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. Okay. 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. Yeah. I thought I had. There. Should be on, right?

Ms. DeGette. No.

There you go. We see you.

Mr. Upton. Okay, 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, [inaudible] 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. Okay.

Dr. Pangalos. -- 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. -- 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. Okay. Mr. Chair, can you hear me?

The Chairman. Yes.

Mr. Tonko. Okay. 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. Okay.

Okay. 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. Okay.

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. Okay. If you could get back to us in writing, I'd appreciate it.

Dr. Gerberding. Absolutely.

[The information follows:]

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

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. Okay. 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. Okay.

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. Okay, 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.

You're muted. You're muted.

There you go. You're unmuted now.

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. [Inaudible] 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.

RPTR MERTENS

EDTR ROSEN

[12:55 p.m.]

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 10 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.

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.

PRELIMINARY TRANSCRIPT

[The information follows:]

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

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.]