DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2021

THURSDAY, JULY 2, 2020

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:05 a.m. in room SD–106, Dirksen Senate Office Building, Hon. Roy Blunt (chairman) presiding.

Present: Senators Blunt, Shelby, Alexander, Moran, Capito, Kennedy, Murray, Durbin, Shaheen, Merkley, Baldwin, Murphy, and Manchin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPERATION WARP SPEED: RESEARCHING, MANUFACTURING AND DISTRIBUTING A SAFE AND EFFECTIVE CORONAVIRUS VACCINE

OPENING STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. The Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will come together.

I'm glad to be here this morning with my colleagues, some of whom are joining us from their offices or from some other location.

This is the first Appropriations hearing being held in-person and virtually and I want to thank Chairman Shelby and his staff for letting us try this and see how this kind of information gathering works for appropriators. It's not a markup. There will be no voting today, but we're going to get some really important information.

Yesterday, coronavirus cases passed 50,000 for the first time, making it a single-day record. This morning, 128,000 Americans have died, and nearly 2.7 million have tested positive for COVID–19, and, of course, the thoughts of myself and everyone on this committee are with those individuals and those families who've been affected.

I've called this hearing really to look at an update on the efforts that the Administration's put together and, frankly, members of this committee were very involved in to see if we couldn't establish a new way to look at responding to pandemics.

I think we have the chance to actually write a new important chapter in what that response looks like. Developing the right vaccine, the right therapeutics, the right testing is important, and I

think we're going to talk today about ways to try to have all of the safeguards in developing all of those things but with a Federal partner going forward more quickly than we would have ever gone forward.

Today, I saw that Pfizer just passed an important mark with the vaccine they're working on. Maybe the most significant thing I saw in that article was that Pfizer believes they may have a hundred million doses of that vaccine available by the end of the year. That would be an extraordinary thing if it happens and I think what we're going to hear from our witnesses today is that there are other companies that would be developing different vaccines that also would add to that figure that might be available late this year or early next year.

I think the Administration's willingness to take this new initiative, the willingness of the Administration and, frankly, our Appropriations Committee and the Congress in what we did in the last COVID Act to put some money behind taking a chance, not a chance with an effective vaccine or test, but a chance that we may move forward with something that doesn't work more to also allow us to move forward early with something that does work.

This committee, the full committee and the Congress has provided nearly $10 billion for this overall effort and the vast majority of this investment will support the research and development of vaccines and treatments.

There are over a hundred vaccines in development worldwide. Operation Warp Speed, I believe, is beginning to focus in on about seven that we would encourage the advancement of in clinical trials and further development.

Importantly, as NIH (National Institutes of Health) and the Biomedical Advanced Research Development Authority continue to oversee the development of these vaccines, we're also going to be talking today about how manufacturing for maybe the first time ever would begin while the vaccine is still going through the other process and maybe while tests are still going through the other process.

As we saw earlier this year with diagnostic testing research at NIH, the current processes can be streamlined to make them faster. Just because something is new doesn't mean it's better, but this is a time to try things and to see what we can figure out to make work.

Under the NIH's Shark Tank Program, the program that particularly Senator Alexander and I spent a lot of time talking to people at this table about, principally Dr. Collins but people at this table, manufacturers and others, we're hoping to fast track diagnostic tests, to have tests that are easier to take with a quicker response that frankly millions of people can take dozens of times, getting schools started in the fall at residential campuses and elementary and secondary schools, and all other campuses. Having a test available will make a big difference.

Some people have warned that the time table to develop both tests and vaccines next year is far too fast. Others have said, well, maybe accelerating the process means the regulatory corners will be cut. We're going to be working really hard to be sure that is ab-

solutely not the case and I think our leaders here today will help reassure us of what they're doing to see that that doesn't happen.

This is an opportunity for our witnesses to explain to our committee and the American people how the development process works, how they'll ensure that the vaccine will be safe, and even with an accelerated research and development time table how the vaccine will be distributed across the country as quickly as possible.

I've said to several people lately on the topic of vaccine and distribution that obviously developing the vaccine is the top priority, but right below that top priority is having a plan that distributes that vaccine in a way that people believe is fair and equitable and meets the standards that we should be establishing right now.

There are clearly concerns about the vaccine. About half of Americans are either reluctant, about one out of five Americans say they're just not going to take the vaccine. I certainly intend to, and I think most Americans will, and as we reassure people about this process, I also think about smallpox and polio and other things that in many cases vaccines have been able to move outside the system because vaccines did their job and, you know, kids in the fourth and fifth grade don't line up any longer so that every single person takes their smallpox shot like they did when most of us were kids.

I hope today's hearing really makes an impact on those concerns, I believe it will, and look forward to our witnesses.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ROY BLUNT

Good morning. I want to thank our witnesses for appearing before the Subcommittee today to discuss the development of a coronavirus vaccine.

This is the first Appropriations Committee hearing that is being held both in-person and virtually. We are virtual because the United States is currently experiencing its worse, large-scale public health outbreak in a generation. Across the country, this has changed our daily lives, and in the Senate, it is no different. Yesterday, new coronavirus cases in the U.S. passed 50,000 for the first time to reach a sing-day record. As of this morning, 128,000 Americans have died and nearly 2.7 million have tested positive for COVID–19. My thoughts are with all those affected.

I called today's hearing to receive an update on the Administration's efforts to develop a COVID–19 vaccine through Operation Warp Speed.

The mantra underlying this pandemic is that we need a vaccine to truly get this pandemic under control.

And I think that is right—that life will not return to resembling pre-outbreak normal until there is an effective and widely available coronavirus vaccine. But how do we get there?

Developing the right vaccine, putting it through its necessary clinical trials to see if it is both safe and effective takes time. Then it must be manufactured, distributed, and administered to potentially hundreds of millions of Americans. These are daunting steps that have already received significant investment by the Federal Government, and will likely need more, to achieve.

It is important to manage our expectations, to understand that as much as we want a vaccine as soon as possible, the most important thing is that it is safe.

The Administration should be commended for their new initiative, Operation Warp Speed. This Committee has provided nearly $10 billion for this effort and the vast majority of this investment will support the research and development of vaccines and treatments.

There are over 100 vaccines in development worldwide and Operation Warp Speed will narrow down those candidates to about 7 to advance into clinical trials and for further development. Importantly, as NIH and the Biomedical Advanced Research and Development Authority continue to oversee the development of these vaccines, we will also provide resources to begin manufacturing now.

This will allow us to have hundreds of millions of doses ready to go when a vaccine is determined to be safe and effective.

As we saw earlier this year with diagnostic testing research at NIH, the current processes can be streamlined to make them faster. Just because something is new, doesn't make it better. But the opposite is also true—just because that's the way something has always been, it doesn't make it right.

Under NIH's Shark Tank program, which is fast-tracking more COVID–19 diagnostic tests to the market, NIH was able to start a new research program that would probably take a year to design and implement before the pandemic and do it in only a month. In the first 24 hours, they had 400 inquiries. As of this week, they had 542 applications.

Unfortunately, for political reasons or not, Operation Warp Speed immediately had its detractors.

Some warned that the timeline to develop a vaccine by early next year was too fast. Others said that by accelerating the process, regulatory corners will be cut. Still others said that there will be pressure to release a vaccine before the election even if clinical trials are not complete. I understand these concerns and that is exactly why I wanted to have today's hearing.

This is an opportunity for our distinguished panel of witnesses to explain to the American people how the development process works, how they will ensure that a vaccine will be safe, even with an accelerated research and development timeline, and how a vaccine will be distributed across the country as quickly as possible.

The other issue this hearing must tackle is that, just because we have an effective vaccine, doesn't mean Americans will take it. A poll by the Associated Press found 31 percent of Americans weren't sure if they would take a COVID–19 vaccine if one was offered. Another one in five said they'd outright refuse. This is going to be a huge hurdle for us as a Nation to overcome.

Despite extraordinary victories fighting devastating diseases like smallpox and polio through vaccination campaigns—we don't even vaccinate for smallpox in the U.S. anymore because the vaccine was so successful—too many have forgotten or are unaware of the havoc that these diseases played on the world before vaccines became available to combat them.

It is concerning to think that future generations who did not live through the coronavirus pandemic may think of the vaccine as more problematic than the disease.

I hope today's hearing allays some of these concerns by providing clear answers on the steps ahead. Americans need to be reassured that the government will not distribute a vaccine that is not safe.

This hearing should allow us all to have a better understanding of where the vaccine development process stands. How far are we really from an effective vaccine? What are we doing to ensure we're manufacturing enough vaccines to stop the pandemic worldwide? What investments have already been made and what might taxpayers be asked to support in the coming months? And what is the plan to distribute the vaccine once we have one?

These are incredibly important issues that this Subcommittee has invested $9.5 billion toward.

Will it succeed? It is too soon to tell. Will some of the vaccine candidates fail? Of course. In science, there is never a straight line to success. But we know we have to invest in this process for success to occur.

I look forward to our panel's testimonies and appreciate your dialogue with us. Thank you.

Senator BLUNT. Senator Murray is here, and I'm going to recognize her for her opening statement.

Senator Murray, thanks for being with us today, and thanks for working together to have this hearing.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman. I really want to thank you and Chairman Shelby for allowing our committee members to participate in this hearing virtually today, and I want to thank all of our committee staff for setting everything up, and I want to thank all of our witnesses who are joining us today, as well.

Your agencies play a critical role in the development of some of the most important tools against the COVID–19 pandemic: safe and effective diagnostics to identify the cases, NRPs (National Response Plan) to help patients and frontline workers fight this disease, and ultimately a vaccine to move towards ending this crisis.

That is why Congress has appropriated more than $6.5 billion to BARDA (Biomedical Advanced Research and Development Authority) and three billion to NIH for work on medical countermeasures against COVID–19, and we know we need more funding, particularly to distribute a safe, effective vaccine down the line, and we also know we're going to need to hold this Administration accountable to avoid repeating the mistakes and delays.

The Trump Administration put politics ahead of COVID–19 by promoting unproven treatments and steering PPE (personal protective equipment) contracts to unqualified political allies. They failed to plan in a comprehensive way for nationwide challenges, like standing up testing and contact tracing, and they ignored and exacerbated existing health disparities that left black, Latino, and tribal communities to face the worst of this crisis.

If we want to get out of this mess any time soon, the Trump Administration has to do better, particularly when it comes to developing a safe, effective vaccine that is widely available.

What I hear from experts is that while we all want a vaccine fast, a vaccine that is fast but ineffective will fall short of what is needed to turn the tide on this pandemic.

That is why it is more than concerning that the Trump Administration sidelined our leading scientists at CDC (Centers for Disease Control and Prevention), removed the head of BARDA reportedly for putting science and public health over allegiance to President Trump, and took BARDA experts off leadership of contracts related to the search for a COVID–19 vaccine.

I also have concerns about why BARDA has chosen to invest solely in new vaccine technologies that have only been studied experimentally and never made it to market while not pursuing older proven technologies.

Meanwhile, the Administration still has not provided any explanation of how it is selecting vaccine candidates, what the risks are of narrowing down that short list, or addressed concerns about potential conflicts in contracts that predate this crisis, and it still has not provided a comprehensive national vaccine plan.

We saw with testing how the Administration stubbornly refusal to plan led to totally avoidable delays. So Congress clearly needs to act and hold President Trump accountable when it comes to vaccines or risk another inadequate plan that offers too little too late or, worse, no plan at all.

That's why I am working on a proposal to require the Trump Administration to provide a comprehensive plan for how to make sure we get a vaccine that is safe and effective produced at scale and distributed nationwide and free and available to everyone in a way that addresses the health disparities this pandemic has made worse.

This plan must ensure that research and development is rigorous, science-proven, and inclusive, and it must lay out specific standards, timelines, and milestones, a commitment to be fully

transparent about the clinical trial data experts will use to evaluate safety and efficacy, and strategies for combating vaccine hesitancy and misinformation.

When we finally develop a vaccine, we will need to safely manufacture hundreds of millions of doses for the U.S. alone and billions globally as fast as possible and that means just as many specialized glass vials, syringes, stoppers, and a lot more. Making all that happen requires planning to manage the supply chain and navigate challenges, like potential bottlenecks.

We also need a plan for when we begin to distribute vaccines, to guide critical decisions about who gets the vaccine first, like frontline healthcare workers, high-risk groups, and tackles barriers that could otherwise limit access by making sure the vaccine is free for everyone, and addressing health disparities which have only made this crisis so much worse for communities of color.

While we need this plan as soon as possible, we also need to be clear about what scientists and clinicians have cautioned, which is that while there is no guarantee a vaccine will be ready by the end of this year, much less by this fall, there are people suffering with COVID–19 right now who need proven therapeutics to help them beat this disease.

While a vaccine is our best hope for stopping this virus, it is not our only means of fighting it nor is it a panacea on its own. So I'm alarmed that while this Administration has invested heavily in vaccine development, it is treating other priorities as an afterthought by investing far less in the diagnostics that can identify infections early in the course of the illness and prevent further spread and tying the plug on therapeutics that could provide lifesaving relief for hospitalized patients at the greatest risk of dying or suffering long-term health effects.

Congress provided funding for HHS (Department of Health and Human Services) to invest in a spectrum of medical countermeasures to fight this virus, not just vaccines. We need to invest in every type of medical countermeasure and to do it in a way that benefits everyone in our country equitably because we know right now this virus is disproportionately impacting communities of color.

For months now, I have been pressing for comprehensive demographic data on access to testing, positive test results, hospitalizations, intensive care unit admissions, and fatalities, and I'm frustrated that we don't have all the data we need yet, but the picture we do have is alarmingly clear. People in the black community, Latino community, and tribal communities are three to five times more likely to be hospitalized with COVID–19 than white people, and the death rate for people of color is two to three times that for white people.

Those devastating health disparities are a symptom of a larger pattern of systemic racism and underinvestment in communities of color and a warning that we need to work as fast as possible on an additional relief package to address those disparities before they get worse, to protect our workers, our students, our families, and continue to support our communities as they fight this historic crisis.

We can't know exactly how long until a safe, effective vaccine is widely available or how long before we can all safely go back to work, back to school, greet our friends with a handshake or a hug, but we do know that the decisions that we make today, whether we prioritize science or not, whether we plan ahead or not, whether we care for every community or not, will make a huge difference in terms of where we are a year from now. So it's absolutely critical we get this decision right.

Thank you very much, Mr. Chairman. I look forward to the testimony and to our questions today.

Senator BLUNT. Well, thank you, Senator Murray.

We've got a great panel today. Dr. Francis Collins, the Director of the National Institutes of Health, Dr. Robert Redfield, the Director of the Centers for Disease Control and Prevention, Dr. Gary Disbrow, who's the Acting Director of the Biomedical Advanced Research and Development Authority, usually referred to as BARDA.

This is Dr. Disbrow's first time to testify but our other two witnesses have been before this committee many times and it's possible that Dr. Collins may have set the record as a witness before this committee.

But, Dr. Collins, why don't you start? We have your statements. Try to limit your opening comments to 5 minutes each and you can do that however you want to, but we're glad all three of you are here, and, as you can tell, we're eager to ask questions.

STATEMENT OF FRANCIS S. COLLINS, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Dr. COLLINS. Well, thank you, and good morning, Chairman Blunt and Ranking Member Murray, and Distinguished Subcommittee Members.

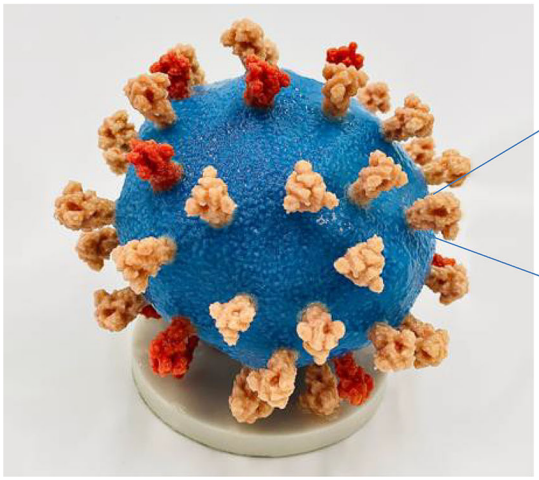
I want to thank you for your sustained commitment to the National Institutes of Health. It has enabled NIH to be at the forefront of research to address the COVID–19 public health emergency.

I'm grateful for this opportunity to update you on that work. You should have at your place or if you're on the video connection maybe an electronic version of a couple of images that I want to point you to in a moment.

Over the last 6 months, COVID–19 has spread around the world with frightening speed. To respond to this crisis, we need to find answers to many urgent questions about how to diagnose, treat, and prevent this disease. At NIH, it is our mission to help find those answers, using the best science and technology in the world.

[The graphic follows:]

SARS-CoV-2: Knowledge Is Power



3D printed model shows SARS-CoV-2 is essentially spherical with randomly spaced spike proteins. The two colors of spikes reflect two different structural configurations.

Colorized version of various regions of the spike protein

Dr. COLLINS. A critical question is to understand what we are up against. When it comes to new infectious diseases, knowledge is power and as you can see on the image on Page 2 of your handout and also in this 3–D printed model that I brought along with me, which happily was not confiscated by the Security people when I entered the building, even though I guess you could say I brought virus to your hearing room, this one will not cause you illness, this model shows you the cause of COVID–19.

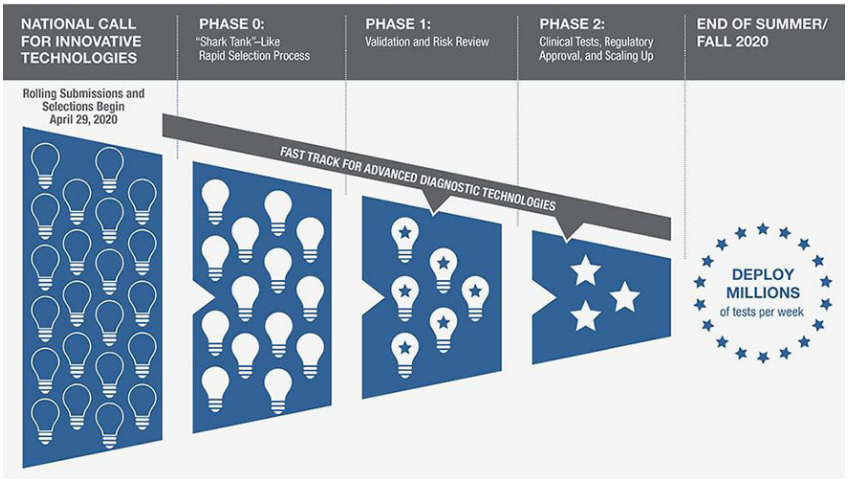
It's this coronavirus called SARS–CoV–2. Note the distinctive array of these spiky proteins on its surface. When the virus invades the human body, these spike proteins literally open the door to infection. They act as keys that fit into specific locks on the surface of cells and once inside the cell, the virus takes over its machinery, begins replicating, producing thousands of viruses like itself and goes on to infect other cells. This can cause severe pneumonia, blood clots, and other life-threatening complications.

Now based on hard work, we now have better means of treating COVID–19 than just a few months ago. Remdesivir and dexamethasone have proven beneficial in rigorous trials and are now standard of care for hospitalized patients, but we have much more to do.

Let me say something about testing. Testing in the U.S. has come a long way. More than 30 million tests for presence of the virus have been administered in the last few months, more than any other nation. Yet these tests, most of which rely on nasalpharyngeal swabs and processing in centralized labs, are not entirely satisfactory for the needs at hand. Scaling to rapid routine point-of-care testing would be a major advantage but that requires new technology.

[The graphic follows:]

Rapid Acceleration of Diagnostics (RADx) initiative



Dr. COLLINS. With that in mind, Congress, on April 25th, provided additional resources for development of new COVID–19 tests. Just 4 days later, NIH launched the Rapid Acceleration of Diagnostics or RAD–X Initiative, and if you turn to the next page, you'll see there an innovation funnel which includes a Shark Tank component.

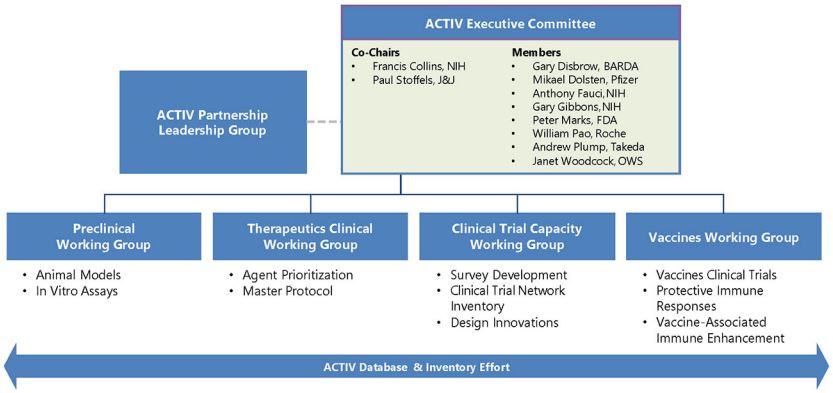
This basically is an opportunity for those who've invested and invented new kinds of technologies to put their ideas forward and have them evaluated by a distinguished team of business, engineering, technology, and scale-up experts. In just 2 months, we have received more than 2,400 expressions of interest and over 560 completed applications, most of these from small businesses.

Many of these proposed tests use convenient samples, like saliva, which would be better than a nasal swab because you could self-collect. These 23 have already made it through the Shark Tank and are undergoing intense validation and what you see here as Phase 1, preparing for possible massive scale-up in Phase 2, and we expect to have at least one of these technologies into Phase 2 within the next week.

By fall, we expect that the winning technologies will make it possible to deploy several million more tests each week. In fact, I would say maybe more than a million more each day.

[The graphic follows:]

ACTIV Public-Private Partnership



Dr. COLLINS. But it's not enough to diagnose the disease. We must treat it as soon as possible to prevent it. To that end, on your next page, you'll see NIH has launched the Accelerating COVID–19 Therapeutic Interventions and Vaccines. That will be an acronym, ACTIV, A–C–T–I–V, Initiative.

This initiative is shown here and the handout provides a high-level overview of the organization of this remarkable and unprecedented public/private partnership involving 18 biopharmaceutical companies, academic experts, and multiple Federal agencies. In 2 short months, ACTIV has developed five master protocols that will accelerate research trials and hasten FDA (Food and Drug Administration) review and possible approval. These will rigorously test the series of antivirals, anticoagulants, immunomodulators, and monoclonal antibody treatments in both inpatient and outpatient settings.

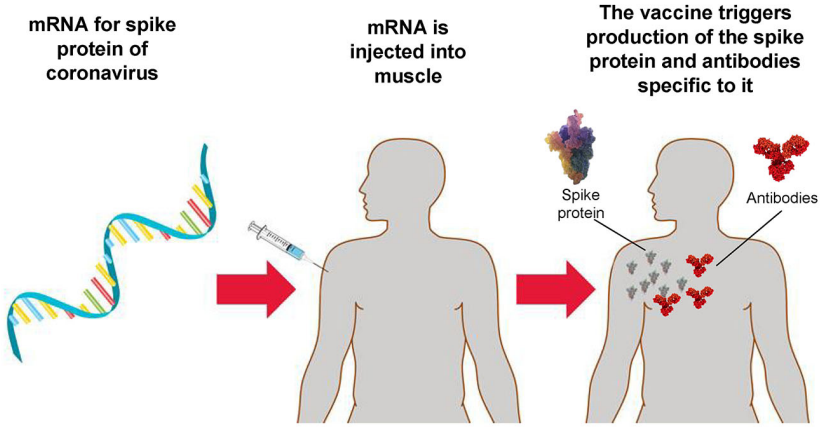
Supported by Operation Warp Speed, we expect four treatment trials to get underway in the next 6 weeks and we're quite excited about their potential for success.

But still the ultimate tool we need to end the COVID–19 pandemic is a vaccine. Operation Warp Speed and the ACTIV Initiative are working together intensively on vaccine development.

[The graphic follows:]

Vaccine Without The Virus: Messenger RNA (mRNA) Approach

NIH Vaccine Research Center and Moderna went from sequence to Phase I in 63 days



Dr. COLLINS. A scientific review of more than 50 candidates has already been conducted. The furthest along in U.S. testing, shown on Page 5, is an experimental vaccine from NIH's Vaccine Research Center in partnership with Moderna. This vaccine features a small non-infectious snippet of messenger RNA. Injecting this mRNA into muscle spurs a person's own body to make the viral spike proteins, which in turn will encourage the production of protective antibodies against SARS–CoV–2.

A Phase 2 clinical trial of this vaccine candidate began on May 29 and this month, we plan to launch a Phase 3 clinical trial that will seek to enroll 30,000 volunteers with results expected in a few months.

So clearly we've already learned much about this devastating virus and we've made significant strides at unprecedented speed in developing diagnostics, therapeutics, and vaccines, yet far more work is needed to end this global health crisis.

With your support, NIH is on the case. So thank you for this opportunity, and I look forward to your questions.

Senator BLUNT. Thank you, Dr. Collins.

Dr. Redfield.

STATEMENT OF ROBERT R. REDFIELD, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. REDFIELD. Good morning, Chairman Blunt, Ranking Member Murray, and Members of the Subcommittee.

I'm pleased to be here today with my HHS colleagues. Together, we are working on the critical issues related to COVID–19 vaccine development, manufacturing, and distribution under the auspices of Operation Warp Speed.

Vaccines are one of public health's greatest scientific achievements. With the support of Congress, investments in CDC's domes-

tic and global immunization programs continue to diminish disease threats and advance the human condition.

Most importantly, vaccines save lives. Preparing for the implementation of a safe, effective COVID–19 vaccine program is a critical next step. Through our existing Influenza Vaccine Program, CDC continues to work with State, Tribal, local territorial health partners to prepare and maintain public health distribution pipeline.

This includes training personnel, building strategic relationships, utilizing data systems, identifying the resources to sustain an efficient and effective immunization infrastructure. Leveraging the existing system, CDC stands ready to support our partners with the distribution once a COVID vaccine is available.

Each year, CDC safely distributes vaccine from manufacturers to nearly 40,000 public and private health providers across the Nation and in a typical year, we provide vaccine for more than 80 million individuals.

During an emergency, this system has the ability to scale and the capacity to manage and distribute up to 900 million vaccine doses. This is possible because CDC has established an extensive integrated network inclusive of public health departments, health providers, and community-based groups that extend far and wide.

Drawing on the lessons from 2009 H1N1 pandemic, we've identified critical considerations for rapid deployment of a new COVID vaccine. Distribution strategies will be based on many factors. One strategy likely will be prioritizing who is vaccinated. The goal is to ensure that vaccine access for all Americans who can benefit from vaccination. To do this, we must consider the logistical aspects of where vaccines are administered and who's administering.

Monitoring systems will be required to document vaccination, manage inventory, and gauge vaccine supply nationwide. CDC currently manages the supply through its Vaccine Order System and collects vaccine coverage data from jurisdictions to help them make informed decisions.

CDC's Immunization Safety Office has a longstanding history of monitoring the safety and efficacy of vaccines and will continue to provide leadership in this area.

Scientifically-based vaccine policies are the foundation of the U.S. immunization system. These policies are formulated by recommendations from the Advisory Committee on Immunization Practice or ACIP and then provided to me as CDC Director.

Another key component is the efficient distribution strategy to ensure that people have clear and accurate and ample information on vaccines so they can make informed decisions about getting vaccinated.

Experience has shown us that vaccines are powerful tools and reaching every individual who could benefit from immunization is an important goal.

A successful vaccine program will require a combination of traditional and new innovative approaches to how to administer and deliver vaccines. Pharmacies and other complementary community locations will be more important during our response to this pandemic.

And, finally, public health considerations have to look at the management of the vaccine itself. Every vaccine has requirements for storage and handling that must be addressed for the vaccine to be effective when delivered.

Ensuring the cold chain, a system that maintains the vaccine's integrity from when it's manufactured to when it's administered. To meet these aggressive goals, it's going to be important to enhance our Nation's cold chain infrastructure.

In the coming months, we will be confronted with a confluence of COVID–19 and seasonal flu. CDC is working to encourage Americans to embrace flu vaccination with confidence. This is an important public health goal and serves two important purposes for COVID–19.

First, increasing flu vaccine coverage can reduce the strain on our health system which we've already seen in some areas from COVID–19. Second, the flu vaccine uptick is another opportunity to test our systems and infrastructure that will need to be leveraged during the COVID–19 vaccine delivery program.

As we confront to fight the pandemic, it's important that all Americans have confidence in all vaccines. Through the CARES Act, CDC was provided a $140 million in funding to support States and local departments for early planning of the flu influenza season and to enhance these immunization programs across our Nation.

COVID–19 is the most significant public health challenge that our Nation has faced in more than a century. In the absence of a vaccine and countermeasures today, we are implementing effective public health measures and encouraging the adherence to what I've referred to as the powerful weapons of social distancing, face coverings, and hand hygiene.

In doing so, I'm confident that we will emerge from this pandemic united together, stronger than ever.

I encourage you to see the possible as both the public and private sectors pursue a vaccine and that we as a Nation confront this pandemic globally.

Thank you and I look forward to your questions.

Senator BLUNT. Thank you, Dr. Redfield.

Dr. Disbrow.

STATEMENT OF GARY DISBROW, PH.D., ACTING DIRECTOR BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, ACTING DEPUTY ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Dr. DISBROW. Chairman Blunt, Ranking Member Murray, and Distinguished Members of this Committee, thank you for the opportunity to testify today.

I want to highlight how BARDA is supporting efforts to develop vaccines, treatments, and diagnostics in response to the COVID–19 pandemic.

BARDA is a unique government organization created to bridge the valley of death between basic research and late-stage development of products, vaccines, therapeutics, and diagnostics, collectively called medical countermeasures, to address 21st Century health security threats.

In its brief 13-year existence, BARDA has formed over 300 industry partnerships and supported products that have received 55 FDA approvals.

BARDA staff are experts in government contracting and in pharmaceutical and diagnostic development, many with over 25 years of experience working in the pharmaceutical industry.

BARDA has a track record of success in delivering effective medical countermeasures in response to public health emergencies. Past examples include H1N1, Ebola, and Zika.

BARDA has unique authorities, allowing my organization to leverage and rapidly expand partnerships to push candidates forward to the review, testing, and approval phase.

BARDA's longstanding expertise in accelerating the advanced research and development of candidate diagnostics, therapeutics, and vaccines is a testament to its dedicated and experienced team.

I want to thank my BARDA colleagues as they work long hours and weekends to support this response.

In the typical fiscal year, BARDA's highly-experienced contracting professionals invest approximately $1.6 billion to support the development of MCMs (medical countermeasures) to address chemical, biological, radiological, and nuclear threats, and pandemic influenza.

This year, in addition, in just 3 months, we have obligated over 3.5 billion as part of the COVID–19 response. BARDA has leveraged funds provided under the CARES Act and additional funds from HHS to invest in multiple vaccine candidates, multiple therapeutic programs, and multiple diagnostics. Twelve diagnostics have been granted emergency use authorization by the FDA. The BARDA COVID–19 portfolio now supports over 40 projects.

When HHS Secretary Azar declared a public health emergency in January, BARDA immediately responded. ASPR/BARDA established an interagency call with industry highlighting our high-level strategy for the development of vaccines, therapeutics, and diagnostics to address COVID–19, attracting over 1,500 participants.

That same day, BARDA opened a medical countermeasure portal to accept market research submissions from stakeholders, receiving over 3,300 submissions to date.

Prior to receiving supplemental funds, BARDA modified our two solicitations to allow for submissions of COVID–19-specific products. To date, we have received over 267 submissions under our broad agency announcement or BAA and 426 to our Easy BAA, a streamlined solicitation with a cap of 750,000 in funding.

This is what we do. We engage innovative stakeholders, establish partnerships, develop medical countermeasures and bring them forward to the American people to save lives.

Early in the COVID–19 outbreak, BARDA developed our strategy for medical countermeasure development. For vaccines, our strategy was to engage with vaccine manufacturers, developing different platform technologies, some already licensed by the FDA or nearing licensure, and who had established manufacturing processes to quickly manufacture large quantities of vaccine.

Our therapeutics strategy was similar, invest in multiple technologies to increase our chances of success. For diagnostics, our

strategy was to invest in multiple technologies, molecular, antigen, and antibody-based tests.

Prior to the first COVID supplemental, BARDA made initial investments in the development of vaccines, therapeutics, and diagnostics, using our existing funding and authorities. This early strategy has partially served as the basis for Operation Warp Speed's strategy or OWS.

OWS is an unprecedented collaboration between the Department of Health and Human Services and the Department of Defense to expedite development of vaccines, therapeutics, and diagnostics and bringing them to the American people.

OWS aims to deliver up to 300 million doses of safe and effective vaccines for COVID–19 in early 2021 as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics for the American people.

BARDA is a key component of OWS, along with various NIH institutes, the CDC, and DOD. The primary goal of OWS is to develop safe and effective medical countermeasures.

As a USG effort, we will need to take financial risks to expedite the development of vaccines and therapeutics. The key to success is to invest in multiple candidates and support parallel development activities to meet the expedited timelines.

The risk is purely financial, a financial risk of manufacturing large amounts of medical countermeasures while we're still determining the safety and efficacy. We will not risk the safety of these products. This financial risk is necessary to ensure MCMs are available for use as soon as the FDA has deemed them safe and effective.

Some of our investments will be in products that do not make it. This is the financial risk that we must take because the risk in lives lost and the impact to our economy is far greater.

This committee and Congress at large have been very supportive of BARDA and our mission and we are very thankful. Today, more than ever, we need your continued support and flexibility to ensure our staff can stay focused on the task at hand.

I look forward to discussing how we can work together on this important issue.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF FRANCIS COLLINS, M.D., P.H.D., ROBERT R. REDFIELD, M.D., AND GARY DISBROW, PH.D.

Chairman Blunt, Ranking Member Murray and distinguished members of this committee.

It is an honor to appear before you today to discuss the Department of Health and Human Services' Operation Warp Speed efforts and the Department's efforts on vaccines, diagnostics, and therapeutics. We are grateful for this opportunity to address how each of our agencies and offices are harnessing innovation to prevent, diagnose, and treat the novel coronavirus SARS–CoV–2.

COVID–19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans. This new disease, officially named Coronavirus Disease 2019 (COVID–19) by the World Health Organization (WHO), is caused by the SARS–CoV–2 virus. There are many types of human coronaviruses including some that commonly cause mild upper- respiratory tract illnesses. Coronaviruses are a large family of viruses. Some cause illness in people, and others, such as canine and feline coronaviruses, only infect animals. Rarely, coronaviruses that infect

animals have emerged to infect people and can spread between people. This is suspected to have occurred for the virus that causes COVID–19. Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) are two other examples of coronaviruses that originated in animals and then spread to people.

The Department of Health and Human Services (HHS) is working closely with all of our government partners in this response. We thank Congress for supporting our efforts through the passage of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020; the Families First Coronavirus Response Act; the Coronavirus Aid, Relief, and Economic Security (CARES) Act; and the Paycheck Protection Program and Health Care Enhancement Act. These laws have provided additional resources, authorities, and flexibility. We thank Congress for your continual partnership that has allowed us to expedite this critical effort to respond to COVID–19.

To accelerate the development and subsequent production of a vaccine for COVID–19, in mid-May, President Trump announced Operation Warp Speed (OWS). OWS aims to deliver up to 300 million doses of a safe and effective vaccine for COVID–19 in early 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures). OWS is a partnership among components of HHS, including CDC, FDA, NIH, and BARDA, and the Department of Defense (DoD), with the aim of a unified government approach to respond to the pandemic. OWS engages with private firms and other Federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. OWS coordinates with existing HHS-wide efforts, including the NIH's Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA and the National Institute of Allergy and Infectious Diseases (NIAID).

To accelerate development while maintaining standards for safety and efficacy, OWS has been selecting the most promising countermeasure candidates and providing coordinated government support. Protocols for the demonstration of safety and efficacy are being aligned, which will allow the trials to proceed more quickly, and the protocols for the trials will be overseen by the Federal Government, as opposed to traditional public-private partnerships, in which pharmaceutical companies decide on their own protocols. Rather than eliminating steps from traditional development timelines, steps will proceed simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety, as happens normally. This increases the financial risk, but not the product risk.

We will be working constantly with the FDA, sending a constant stream of data to their scientists. Once the data are complete, FDA will perform the analysis they need to determine safety and efficacy as quickly as possible. The FDA will pursue its regulatory work in the standard manner, and by keeping the lines of communication open, they can produce ongoing guidance to support the clinical trials for the OWS candidates, as they often do for agency priorities.

To put it really simply, drug development is a series of boxes you have to check—very complicated boxes, but boxes nonetheless. You proceed through the different development phases, you need certification of your manufacturing processes, then you begin large scale manufacturing, and then you begin distribution. OWS requires checking each and every one of those boxes just like we would for any other project, but we aren't going one by one down the list. We're aiming to check as many of them simultaneously as we can.

The following testimony will detail how the NIH, BARDA and CDC are contributing to OWS and overall vaccine, therapeutic, and diagnostic efforts.

NATIONAL INSTITUTES OF HEALTH

NIH is the HHS agency leading the research response to COVID–19 and the novel coronavirus that causes the disease, SARS–CoV–2. Research to address the COVID–19 public health emergency is an NIH-wide effort.

NIH, in collaboration with the Foundation for the NIH, recently launched an innovative public-private partnership to speed the development of COVID–19 therapeutics and vaccines.

The ACTIV public-private partnership brings together stakeholders from across the U.S. government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID–19 pandemic. Other Federal partners include BARDA, DoD, the Department of Veterans Affairs, CDC, and FDA. The ACTIV working groups are making rapid progress. For

example, the Therapeutics Clinical Working Group developed and openly shared master protocols with agreed upon endpoints, sampling, and analysis for evaluating monoclonal antibody and vaccine candidates, in order to enhance trial efficiency.

Developing Vaccines to Prevent SARS–CoV–2 Infection

A safe and effective vaccine for SARS–CoV–2 will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks.

HHS NIAID is supporting development of several SARS–CoV–2 vaccine candidates, including vaccines based on platform technologies that have shown promise against the coronaviruses that cause SARS and MERS. As part of a longstanding collaboration, the NIAID Vaccine Research Center worked with the biotechnology company Moderna, Inc., to develop a vaccine candidate using a messenger RNA (mRNA) vaccine platform expressing the SARS–CoV–2 spike protein. On March 16, 2020, NIAID initiated a Phase 1 clinical trial of this experimental vaccine at the Kaiser Permanente Washington Health Research Institute, and later added clinical sites at Emory University and the NIH Clinical Center. This trial was recently expanded to enroll older adults to better define the safety of and immune response to the vaccine across various age groups. On May 18, 2020, Moderna announced encouraging interim findings from the Phase 1 clinical trial and, on May 29, 2020, a Phase 2 clinical trial was initiated to further study safety and the immune response to the experimental mRNA vaccine. NIAID and BARDA are working with Moderna to launch a Phase 3 clinical trial as early as this month, pending positive results from this Phase 2 trial. The Coalition for Epidemic Preparedness Innovations funded the manufacture of the vaccine candidate for the Phase 1 trial, and BARDA is supporting advanced development of the candidate.

Scientists at NIAID's Rocky Mountain Laboratories in Hamilton, Montana have collaborated with University of Oxford researchers to develop a SARS–CoV–2 chimpanzee adenovirus-vectored vaccine candidate AZD1222, formerly known as ChAdOx1, now in a Phase 3 clinical trial in the United Kingdom, supported by the University of Oxford. BARDA recently announced plans to support advanced development and production of AZD1222 in the U.S. NIAID is working with additional academic and industry partners to develop several other vaccine concepts.

The rigorous clinical testing required to establish vaccine safety and efficacy means that it might take some time for a licensed SARS–CoV–2 vaccine to be available to the general public, but there is growing optimism that one or more of these vaccine candidates may prove safe and effective by late 2020 or early 2021.

Identifying Therapeutics to Treat COVID–19

Effective therapeutics for COVID–19 are critically needed to treat patients who have been infected with SARS–CoV–2. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial, the Adaptive COVID–19 Treatment Trial (ACTT), to evaluate the safety and efficacy of therapeutics for COVID–19, initially examining the antiviral drug remdesivir for treatment of severe COVID–19 in hospitalized adults (ACTT–1). An analysis of preliminary data from ACTT–1 indicated that those who received remdesivir had a 32 percent faster time to recovery, a median of 11 days compared with 15 days for those who received placebo. Additionally, the analysis found that remdesivir may benefit survival, although the mortality data did not reach statistical significance. A mortality rate of 7.1 percent was observed for the group receiving remdesivir versus 11.9 percent for placebo. These initial findings were published on May 22, 2020, in the New England Journal of Medicine. Working as part of the ACTIV partnership, NIAID is developing and testing other novel and repurposed therapies. The adaptive design of this trial will enable the evaluation over time of additional promising therapies, such as the anti-inflammatory drug baricitinib, which has been added to the next iteration of the study (ACTT–2), currently underway.

Another promising therapeutic is the use of monoclonal antibodies or mAbs. There are 21 companies developing mAbs and a number of them have started early clinical trials. As part of the ACTIV partnership, and in collaboration with other NIH Institutes, NIAID plans to launch a study to evaluate mAbs in outpatients with mild-to-moderate COVID–19 early this month. A separate trial will evaluate mAbs in inpatients. NIAID also is planning separate clinical trials to assess hyperimmune intravenous immunoglobulin and mAbs for treatment of COVID–19 in hospitalized adults.

The National Heart, Lung, and Blood Institute (NHLBI) sponsored the addition of a U.S. site for a Canadian Institutes for Health Research-funded trial of colchicine—an anti- inflammatory drug commonly used to treat gout—for treating COVID–19 in the outpatient setting. Additionally, NHLBI is leveraging the NIH-

funded Strategies to Innovate Emergency Care Clinical Trials Network to study whether convalescent plasma, or blood plasma from individuals who have recovered from COVID–19, can help reduce the progression of COVID–19 in patients with mild symptoms. In the near future, NHLBI will begin a clinical trial on the use of anticoagulants, hoping to stem the life-threatening blood clots that COVID–19 causes in many patients.

The National Center for Advancing Translational Sciences (NCATS) is leveraging the NCATS Pharmaceutical Collection, a compilation of every drug approved for human use by major regulatory agencies worldwide, and other collections of small molecules and compounds to identify potential SARS–CoV–2 therapeutics for further investigation. Other Institutes and Centers across NIH also are working concurrently with partners in academia and industry to pursue the development and testing of mAbs, antiviral, and anti-thrombotic drugs for potential treatment of COVID–19. NIAID, NCI, NHLBI, NCATS, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the National Institute of Neurological Disorders and Stroke (NINDS) are all engaged in this critical effort.

NIH also has convened the COVID–19 Treatment Guidelines Panel, comprised of representatives of NIH and five other Federal agencies along with representatives of eight professional organizations, academic experts, and treating physicians including providers from high COVID–19 incidence areas. On April 21, 2020, the panel issued the first release of COVID- 19 treatment guidelines for clinicians. The guidelines provide recommendations regarding specific treatments currently available and address considerations for special populations, including pregnant women and children. On May 12, 2020, in response to the preliminary analysis of ACTT–1, the Panel updated these treatment guidelines to recommend remdesivir for the treatment of COVID–19 in hospitalized patients with severe disease requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation. The guidelines are updated regularly as new evidence-based information emerges, including the recent report of benefit of the drug dexamethasone in hospitalized patients, based on results of a randomized trial in the United Kingdom.

Enhancing Diagnosis and Understanding the Pathogenesis of COVID–19

NIH is supporting an HHS-wide effort to promote the development and commercialization of diagnostic tests to detect current SARS–CoV–2 infection. On April 29, 2020, NIH announced the Rapid Acceleration of Diagnostics (RADx) initiative, which is working to identify, support, and make innovative strategies for COVID–19 testing widely accessible, in collaboration with FDA, CDC, and BARDA. The RADx initiative has four focused programs to scale-up testing and enhance access to those most in need. The RADx Tech initiative is leveraging the Point-of-Care Technologies Research Network established by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to allow for the potential roll out of new products by fall 2020. NIH has received over 2,000 expressions of interest and over 500 complete applications for RADx Tech. Innovators will be matched with technical, clinical, regulatory, business, and manufacturing experts to increase the odds of success. So far, nine companies have products in Phase 1 testing and are close to commercialization. In addition, NIAID is using CARES Act funds to support diverse SARS–CoV–2 diagnostic platforms including RT–PCR and enzyme-linked immunosorbent assays, and facilitating development of sensitive, specific, and rapid diagnostic tests by providing critical SARS–CoV–2 isolates and reagents to the developers of tests.

The RADx Underserved Populations (RADx-UP) initiative will augment the reach and power of technologies developed and enhanced through RADx by identifying and addressing implementation factors that present barriers to testing and follow-up in populations that need it the most. On June 12, 2020, NIH announced four new funding opportunities for community- engaged projects within RADx-UP. The goal of this is to understand factors that have led to disproportionate burden of the pandemic on vulnerable populations so that interventions can be implemented to decrease these disparities.

The National Cancer Institute is coordinating with FDA and NIAID to assess the sensitivity and specificity of certain SARS–CoV–2 serological tests, which can detect antibodies indicative of a prior exposure to SARS–CoV–2. NCI and NIAID also are working to establish a collaborative national network to increase national capacity for high-quality serological testing with return-of-results to subjects. In addition, they will conduct research to increase the understanding and application of those results and support related clinical efforts, including clinical trials of convalescent serum and the creation of registries of tested subjects for sero-protection studies.

NIAID, NCI, NCATS, and NIBIB also are partnering on a new study to investigate whether adults in the United States without a confirmed history of infection

with SARS–CoV–2 have antibodies to the virus, indicating prior infection. In addition, NIH is supporting COVID–19 natural history studies to understand the incidence of infection in specific populations, including children and their household contacts, and aspects of the clinical course of infection, including incidents of thrombosis, strokes, heart attacks, and other sequelae of infection. Some of these studies will examine the quality and durability of the immune response to SARS–CoV–2 and evaluate whether unique immune responses may be associated with clinical disease trajectories; this information may be leveraged to develop SARS–CoV–2 therapeutics or vaccines. Natural history studies also will inform our understanding of COVID–19 pathogenesis, including factors that may predict disease progression and help to identify individuals or groups at high risk.

In order to improve understanding of neurological consequences of SARS–CoV–2 and inform potential treatment strategies, NINDS is supporting development of a database that would collect data on the prevalence and spectrum of neurological symptoms observed in patients with SARS–CoV–2 infection. NHLBI and the Eunice Kennedy Shriver National Institute of Child Health and Human Development are leading a trans-NIH effort, with participation from NIAID, to coordinate research into the multisystem inflammatory syndrome in children (MIS–C), an extremely serious inflammatory condition that has been associated with SARS–CoV–2 infection in children and adolescents.

NIH continues to expand efforts to elucidate the viral biology and pathogenesis of SARS–CoV–2 and employ this knowledge to develop the tools needed to diagnose, treat, and prevent disease caused by this virus. NIH is focused on developing and evaluating safe and effective COVID–19 vaccines and therapeutics, and sensitive, specific, and rapid point-of-care molecular diagnostic and serological tests. These efforts will improve our response to the current pandemic and bolster our preparedness for the next, inevitable emerging disease outbreak.

CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC has worked for decades with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure, which will help ensure effective distribution can occur once a safe and effective COVID–19 vaccine is available.

CDC is working closely with our government partners in response to this pandemic, including with our sister agencies at HHS. Each year through the Vaccines for Children program and the section 317 immunization program and in partnership with State immunization programs, CDC safely distributes over 80 million doses of vaccines from every vaccine manufacturer to approximately 40,000 public and private health providers across the country. We have strong networks connecting public health departments, healthcare providers, community groups, and others that can be used to efficiently reach the population. From these sites, vaccine may be transported in small quantities to clinical sites for immediate use, while maintaining cold chain. During an emergency, this proven system has the capacity leveraged to manage and distribute many more doses of vaccine than in a typical year.

For decades, CDC's public-private partnerships have safely distributed tens of millions of doses of routinely recommended vaccines to thousands of provider sites each year. CDC's experience shows the importance of strategic engagement across public and private components of the vaccine enterprise in a collaborative effort to ensure appropriate planning and coordination from development and manufacturing, to distribution, administration, and tracking. Early engagement and planning can help ensure quick and efficient bi-directional exchange of information, so that everything needed to administer the vaccine, including personal protective equipment, is available where and when it is needed. And finally, the public must be well- informed, and misinformation must be addressed with timely, accurate, and trusted information.

CDC tracks and manages public vaccine inventory through its vaccine ordering system, allowing visibility into vaccine supply nationwide. CDC monitors vaccination coverage across the country providing national, regional, and local level data that can inform decisionmaking and outreach priorities. Vaccine coverage is monitored by jurisdictions through their Immunization Information Systems and CDC's National Immunization Surveys. Suspected adverse events are captured through the Vaccine Adverse Event Reporting System and evaluated through the Vaccine Safety Datalink. Together these systems help streamline the inventory management of Federal vaccine assets; monitor national, regional, State, local vaccination coverage to guide targeted outreach and program priorities; inform vaccine program modifications based on vaccine safety findings; implement outreach and program activities;

tailor communications and provider education; and coordinate data sharing across jurisdictions.

Building on lessons learned from the 2009 H1N1 pandemic and CDC's experience with routine domestic and global vaccine delivery, there are many critical components to consider in rapid implementation of a new vaccine during and in response to a pandemic. Many of these factors will be determined by the vaccine or vaccines that are licensed for use, and when and how much vaccine is available. Priority populations for receiving the initial supply of vaccine will need to be identified. This could be based on high-risk for exposure, high-risk for disease or other factors. In addition, critical plans will need to be developed for how the vaccine is allocated, distributed, and administered across the United States. These decisions have implications for both the public and private sectors, including who pays for the vaccine and administration fees, where and by whom vaccine is administered, and how to ensure equity and avoid disparities in access. Monitoring supply, tracking who received vaccine, especially if more than one dose is needed, and assessing vaccination coverage are important. Critical to success of the Nation's immunization program is ensuring vaccine safety, effectiveness, and ultimately confidence in the Nation's immunization programs and policies.

COVID–19 is not the only health threat in our midst. The 2020–2021 influenza (flu) season is fast approaching, posing a risk of serious complications, hospitalization, or death, even among otherwise healthy children and adults. Pediatric outpatient visits and routine childhood vaccination have also declined substantially in recent months, leaving children and communities at risk for preventable disease outbreaks. Utilization of core preventive services has been disrupted by COVID–19. In order to ensure adequate hospital and medical care capacity, we must work aggressively to increase influenza and other routine childhood immunizations. Further, as we continue to fight the pandemic, it is important that Americans have confidence in all vaccines. CDC will leverage its immunization program to help maintain high coverage in routine childhood immunizations, to increase coverage for flu vaccinations, and prepare for a potential COVID–19 vaccine.

CDC's Immunization Program

Vaccines are one of public health's greatest achievements. Investments in CDC's immunization program have improved the health of Americans. The immunization of children in the United States has saved millions of lives, contributed to longer life expectancy, reduced health disparities, improved quality of life, and saved trillions of dollars in societal costs.

Immunizations have become a routine part of how we care for our children. Coverage for many childhood vaccinations are at, near, or above 90 percent, and reported cases for most vaccine preventable diseases have decreased by 90 percent or more in the United States with the introduction of vaccines. Adults need vaccines too. Every year thousands of adults in the U.S. become seriously ill and are hospitalized because of diseases that vaccines can help prevent.

CDC's immunization program plays a fundamental role in achieving national immunization goals and sustaining high vaccination coverage rates to prevent death and disability. The signature pieces of this program include the Vaccines for Children (VFC) entitlement program and CDC's discretionary Section 317 Immunization Program.

VFC is one of the largest and most successful public-private partnerships, designed to ensure that eligible children do not contract vaccine-preventable diseases because of inability to pay. Approximately 50 percent of children from birth to 18 are eligible to receive free vaccine through VFC as part of routine care, supporting the reintegration of vaccination and primary care. CDC works with its 61 awardees to distribute vaccines directly to more than 40,000 public and private providers enrolled in the VFC program. VFC has been instrumental to achieving high childhood and adolescent vaccination coverage rates and reducing disparities.

The Section 317 Immunization Program is a national resource that will continue to fill critical public health needs, such as providing a safety net for adults with no health insurance and responding to outbreaks of vaccine preventable diseases (VPDs) and other urgent public health issues. The program supports the Nation's ability to maintain public health preparedness for a response to a vaccine-preventable emergency, such as a pandemic or biological attack. To implement the program, CDC works collaboratively with 64 awardees comprised of the 50 States, six large cities including the District of Columbia, five territories, and three Pacific Freely Associated States.

CDC's support of national, State and local programs has dramatically improved access to vaccination for all children and put systems in place to detect and respond to outbreaks of VPDs and to monitor vaccine effectiveness and safety. However, we

know from our surveys and data systems that COVID–19 interrupted access to routine medical services. CDC observed notable declines in pediatric outpatient visits and routine childhood vaccination since March, leaving some children and communities at risk for preventable disease and outbreaks. Corresponding declines were also observed in the number of measles-containing vaccine doses administered in eight U.S. healthcare organizations serving publicly and privately insured patients. On a positive note, however, we have started to see recovery in vaccine ordering data.

CDC is working with partners to catch up and restore the high levels of immunization. Fortunately, these efforts will provide opportunities to develop innovative systems and partnerships that will pave the way for COVID–19 vaccine distribution. For example, CDC is supporting providers in the safe administration of vaccines during the COVID–19 pandemic through development of guidance and support materials and helping to support catch-up vaccination for children who missed visits through the use of reminder/recall systems. CDC is increasing communication efforts to remind parents, providers and partners of the importance of routine vaccinations during the COVID–19 pandemic and expanding outreach to provide information about the VFC program to families, especially those who may have recently lost insurance coverage. CDC is also working with partners to encourage back-to-school vaccination activities during the summer and influenza vaccination in the fall. Continued coordinated efforts between healthcare providers and public health officials at the local, State, and Federal levels will be needed to restore and maintain routine pediatric vaccination services during the pandemic.

Another activity that is key to effective distribution and uptake of COVID–19 vaccine is ensuring people have accurate information to make decisions about getting the vaccine.

Preparing for COVID–19 Vaccines

CDC is working closely with the interagency staff to determine a path forward on critical issues related to a COVID–19 vaccine program through OWS. CDC stands ready to use its expertise in public health preparedness and response along with its immunization infrastructure to support OWS in vaccine promotion, distribution, administration, and monitoring. Congress's recent investments through the Coronavirus Aid, Relief, and Economic Security Act have allowed CDC to provide its immunization awardees $140 million in supplemental funding to support and enhance their immunization programs. This supplemental funding will be used to support awardee and local health department staffing, communications campaigns, pandemic preparedness, and mass vaccination. In addition to other COVID–19 vaccine response work, awardee activities will include a specific focus on enhancing influenza coverage, especially in historically underserved populations, and enrolling and working with additional vaccinators (e.g., pharmacists, mass vaccinators).

Scientifically-based vaccine policies are a foundation of the U.S. immunization system. In the U.S., the Advisory Committee on Immunization Practices (ACIP) advises the CDC Director on national vaccine policy for preventing infectious diseases in the civilian population. The immunization systems and expertise supported by CDC's immunization program make substantial contributions to the evidence base that informs immunization recommendations made by ACIP. The ACIP makes recommendations based upon data about the burden of disease, safety and efficacy of vaccines, economic analyses, including cost-effectiveness data, and information about other factors such as how recommendations can be implemented by the healthcare system in conjunction with other recommended vaccines.

To prepare for potentially FDA-licensed COVID–19 vaccines, ACIP has established a workgroup that is evaluating safety and immunogenicity data of vaccine candidates, as well as the epidemiology of COVID–19 to target populations and priorities for vaccination. ACIP workgroups are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. While the ACIP workgroup does not have the authority to act on behalf of the advisory committee and they cannot vote on ACIP vaccine recommendations, workgroups review specific topics in detail and clarify issues in a way that helps ACIP voting members make informed and efficient decisions, with the best and most current information available. ACIP meets routinely approximately three times per year (February, June, October), but may meet more frequently as needed. An additional meeting to discuss COVID–19 vaccines is already being planned for August 2020. In addition, under exceptional circumstances, an emergency ACIP meeting may be called without prior notice. If COVID–19 vaccines became available, it is expected that an emergency meeting will be called for the vaccine to receive consideration.

Experience shows that, while vaccines are powerful tools, reaching every individual who would benefit from an immunization is not easy. For example, persistent racial and ethnic disparities exist among adult influenza vaccination rates with 9 percent and 12 percent lower coverage among black, non-Hispanics and Hispanics, respectively, as compared to the vaccination rate of whites.[1] To ensure that every American has access to the COVID–19 vaccine will require enhanced partnerships across sectors. This can build on and expand on existing partnerships that are in place for routine immunizations, and can also leverage other public health programs as well as the private sector. It is also important to recognize that the COVID–19 pandemic has affected the ways people engage with the healthcare system, and that a successful vaccine program will need to incorporate various sites and approaches for vaccine administration. For example, worksites that have served as locations for adult immunization may be less accessible due to increased telework, so other complementary sites such as pharmacies and innovative locations that work for a given community may be more important during our response to this pandemic. Regardless of traditional or complementary vaccine provider site, it will be critical to ensure that all sites are linked to data monitoring systems.

A final public health consideration relates to the management of the vaccine itself—every vaccine has requirements regarding storage and handling that must be addressed in order for the vaccine to be effective when administered. Most vaccines require refrigeration, while others require being held at specific temperatures beyond the capacity of regular refrigerators. Ensuring that the cold chain is maintained from the point of manufacture until the time of use is a significant concern in any vaccination program. Improper storage can lead to vaccine being wasted, or more importantly, reduce its effectiveness. Careful consideration of all of these factors will be critical to ensuring that the investments that have been made in the development of a vaccine for COVID–19 achieve their intended purpose—protecting Americans from the threat of this novel coronavirus.

Preparing for the 2020–2021 Influenza Season

Unfortunately, COVID–19 is not the only public health threat we are facing. CDC is also working to increase vaccination coverage for the 2020–2021 flu season. This is an important public health goal in its own right, but also serves two important purposes related to COVID–19. First, increasing vaccine coverage this fall can reduce the strain on the healthcare system, which will be facing COVID–19 at the same time as seasonal influenza. Second, it is another opportunity to test the systems and infrastructure that will be leveraged to deliver a COVID–19 vaccine.

During the 2018–2019 flu season, only 49 percent of the U.S. population received the flu vaccine. Still, flu vaccination helped to prevent 4.4. million flu illnesses, 58,000 flu-related hospitalizations, and 3,500 deaths. Any flu infection can carry a risk of serious complications, hospitalization or death, even among otherwise healthy children and adults. Increased flu vaccination coverage will protect more Americans from this seasonal health threat, while decreasing stress on the healthcare system.

CDC is committed to the goal of increasing flu vaccine uptake, especially in people at higher risk of serious flu and COVID–19 outcomes. We will continue to work with our public health and clinical partners to eliminate barriers to vaccination. The ongoing COVID–19 pandemic may affect where and how vaccines are given, and we are working with health departments to develop contingency plans. CDC is also looking at operational considerations such as access to vaccine with potential need for social distancing, and prolonging vaccine uptake throughout the flu season. CDC is making additional influenza vaccine available to State health departments for uninsured adults at higher risk for morbidity and mortality. To support this effort, we are enhancing communications to target audiences, including older Americans, persons with disabilities, people of any age with underlying health conditions, workers in long- term care facilities, other essential workers, African Americans, and Hispanics. Understanding that African American and Hispanic communities have lower rates of flu vaccination and a higher risk for COVID complications, we will enhance our education and communication efforts toward these key communities. We will be assessing the impacts the pandemic may have on vaccination, evaluating the quality of communications with patients regarding vaccinations, and focusing on influenza vaccination and African American and Hispanic patients.

We are taking many considerations into account in our efforts to expand flu vaccine coverage and focusing on specific efforts to address racial and ethnic disparities. Specifically, CDC will be working with the National Association for Community

[1] CDC. Flu Vaccination Coverage, United States, 2018–19 Influenza Season. Available from: https://www.cdc.gov/flu/fluvaxview/coverage-1819estimates.htm.

Health Centers to implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations. We will be engaging in expert consultation to develop strategies for addressing racial and ethnic disparities in adult immunization, soliciting simultaneous individual expert opinion from 15 national leaders in health disparities, health equity, and social determinants of health.

On June 4, CDC awarded $140 million from the CARES Act to 64 jurisdictions through CDC's existing immunization cooperative agreement to enable State health departments to launch an initial scale up for influenza season, given the increased risk of COVID–19. Funds will begin to support staffing and preparedness early this summer and focus on ensuring flu coverage for vulnerable populations.

There are many critical components to consider in implementation of a pandemic vaccine. Many of these factors will be determined by the availability and characteristics of licensed vaccines and the priority populations identified for receiving the vaccines. Critical to success of the vaccine program is ensuring vaccine safety, effectiveness, and ultimately vaccine confidence. COVID–19 is the most significant public health challenge to face our Nation in more than a century. CDC is building upon our existing programs to provide the American public with the information and assistance it needs to address COVID–19 head on, while simultaneously working with our State and local public health partners to maintain routine childhood immunization coverage and prepare for the upcoming flu season. As we continue to work together to fight COVID–19 and end this pandemic, CDC is committed to its mission to protect all Americans from disease.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

ASPR's Role in Response

The Assistant Secretary for Preparedness and Response's (ASPR) mission is to save lives and protect Americans from 21st century health security threats. During previous public health emergencies, ASPR has led, on behalf of HHS, Emergency Support Function #8: Public Health and Medical Services, under the National Response Framework. This means ASPR serves as the primary coordinator for public health information and deployment of assets to support the health components of a response.

For the current COVID–19 pandemic response, ASPR. funding has been used to not only to accelerate development of medical countermeasures under BARDA but also to deploy trained medical teams to augment care in communities overwhelmed with COVID–19 cases, enter into contracts to resupply personal protective equipment and other critical components deployed from the Strategic National Stockpile (SNS) to aid in the treatment of persons with or suspected of having COVID–19 and provide grants to hospital associations and healthcare centers to aid in the ongoing response. We appreciate this Committee's support of our efforts and are utilizing the provided funds to ensure communities have the tools and resources to detect and treat those diagnosed with or suspected of having COVID–19.

Vaccine Development Efforts

Since late January, BARDA has collaborated with counterparts across the government to identify potential COVID–19 medical countermeasure candidates and accelerate their development. BARDA has a track record of success in delivering effective countermeasures in response to public health emergencies. Past successes include the 2009 H1N1 influenza pandemic, Ebola outbreaks in 2014–2016 in West Africa and in 2018 the Democratic Republic of the Congo, as well as the Zika outbreak in 2015. For these past response operations as well as the current response to COVID–19, Congress has provided emergency supplemental funding to support the urgent need for medical countermeasure development.

At the onset of the pandemic, BARDA reviewed investments, modified contracts, and began working with Regeneron, Janssen, and Sanofi Pasteur to initiate the development of vaccines and therapeutics for COVID–19. All three have successfully developed both prophylactic and therapeutic medical countermeasures for emerging infectious diseases in the recent past. BARDA's early leveraging of these existing partnerships and established platforms may help shave months off the development timelines for medical countermeasures and has been made possible by flexible authorities authorized and provided by Congress as well as prior investment into these platforms.

The BARDA portfolio now includes over 40 medical countermeasure projects including nine therapeutics, 26 diagnostics (12 of which have been granted Emergency Use Authorization by the FDA) and five vaccine candidates. Three of these five candidates are operating under OWS. On March 30, 2020, HHS announced $456 million

in funds for Janssen's (part of Johnson & Johnson) candidate vaccine, with Phase 1 clinical trials set to begin this summer. On April 16, 2020, HHS awarded $483 million to support Moderna's candidate vaccine, which began Phase 1 trials on March 16 and received a fast-track designation from the FDA. Lastly, on May 21, 2020, HHS announced up to $1.2 billion in support for AstraZeneca's candidate vaccine, developed in conjunction with the University of Oxford.

It is important to note that we are strictly adhering to and following all required regulatory and safety requirements required for vaccine development. We are not sacrificing the safety of the vaccine in order to expedite its development. We are instead supporting two steps at the same time. In addition to vaccine development, we are supporting manufacturing efforts to ensure we are positioned to produce and manufacture the vaccine quickly and effectively.

Specifically, we are making investments in the necessary manufacturing capacity at Federal risk, giving companies confidence that they can invest aggressively in development and allowing faster manufacturing and potential distribution of an eventual vaccine. Manufacturing capacity for selected candidates being advanced while vaccine candidates are still in development, rather than scaled up after approval or authorization. The May 21, April 16, and March 30, 2020, HHS agreements with AstraZeneca, Moderna, and Janssen/Johnson & Johnson respectively include product development and investments in large-scale manufacturing capabilities. Additionally, the June 1, 2020, HHS task order with Emergent BioSolutions to advance domestic manufacturing capabilities and capacity for a potential COVID–19 vaccine, as well as therapeutics, worth approximately $628 million. Under the terms of the contracts for manufacturing capacity, reservations can be shifted as needed from one candidate vaccine to another more promising candidate based on the findings from clinical trials that are being conducted in parallel with manufacturing scale-up. OWS has also been working to address fill/finish capacity, to acquire needles and syringes, and to expand domestic capacity for manufacturing of needles, syringes, and vials.

BARDA is also working with and reviewing the capabilities and capacity of our Centers for Innovation in Advanced Development and Manufacturing (CIADMs). The CIADMs are government-sponsored facilities that were created as public-private partnerships to establish domestic manufacturing capacity and response capabilities in order to ensure the Nation has adequate surge capacity for rapid medical countermeasure production to address pandemics or other biological threats. The two HHS CIADMs are Emergent BioSolutions in Baltimore, MD, and Texas A&M University System in College Station, TX. Currently, AstraZeneca and Janssen have reserved space at the Emergent facility to manufacture vaccines at scale. In addition, BARDA is engaged in active discussions to reserve and expand capacity at the Texas A&M University System CIADM. Through OWS, manufacturing capacity at the DoD ADM, Ology Bioservices Inc. could also be utilized if necessary. I would be happy to keep the Committee updated on the progress of utilizing CIADMs as we move forward in this space.

Since its establishment in 2006, ASPR has proven its success in supporting past public health and medical emergencies. Whether the organization supported hurricanes, floods, influenza outbreaks, and other infectious diseases such as Pandemic Influenza, Ebola, Zika, or the current COVID–19 pandemic, we have utilized the authorities and resources provided by Congress to best support the Nation in responding to the threat and mitigating the lasting impact. BARDA has successfully established over 300 industry partnerships and obtained 55 FDA approvals for medical countermeasures. Further, BARDA has worked with its partners to develop robust platform technologies that facilitate rapid development and manufacturing of medical countermeasures in the face of a newly emerging threat.

Thank you again for your support. Your partnership and support enable our mission accomplishment. I am confident that we can quickly develop and distribute a safe and effective vaccine to reduce the impact of COVID–19 to our Nation.

CONCLUSION

HHS appreciates the support and interest of Congress in our work related to Operation Warp Speed and the development of vaccines, therapeutics, and diagnostics. Considering the potential health, social, and economic benefits of getting a safe and effective vaccine faster, placing big financial bets on these vaccines is a fiscal investment for the Nation. One economic analysis put the costs of nationwide stay-at-home orders at about $20 billion a day—to say nothing of the lives that are being lost that we can save with faster progress toward a vaccine. We're putting billions of dollars on the line to solve a multi-trillion-dollar challenge.

We look forward to partnering with Congress and working together as the country continues to open safely again. Thank you for the opportunity to testify today and we look forward to your questions.

Senator BLUNT. Well, thank you, Dr. Disbrow.

We're going to do our best to stick with 5 minutes so every member has time. There will certainly be a second round and everybody's going to be dissatisfied at the end of their first 5 minutes with what they didn't get to ask, but the person that follows them will be particularly satisfied that they stayed close to the 5 minutes.

VACCINE SAFETY

Dr. Collins, Dr. Disbrow just said development has not risked safety.

Do you have any concerns on the vaccine side that FDA is not going through every safety step that they would normally go through?

Dr. COLLINS. Mr. Chairman, I have no concerns, and I'm deeply engaged in this whole process, working with Operation Warp Speed.

I think the ability to do things so quickly is not compromising safety. It's taking advantage of other areas where we can speed things up, even though it may involve doing manufacturing at risk when we don't know yet whether that vaccine is going to work and ultimately throw out a lot of what gets manufactured if it doesn't work, but there will be no compromise at all on the safety and the efficacy standards. That is absolutely clear.

Senator BLUNT. Dr. Disbrow, let's follow up immediately. You mentioned the risk factor and Dr. Collins just said we will throw out anything that's produced that doesn't go through the final certification of safety and efficacy. Tell us a little more about that process.

I also noticed you said we were engaged in review, testing, and the approval phase. Are we engaged yet with anybody in the manufacturing phase?

Dr. DISBROW. We are fully engaged with multiple companies in the manufacturing phase under Operation Warp Speed. We're investing in a diverse array of technologies, different technologies, because we're uncertain of which vaccine technology may produce a safe and effective vaccine.

We are doing, as Dr. Collins mentioned, manufacturing at risk. This is a risk that we have to take if we want to expedite the timeline. So there is a reason that the FDA is not part of Operation Warp Speed. They are an independent regulatory body and they will review the safety and efficacy, but we will manufacture at risk large volumes of vaccine and there is the potential that if those vaccines do not prove to be efficacious in Phase 3 studies, that we would not move forward with that vaccine.

Senator BLUNT. All right. Every time I hear "at risk," and I'm pretty comfortable with vaccines, I think, oh, somebody's hearing at risk. I don't think we can emphasize enough that what we're risking is losing some money that we invested to move multiple products forward so that when the products that did get through

the whole process would be available at maybe roughly the same time they're finally approved for use.

Nothing will be more frustrating in this moment than for FDA to certify a product and then hear it's going to be months before that vaccine would be available, and am I right in believing that those months are what you're trying to avoid through BARDA?

Dr. DISBROW. That is correct. Again, under the entirety of Operation Warp Speed, but, yes, BARDA is investing in multiple vaccine candidates and you are exactly right. It is a financial risk, it is not a safety risk, and we are manufacturing and the government is assuming that financial risk.

Senator BLUNT. And I'm sure we're going to talk more about specific money later, but, remember, we've already invested $3 trillion to try to fight the virus and save the economy.

If somehow we lose $3 billion in an effort to get both of those fights in the right place quicker, I think we all ought to be willing to eagerly talk about the fact that, frankly, if we don't lose some money, we didn't try hard enough.

If you choose six vaccines and they all make it, I think the question will be, well, why didn't you choose eight vaccines because again, as Dr. Disbrow pointed out, that all of these vaccines will be slightly different than the other vaccine.

When you get a vaccine for COVID, am I right in assuming that people will not all get the same vaccine in all likelihood for their COVID vaccine?

Dr. DISBROW. So there's the potential. Again, we're investing in multiple candidates. We hope to develop one or more safe and effective vaccines. If there are one or more safe and effective vaccines, there is the potential that one vaccine may work better in a certain population than the other vaccine, but we will continue to evaluate those through the safety and efficacy trials, the Phase 2 trials.

Senator BLUNT. And, Dr. Redfield, I'm going to come back to you later on this question, but in your view, who is responsible for the plan for distribution in the current structure?

Dr. REDFIELD. Thank you for the question, Mr. Chairman. This is really the center space for the CDC. As I mentioned before, we're currently involved in the distribution of a variety of vaccine programs throughout this Nation. So this is really the prime responsibility of the CDC to work in coordination to take advantage of some of the logistical capabilities of the Department of Defense, but this is really CDC's prime responsibility.

Senator BLUNT. Thank you, Dr. Redfield.

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman. Thank you to all of our witnesses today.

Dr. Redfield, this crisis, as we all know, will not end until we do have a safe and effective vaccine that can be widely and equitably distributed.

VACCINE DISTRIBUTION

On Tuesday, you agreed that we need a comprehensive national plan whose implementation will hinge on the ability of public health agencies to deploy vaccine to every community once it is available.

CDC's deputies are experienced at managing a national immunization program and have to central to that planning. I think I just heard you answer Chairman Blunt, but under Operation Warp Speed, does CDC lead the planning for the immunization infrastructure and distribution or is that in any way the Department of Defense responsibility?

Dr. REDFIELD. Thank you very much for the question, Senator Murray. Again, it's leveraging. We're going to leverage the logistical capability of DOD with obviously the experience and essential role that we play in distribution with the State, local, Tribal, territorial community partners around the Nation.

So again, as I said to the Chairman, this is CDC's lead with the logistical support of the Department of Defense.

Senator MURRAY. Has the DOD ever managed vaccine distribution at this kind of scale before?

Dr. REDFIELD. I would have to refer that question to the Department of Defense, but I can just reiterate, which I mentioned, that CDC has a system in place that we use routinely and in the——

Senator MURRAY. Okay. I'm going to move on. That's a question that's important here.

Let me ask you. CDC hasn't used funding for any of the supplemental appropriations bills to prepare for a mass vaccine distribution campaign. Can you tell us why that is?

Dr. REDFIELD. I'm sorry, Senator. I didn't quite understand the question.

Senator MURRAY. CDC has not used any of the funding of the supplemental appropriations bill that you've been given to prepare for a mass vaccine distribution campaign, and I wanted to know that why that was.

Dr. REDFIELD. Yes. Senator, I'd have to have our group get back to you, but we've expended a substantial amount of the money that Congress has provided as I know I've moved out over $12 billion already to State and local, territory, Tribal health departments to begin to augment their public health capacity.

So I would need to get our team to get to the specifics of it. We moved out the $140 million that you gave us to help us improve——

Senator MURRAY. Yes. But you used that for flu vaccine, important, but the lack of preparation for COVID–19 vaccine distribution is concerning to me, and it doesn't sound to me like CDC is in that effort.

So, Mr. Chairman, I will move on, but I do need an answer, I think we all do, to that question.

Dr. Disbrow, last month HHS announced a $628 million deal with Emergent BioSolutions to help manufacture the eventual COVID–19 vaccine. As the second largest award in the government's COVID–19 response, that deal cemented Emergent's dominance as the highest-paid contractor for the HHS Office of the Assistant Secretary for Preparedness and Response.

A *Washington Post* investigation revealed that before the pandemic, ASPR (Assistant Secretary for Preparedness and Response) paid Emergent more than double what it paid any other contractor. Dr. Kadlec, who oversees ASPR, consulted for Emergent as a strategic advisor for years and was once part-owner of a Biodefense

company with Emergent's founder and chairman, a connection, by the way, which he failed to disclose to the Senate during his confirmation process in 2017.

BARDA CONTRACTS

So, Dr. Disbrow, this is my question to you today. Can you say with a hundred percent confidence that companies are awarded BARDA contracts based solely on scientific merit and not their personal relationships?

Dr. DISBROW. Yes, I can.

Senator MURRAY. Okay. Well, it was reported yesterday that three companies making coronavirus drugs and vaccines removed standard language from their contracts with BARDA that give the government march-in rights to intervene in cases of unreasonable drug prices.

I'm very concerned that pharmaceutical companies have dictated the terms of BARDA contracts and watered down the government's march-in right protections. At a time when we are spending billions of dollars in vaccine development, why did we weaken our ability to ensure fair vaccine pricing?

Dr. DISBROW. So I appreciate the question, Senator. So for the U.S. Government to use march-in rights requires a very high threshold.

The U.S. Government can ask the holder of the IP to grant a non-exclusive, partial exclusive or exclusive license to responsible applicant and if that does not move forward, then the U.S. Government may grant that license.

However, the contractor has to show that they are not or expected to not within reasonable time achieve practical application of invention that is not occurring. We are all working very quickly to push forward with the development of vaccines and therapeutics.

Action is necessary to alleviate health or safety needs not reasonably satisfied by the contractor. I also do not believe that threshold has been met.

So again under BARDA contracts, we work under the Federal Acquisition Regulations. We do have some contracts, which are called Other Transactional Agreements, which are outside of the FAR, but we always—everything is based on science and to protect the Federal Government's investment.

Senator MURRAY. Mr. Chairman, respecting time, I just want to say this. We are spending billions of dollars in vaccine development. We should not be weakening our ability to ensure fair vaccine pricing for the people of this country.

Thank you.

Senator BLUNT. Thank you, Senator Murray.

Chairman Shelby.

Senator SHELBY. Thank you.

I'll address this to all three of you. Where are we today? The American people are watching this hearing. We believe that we have sent you enough money. If we haven't, tell us why not, but tell us where we exactly are, if you can be exact, on coming up with a vaccine. I think the vaccine—I know you're trying every approach in the world, you know, logical approach, and you've got a lot of people working on it, but the American people are dying and get-

ting sick and they're looking for results, and we know you just can't just wave the magic wand.

VACCINE PROGRESS

Dr. Collins, I'll start with you. What do you say to the American people today of where we are and when the timeline and what do you think we will be where?

Dr. COLLINS. Yes. Mr. Chairman, this is the right question and something that I think all of us working on COVID–19 are obsessed about night and day because this is one of those crises where science is not only important, it's crucial, and every mistake we make would set us back and every wasted opportunity would have a consequence for somebody's life. So I want to tell you we are all in, everybody working on this Warp Speed Team.

Where we are with the vaccine, remember that generally it takes 5 to 10 years to develop a vaccine from a new infectious agent. We don't have that time. So in record time, the very first vaccine went from knowing what the sequence of this viral genome was to injecting the first patient in a Phase 1 trial in 63 days. That's a world record by a long shot because of new technologies that made that possible.

Then going quickly from the Phase 1, which looks very promising, to Phase 2, which started on May 29th, and Phase 3 which will begin this month, and how long will that take? We need to enroll 30,000 volunteers and that should take a matter of some months, we are all optimistic that the goal that we have set to have a vaccine that works and is safe by the end of 2020 will be met by one of the vaccines. I've just mentioned one, but, of course, there's several all being conducted side-by-side, and that we would then have by early 2021 300 million doses of a vaccine that's safe and effective.

So all of that is where we're putting ourselves on the line and I think everybody at this table would agree that's really a stretch goal but it's the right goal for the American people.

Senator SHELBY. Dr. Redfield.

Dr. REDFIELD. Thank you, Chairman. Two comments. First and foremost, the most important thing is we move forward with these vaccines. As was said before is that our role at CDC again, along with others that are here, and FDA is to assure that they're safe and efficacious.

Where we are right now, the two areas that we have the most important role is to figure out how to get that vaccine into the individuals that would benefit from it. So two things there, building vaccine confidence. We talked about that——

Senator SHELBY. That's presupposing you come up with a vaccine, right?

Dr. REDFIELD. Yes. I think we have to start working on that right now.

Senator SHELBY. Absolutely.

Dr. REDFIELD. We are working on that right now, Chairman, just because the complexity of giving a new vaccine to the American public, as we learned during the H1N1 in 2009, it's seriously complicated, and so we are working on that, if you will, distribution mechanism now, and we are working on building the confidence of

the American public now with the supposition that our colleagues that are evaluating the actual vaccine itself between their seven shots on goal or as many different vaccines as they're developing now, that one of those vaccines will come and show an adequate safety and efficacy profile to go forward and be distributed.

Senator SHELBY. Dr. Disbrow.

Dr. DISBROW. Thank you, Senator. So building off the previous comments, I think we look at incremental success as we're moving along.

You saw some results yesterday. Pfizer published results from a Phase 1 clinical trial. I think those are important to get out to the American people. Initiation of Phase 3 clinical trials has already been reported by one of the companies that we're working with. They will initiate their Phase 3 trial, as Francis said, in July. There will be additional Phase 3 trials that are staggered later in the summer. I think those are important milestones to let the American people know that we are making progress.

In addition is the scale-up and manufacturing and validating those process. That is a critical milestone, as well.

So where we are right now is we're in the phases of the different clinical trials, Phase 1, Phase 2, Phase 3, and we're ramping up manufacturing.

Senator SHELBY. Dr. Collins, how much cooperation around the world since so many nations and so many people are affected do your researchers collaborate on and what are they getting?

Dr. COLLINS. Science has always been an international effort and never more so than when we're faced with a global pandemic. I think the collaboration and cooperation is really excellent.

One of the vaccines we're talking about actually was originally developed in the United Kingdom, has now been embraced in a way that the U.S. can take advantage of it, also, with support from BARDA's very excellent way of doing those negotiations.

So, yes, we are looking in every nook and cranny for the kinds of collaborations and cooperation that will make this go faster. That's our scientific tradition.

Senator SHELBY. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Shelby.

Senator Durbin.

Senator DURBIN. Mr. Chairman, I want to follow up on Senator Murray's question. We're in the middle of a national pandemic. We're also in the middle of a national presidential campaign, and I think her question goes to the fundamental basic desire for testimony here on where we stand in terms of the political world before we address the medical world.

POLITICAL INFLUENCE IN VACCINE DEVELOPMENT

I'd like to ask the three witnesses here if any of them have felt any pressure, political pressure from the White House or other agencies in terms of the selection of the companies to develop a vaccine, the timing of the vaccine development, the announcement of a vaccine, or any other aspect that is part of your responsibility on the medical side.

Dr. COLLINS. No, sir, no political pressure, lots of internal pressure as a physician and as a member of the world, to find the answers.

Senator DURBIN. Dr. Redfield.

Dr. REDFIELD. Senator, my answer is no.

Senator DURBIN. Dr. Disbrow.

Dr. DISBROW. My answer is no, as well. I'm a scientist, not a politician.

Senator DURBIN. Thank you. That's what I was hoping for and I think that's what the American people are looking for and so let me go to the next question on the medical side and here's where I think we have to have some candor.

What I'm told that the Phase 3 clinical trial of the Moderna vaccine that's being conducted by the University of Illinois at Chicago will kick off in about a week and they anticipate that it will last years, 2 years before they've completed it, collecting information from all of the people who volunteered for the test, blood samples, and the like, to determine the safety and effectiveness of that vaccine.

I find it difficult to square that reality that's been announced in their Phase 3 clinical trial with the promises that I'm hearing over and over again that within 12 months we're likely to have a vaccine. It suggests to me that the Phase 3 clinical trial which ordinarily takes 2 years is going to be somehow abbreviated.

Now I understand the emergency use authorization at FDA that may be utilized to choose a vaccine and go into production and distribution of such a vaccine, but that has had at least some mixed results recently when it came to the hydroxychloroquine EUA that was announced.

VACCINE SAFETY IN ABBREVIATED TIMELINE

So how do we maintain the confidence of the American people of the safety and effectiveness of vaccine if it appears that we are shortcutting this Phase 3 clinical trial that is usually required in these vaccine circumstances?

Dr. COLLINS. Senator, maybe I can help explain why that 2-year time interval might have been there in terms of the assessment of the vaccine.

Again, what we would need to know as soon as possible is does this vaccine, when administered to people who currently are not infected but are likely to get exposed, does it protect them from becoming infected?

So each of the vaccine trials will aim to enroll 30,000 participants, half of whom will get the vaccine, half of whom will get a placebo, and we will watch then as these individuals, and they're going to be particularly recruited in areas where the vaccine is currently spreading, either get infected or don't, and it will only take about a 126 episodes where somebody with the placebo gets infected and somebody with the vaccine doesn't to know that this has worked. That will be the point where you'd be happy to say this now has efficacy and, of course, you'll also have a lot of people to see if there was any safety signal.

The reason, though, to prolong the study after that has already been achieved is a number of other things. Are there any long-term

side effects that weren't anticipated? We don't think so, but you want to be able to follow. Also, how durable is this particular immunity? Is this vaccine going to be something that works for life or will you need a booster in a year or two? Hence the reason to extend the time table.

Senator DURBIN. But, Doctor, if I'm going to make the decision, good news, 126, whatever it happens to be, in a span of 3 or 4 months, here's your vaccine, if I'm going to make that decision, what you're telling me is the Phase 3 clinical trial still has elements, important elements in my decisionmaking process to be resolved which are going to take time in terms of long-term impact to the vaccine, is that correct?

Dr. COLLINS. And that is actually the way we do a lot of trials of drugs, not just vaccines, where you assess whether the drug is safe or effective in the circumstance where you really need a treatment, but then you don't stop looking once FDA has given an approval. You carry out long-term studies to make sure there's not some unexpected result or the drug stops working.

So that's basically the plan here with vaccines, as well. We don't want to miss the chance to collect that downstream data.

Senator DURBIN. Dr. Collins, are you familiar with the Cutter vaccine issue?

Dr. COLLINS. I am.

Senator DURBIN. Dr. Salk and polio vaccine?

Dr. COLLINS. Yes.

Senator DURBIN. Can you reflect on that for a moment of what the world of vaccine development looks like today compared to then?

Dr. COLLINS. Well, yes, that was a terrible tragedy and a circumstance where a vaccine actually turned out not to be fully inactivated and therefore created actually the illness that it was supposed to prevent.

I think I could reassure you and the American people that that strategy of trying to administer a killed vaccine is not currently being pursued for SARS–CoV–2 because of those risks.

Instead, the vaccines choose to produce just a small component of the virus. I think I showed this before. These proteins, these spike proteins that sit on the surface, that's what the vaccine produces. There's no intact virus there at all but yet you can still generate the immunity.

So the Cutter experience, which was a terrible tragedy, is really not possible with the way these vaccines are being designed.

Senator DURBIN. Thank you.

Senator BLUNT. Thank you, Senator Durbin.

Senator Alexander.

Senator ALEXANDER. Thank you, Mr. Chairman, and thank you to the witnesses.

We've been talking about vaccines and next year, I'd like to talk about tests and treatments and this fall, which is only a few weeks away, let's start with tests.

Dr. Collins, with all the depressing news we hear about COVID–19 for the last several months, Americans are hungry for sports. So will there be enough COVID–19 tests that we can watch some football this fall or some basketball this winter?

I noticed the National Hockey League said it was going to test every player every day. The president of Brown University told our committee that she wanted to test every student before they come back.

TESTING CAPACITY

Admiral Giroir has said that the country will have 40 to 50,000 test capacity a day by September. That will probably be enough to have widespread testing to go back to school and back to work, but will it be enough for sports teams to take the field? Probably the answer lies with your RADx effort to make a new way of creating quick, reliable diagnostic tests that can be administered frequently, maybe even every day.

So we'll be able to watch some football and some basketball this year or do we have to wait until next year?

Dr. COLLINS. Well, I'm probably the least qualified sports fan, but I do appreciate that this is important to a lot of people and we want to see Americans have a chance to have some normal experiences of enjoying life.

I do believe this should be possible. What RADx is doing, and appreciate the strong support from this Congress to make this possible, is to speedily put together these kinds of point-of-care tests that can be done onsite, can give you a result within an hour, and can tell you immediately whether that person is actually infected with the SARS–CoV–2 virus, in which case they can be immediately quarantined.

I think the general sense is for athletic teams, you really need to know that. Otherwise, you're going to have an outbreak that will wipe out the entire team.

Senator ALEXANDER. But your goal is to have these tests available this fall?

Dr. COLLINS. Yes.

Senator ALEXANDER. September? That's your goal?

Dr. COLLINS. That is the goal. The path we are on right now, and again this is a white knuckle goal because it's never been done at anything like this kind of time-table before, would be to have an additional one million tests per day available for the kind of point-of-care on-the-spot testing that's very much needed for going back to school and going back to sports events.

Senator ALEXANDER. And these would mostly not be the tests that have to be shipped off to a lab and then come back?

Dr. COLLINS. That is our goal or if they're going to be shipped to the lab, the lab needs to be very nearby. We're aware that there are places where there are labs that have instruments that could be brought to bear on this that are widely distributed already but haven't been adapted to this purpose. That would be sort of a next best thing is to have them at least in your own local arena.

The best, of course, is to have your gadget right there at the front desk when somebody shows up for practice and find out is this person somebody who's safe to send to the field.

Senator ALEXANDER. Okay. That's this fall. Now let's go to treatments in medicine. I think Senator Kennedy may be here. He said in his inimitable way that he thinks what people are really afraid of with this virus is not just getting it but that they might die and

they might die or have a very severe illness because there's no medicine for it, except you mentioned two that have been approved by the FDA.

So as we go back to school, for example, with 75 million students going back to elementary and secondary school, we're happy that COVID–19 doesn't seem to affect children very much or even college students very much, but there is the danger that they might infect their teachers or their older administrators or they go home to their parents or their grandparents and might infect them.

Dr. COLLINS. Exactly.

TREATMENTS AVAILABLE IN FALL

Senator ALEXANDER. So what can you say to the teachers and the administrators and the parents and the grandparents about medicines that this fall will help them not die and not have a severe illness? What will be available this fall when the kids go back to school?

Dr. COLLINS. Well, there are intense efforts to expand that repertoire from remdesivir and dexamethasone, which are already approved, as you mentioned, to other kinds of ways to do effective treatment.

A big promise here is the use of what you might call "passive immunization" where you basically provide to somebody who's ill antibodies derived from somebody who has survived already and this is the idea behind convalescent plasma which is being rigorously studied and right now analyzed by the FDA to see what the results have been.

But even more than that, one could develop what are call monoclonal antibodies——

Senator ALEXANDER. Is this the so-called "antibody cocktail" of the kind that was developed and approved by the FDA with Ebola?

Dr. COLLINS. Exactly. It worked for Ebola. It worked really well, and the idea is you have these antibodies taken from somebody who has survived the disease and you turn that into a product and those trials are going to get started this month.

Senator ALEXANDER. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Alexander.

Senator Shaheen.

Senator SHAHEEN. Thank you, Mr. Chairman. Good morning, and thank you all for being here, for your testimony, and for your service to try and address what is obviously the worst threat to Americans in my lifetime.

I am particularly concerned about the impact on older Americans and those in long-term care facilities. In New Hampshire, 80 percent of our COVID–19 deaths have been in long-term care facilities. That's the highest percentage in the country.

VACCINE PRIORITIZATION EFFORTS

I'm concerned, as you've talked, Dr. Redfield, about how you prioritize who gets the vaccine when we have one. How do you prioritize these residents and those with underlying conditions, like diabetes?

Dr. REDFIELD. Thank you very much, Senator. A very, very important question. Obviously this is going to be discussed through

our Advisory Committee on Immunization Practices, but clearly the most vulnerable and those individuals that are at greater risk for mortality have to be highly considered as well as those individuals at great risk for infection because of what they do.

It turns out among healthcare workers that get infected, we've recently looked at it, turns out the most common healthcare workers who get infected were the non-nurse, sort of the caregiver in the nursing home were the most common there. So these are going to be critically important.

I will say one thing, though. Depending on which vaccine is approved, it may have particular characteristics that make it more or less appropriate to begin with in different populations and this is why I think it's hard to know exactly until we know——

Senator SHAHEEN. Sure.

Dr. REDFIELD [continued]. Which of the virus, but clearly the vulnerable are going to be, if not the top priority, one of the top priorities.

Senator SHAHEEN. And do you have a time table for when you're going to make those decisions because obviously things are moving rapidly?

Dr. REDFIELD. There's discussions already going on to work frameworks for, but as I mentioned, at the end of the day it's going to really be dependent on the characteristic of the particular vaccine product that we're now planning to do.

PFAS EXPOSURE AND COVID–19 RISK

Senator SHAHEEN. Staying with you, Dr. Redfield, last month the Agency for Toxic Substances and Disease Registry issued a statement expressing concerns about the relationship between exposure to PFAS (Perfluoroalkyl and Polyfluoroalkyl Substances) chemicals and the risk for COVID–19 infections and complications.

In New Hampshire and in communities across this country, we have a number of people who have been exposed to PFAS who are very concerned about this statement.

So can you tell us what the agency is doing, what CDC is doing to assess the impact of PFAS exposure on COVID–19 risks?

Dr. REDFIELD. Yes. We're currently working—both our Agency for Toxic Substances and Disease Registry and the National Center for Immunization and Respiratory Diseases Influenza Division are working together in a study to try to learn better about the interrelationship between the PFAS serum concentrations, for example, and the association between symptomatic rates or asymptomatic COVID infections, severity, symptoms, and hospitalizations. So we do have a study ongoing to try to understand that association, Senator.

Senator SHAHEEN. And do you have any timeline again for that study when you expect to have data that could give us some insights on that?

Dr. REDFIELD. I think I've really learned that I have to be careful in trying to predict. You know, as my colleague, Dr. Collins, said, science has its own timeline.

Senator SHAHEEN. But do you think we're talking months, years, decades?

Dr. REDFIELD. We're not talking decades, okay, but obviously we're trying to get that information as soon as we can and I really am not able to commit how fast the science will be done, Senator.

Senator SHAHEEN. Well, it seems to me that would speak to trying to address PFAS exposure wherever we can.

VACCINE SUPPLY CHAIN

I think this is for you, Dr. Disbrow. As we're talking about the challenge in this pandemic, one of those testing at least has been trying to provide access to all of the ancillary supplies that are required. I think that is probably going to also be true as we think about the vaccination plan and distribution.

We've heard from one manufacturer in New Hampshire who makes syringes that they need some certainty so they can order the equipment they're going to need to make those syringes that are going to be available for vaccinations.

So can you give us any details on the anticipated timeline for the award of contracts for production and supplies?

Dr. DISBROW. Sure. Thank you for that question. So as everybody knows, making a vaccine is more than just making the bulk vaccine. There are multiple steps involved.

You have to have fill finish capacity. So BARDA is working very hard with our partners, the Joint Program Executive Office, CBRND at DOD, as well as under OWS, to reserve excess capacity for fill finish so that you can not only make the vaccine but you can fill it.

We're working with JPEO to expand capacity for vials because you need the vials to put the vaccine in. We have awarded contracts for needles and syringes acquiring needles and syringes.

We're also working with JPEO to expand capacity for needles and syringes, so that there are sufficient needles and syringes when the vaccine becomes available. So we are working on all aspects of the vaccine.

There's also kitting. When you send out a vaccine, you have to have, you know, the needles and syringes, alcohol wipes, band-aids, all of that, and then there's the distribution, and as Dr. Redfield mentioned earlier, it is very important that the people who are developing a vaccine—and under Warp Speed are tied in with the group that is talking about distribution and kitting because they have to know what that vaccine is going to look like.

Is it a single-dose vial, a multi-dose vial? What is the cold chain requirement? So we are working across Operation Warp Speed in multiple different work streams that are fully integrated.

Senator BLUNT. Thank you, Senator.

Senator Moran.

Senator MORAN. Chairman, thank you. Thanks to you and the Ranking Member for having this hearing. Gentlemen, thank you for joining us.

Dr. Collins, let me first thank you for joining me on a phone call with the University of Kansas Health System in which your report on a vaccine was the highlight of the day, month, and year. So I'm pleased to hear that medical researchers and practitioners in Kansas heard what you said and found it to be a very pleasing kind of an optimistic note.

FUTURE PANDEMIC PREPARATION

Let me ask something. Is COVID–19 or is a virus so unique that there are not things that can be done to better prepare us for the next virus, the next pandemic, so that a vaccine development is developed, the development occurs in a shorter period of time, or is it just starting—I don't know that scratch is the right word, but starting from scratch each time?

Dr. COLLINS. It's a great question, Senator, and, yes, I enjoyed talking to the folks in Kansas. It's a wonderful bunch of scientists and physicians.

Coronaviruses, of which this is one, have been around a long time. Some of them cause the common cold and we still haven't cured that one, but it hasn't been such a high priority, and SARS and MERS were also Coronaviruses. We learned something from them.

If we had not had already an effort to try to develop vaccines for SARS and MERS, we wouldn't have been able to jump on SARS–CoV–2, this guy, quite as quickly.

So every time you do this, you get a little better at it and, plus, the overall technology for how we develop vaccines has been advancing. The lead vaccine now in terms of its earliest out-of-the-gate, which is the Moderna vaccine and also the Pfizer one that was announced yesterday, same principle, utilizing RNA as the thing that you actually inject so that you ask the body to make the protein which then becomes the antigen that your immune system reacts to, that's pretty new.

We would not have done that 10 years ago. We wouldn't have known how and we'll keep getting better at new ideas at that.

I do hope, and maybe this is part of your question, that we learn from this experience, that when we get through this because we're going to get through this, we don't then go back in-to some complacency and say, well, that's it, we won't ever have another one like that again because we all know we will. What will it be? Will it be another coronavirus? Will it be that influenza epidemic that we've been worried we're overdue for coming out of somewhere that's actually going to be very dangerous?

We should never again step back to the point of complacency with these kinds of emerging infections and I hope we will therefore from what has been built to deal with COVID–19 sustain that.

Senator MORAN. Dr. Collins, thank you. I want to follow up on that, but I want to make sure I get a question to Dr. Redfield, and I'll try to be back to Dr. Collins.

Dr. Redfield, thank you for the telephone conversation we had several months ago. I would highlight for you and others who might be listening that the issue of PPE, personal protection equipment, is back front and center. It seemed to me in my life it had diminished a bit, but in a conversation with community leaders, including hospital and public health officials, the concern is the supply is short once again as the numbers increase and the potential of a greater circumstance, a more challenging circumstance comes in this fall.

So any suggestions that anyone who hears this statement of mine has on how I can get additional PPE to Kansas public health, hospitals, and employers, I would welcome that.

But let me ask you. One of the things I take away from what's transpired is the importance of public health departments and I think generally we have—until I served on this committee, I didn't realize the significant role that CDC plays in support of our community and public health departments.

PUBLIC HEALTH DEPARTMENT'S ROLE IN VACCINE DISTRIBUTION

What is it that needs to take place so that when the vaccine is developed, our public health departments are prepared to administer that vaccine in the distribution? How can CDC, how can this committee help make certain that occurs well?

Dr. REDFIELD. Thank you very much, Senator. I think you heard me say before we've had decades of underinvestment in our public health departments across this Nation and this is the time now to correct that and you all have really made great support.

CDC has already awarded $12 billion with a B to the local, State, territorial, Tribal health departments in the last 8 weeks or so to begin to give them the resources they need to begin to build up their capacity.

You know, the human capacity usually takes longer than weeks to build up and we're obviously,—as you know, I said CDC has over 650 people now embedded in the local health departments to help with that human capacity, and we're going to continue to work with them.

Recently, with the resources you did with the CARES Act, we were able to get a little over 10 billion out for each of the jurisdictions to put up plans as to how to expand their testing, their contact tracing, their isolation, their public health infrastructure.

So we're doing it on the run. I think you've heard me say before when it comes to public health, this is something we as a Nation should plan to be over-prepared, not underprepared, and I do believe this is the moment in time when this Nation can actually help put the public health infrastructure across this Nation not only that we need but this Nation deserves.

As you mentioned, most of CDC's money actually gets distributed to the local, State, territorial, Tribal health departments, and some of these health departments, it's 70 percent of their overall funding.

So we are the Nation's funder through you of the public health infrastructure of this Nation and we need to augment that to where we're now over-prepared for the next pandemic.

Senator MORAN. Mr. Chairman, if you have a second round, I'll try to follow up with Dr. Collins.

Senator BLUNT. Thank you, Senator Moran.

Senator Merkley.

VACCINE MODIFICATIONS AND EXPECTED VARIANTS OF THE VIRUS

Senator MERKLEY. Thank you very much, Mr. Chairman.

Dr. Collins, I wanted to get some sense from you of our understanding in a short, simple version of whether this coronavirus is such that we anticipate that its mutations will mean that different

vaccines may be effective against some versions of the disease but not others and whether it means we will likely have to have an annual production of modified vaccines based on those mutations, like we have with the flu.

Dr. COLLINS. Senator, thank you. That's a very important scientific question that many of us are wrestling with, trying to collect as much data as we can.

I think the somewhat reassuring news is that this particular virus, which is an RNA virus, does not have a rapid mutation rate. It's not like influenza or HIV where you know you're going to have to have a really tough time getting a vaccine to work or to stay effective, but it does change over time.

There is at least one significant variant in the virus that's already happened since it originally appeared about 6 months ago that may have made it somewhat more infectious than the original strain coming out of Wuhan. We're not absolutely sure of that but it looks like that might be the case.

The good news is that those variants that we've detected do not seem to be those that would interfere with the effectiveness of the current vaccines that are being designed and tested nor with the monoclonal antibody strategies that are also being attempted, but we're going to watch that very carefully.

A big question we will all have is whether this is a circumstance where, once vaccinated, you are basically protected for life or whether over the course of time this virus will change its coat enough that you will need to have a booster that's slightly better in its design for whatever it is that this turns into next.

We don't know the answer to that, but I think the good news is this is not like HIV, this is not like influenza. It's a fairly well-behaved virus that we think we ought to be able to tackle effectively with a vaccine strategy.

CONTRACTS AND PRICE SAFEGUARDS

Senator MERKLEY. Thank you very much, Doctor, and I want to turn to the question that Senator Murray raised about the elimination of the Bayh-Dole safeguards. Those safeguards for reasonable pricing when the government has invested in the development have never been implemented but many people feel they serve as an effective instrument of leverage should the American people be gouged after investing millions or now perhaps billions of dollars.

Was NIH consulted about removing the Bayh-Dole safeguards from the contracts?

Dr. COLLINS. We were not asked about that. We've been asked about those safeguards in other circumstances.

Senator MERKLEY. And do you support inclusion of those safeguards to protect the American people from price gouging after we invest in the development of drugs?

Dr. COLLINS. I certainly think the American people ought to have access to vaccines that they're helping to pay for and I think the plan has been nicely made to be sure that that is the case so that nobody would be denied access to this, regardless of their healthcare coverage.

The march-in rights issue actually is rather complicated. When you look at the original language of Bayh-Dole, it does seem, as Dr.

Disbrow said earlier, that these were intended to try to allow the government to step in when there was a company that basically refused to try to produce a product that would benefit the public.

It does not look as if those particular parts of the bill were intended to do something where the price was considered to be unacceptable.

We've been caught in this many times before and that's what the lawyers tell me. So in this circumstance, I have to defer to BARDA in terms of why the decision was made, but my understanding was there was really no likelihood that the product wasn't going to be pursued, in which case march-in rights would be a tough thing to try to apply.

Senator MERKLEY. In which case it would be okay to leave them in the contract. The Moderna contract still has those march-in rights and NIH claims joint ownership of the Moderna vaccine. So I find it interesting that NIH wasn't consulted over the difference between that contract and some of these other contracts.

Dr. COLLINS. I have to be careful here because it's possible somebody at NIH was consulted, but I was not made aware of it. So I'll have to check on that and see if there was a consultation.

Senator MERKLEY. Thank you.

And, Dr. Redfield, was there a CDC consultant over the elimination of this contract language designed to ensure fair pricing?

Dr. REDFIELD. Not to my knowledge, sir.

Senator MERKLEY. Okay. Thank you.

And, Dr. Disbrow, why suddenly eliminate this language in some of these contracts but not others? Who was it who asked you to do this, and why did you include language in some contracts and not others?

Dr. DISBROW. So I think some of the confusion is that in our FAR-based contracts, it is in there. Some of the documents that were requested by the group that asked for them under FOIA, Freedom of Information Act, were other transactional agreements, which are outside of the FAR, and also remember that these are research and development contracts. We are not acquiring product under these contracts.

Senator MERKLEY. Well, recognize, too, that it's research and development being funded by the American people with a vast potential for profit for the companies. So the American people have a stake in fair pricing.

I think the American people are aware that they are gouged on drugs routinely, that we pay more than citizens in any other developed country. 80 percent of Americans routinely respond they want fair pricing, that they shouldn't be charged more than the citizens of other countries. We spend more on the development of the products and I think that plays double here.

The reason I'm emphasizing this is we're going to spend billions of dollars in this development and we should absolutely use that investment to make sure that we're not gouged on the back end and so I just want to say that this conversation that Murray initiated and I'm following up on here is an important one and I hope you're going to take full and thoughtful consideration on how to make sure that Americans do not pay more for these drugs through

the government payments or through citizens having to pay for them than do the citizens of any other developed country.

In fact, I hope you'll pledge to make sure that that's the case.

Senator BLUNT. Thank you, Senator Merkley. If you want to come back for a second round, you can.

Senator Capito.

Senator CAPITO. Thank you, Mr. Chairman, and thank you all for not just being here today, I know you've been on Capitol Hill many times, but thank you for what you've done and what you're going to do to meet this crisis.

SUPPLY CHAIN CONCERNS

Dr. Disbrow, I had a question. Many of my questions that I had initially you all have sort of answered on the safety and efficacy issues around a vaccine, but as I recall back when we first started, we had an issue with China making the PPE, with Italy having the swabs, I might have this a little wrong, but the reagents in Germany, and there was a competition globally for all of these supplies.

I imagine that there's going to be a competition globally for the vaccine supplies and the vaccine itself.

Dr. Collins mentioned that they have been working with the U.K. in a collaborative way, but how much of what you're seeing of the development is actually manufactured in this country where we can sort of control our own destiny?

Dr. DISBROW. Thank you for the question, and it's a very important question.

This global pandemic has highlighted the vulnerability in our supply chains for medical devices, raw materials, and active pharmaceutical ingredients for drugs.

I can't give you the specific number of what percent of the products are manufactured here in the United States, but what we are doing, as I responded to one of the earlier questions, is we are working for needles and syringes and vials to expand domestic capacity so that we don't have to worry about this in the future, in the immediate future and the near future.

We are also working with all of our manufacturers to make sure they acquire the raw materials that are needed to manufacture vaccines and/or therapeutics because, don't forget, therapeutics are also important.

Senator CAPITO. Right.

Dr. DISBROW. So that they can manufacture at scale.

Senator CAPITO. Is this a question that you ask when you're looking at giving contracts, whether it's produced in the United States where you can control your own destiny?

Dr. DISBROW. So we look at their raw supply material chain. We do that for all of our manufacturers to identify risks early on and try to address those risks very early on.

Senator CAPITO. I'd like to dig down on that because I think, you know, that that's concerning I think obviously because this is a global issue but also I think it sort of shook the American public when we realized we weren't really controlling the ability to have testing supplies or the ability to produce our own PPE.

OPIOID EPIDEMIC DURING THE PANDEMIC

Dr. Collins, a question I have that's a little off topic but equally as important. You know that NIH has invested heavily and so have we here on the opioid epidemic, but the latest stats coming out of our State of West Virginia, Senator Manchin's here, and across the country is that there has been a big spike in overdoses during this COVID epidemic and I'm wondering—I know you're fast at work on this in a lot of different various ways, but how are you seeing that and how might having a vaccine or having better therapeutics be able to help us meet this challenge of folks that are in therapy for addiction or have this addiction issue to be able to cope during these very stressful times?

Dr. COLLINS. Senator, I really appreciate your bringing this up and it's not off topic at all. It's a really serious national tragedy that has now gotten even worse because of the coalescence of the COVID–19 crisis and the opioid use disorder crisis, and I've seen those same statistics about maybe a 42 percent increase in overdoses in just the last 3 months and deaths associated with that are going up.

After we had started to make some headway with this crisis, with all of the things that have been done with various programs and use of medications that we know can work, and yet now prescriptions for those medications have plummeted because people aren't able to get into treatment programs.

We are doing everything we can at NIH with supplements to some of our research programs to try to understand how best to intervene, how to provide people with support, even if it has to be done remotely by telemedicine kinds of interventions.

We've been supporting the idea that methadone, which traditionally required people to show up every day in a crowded location, could actually be done in a fashion where people could receive this at home because otherwise the dangers are too great and people were simply dropping out.

But I can tell you how desperately we need to get back in a place where people can congregate together and that will require, of course, effective treatments and vaccines and that's on my mind every day as we're trying to accelerate that progress. This is a very serious situation indeed.

Senator CAPITO. It is, and, anecdotally, I heard that really the counseling that was going on by telehealth initially was actually having greater—they were staying more true to their appointments and it was going well and then it just has gone back down.

Dr. COLLINS. People need interaction more than just through a Zoom call and that's hard to do right now.

VACCINATION EFFORT OUTREACH

Senator CAPITO. All right. Dr. Redfield, I have four seconds. Our vaccination rate in West Virginia is falling. How are we going to do a PR campaign to say the vaccination for this is important and other vaccinations?

Dr. REDFIELD. That's a critical point, Senator, and I always look at the consequences of COVID. As the Secretary said, health versus health.

85 percent decline in pediatric vaccinations in those just under five. We're obviously in the process of making a play with the American Academy of Pediatrics and throughout to really respond to that. It's really, really important.

Globally, it's a big issue, too. I've tried to say in Sub-Saharan Africa, where COVID now is a significant problem, but a much bigger problem is there's a 120 million children now who haven't gotten the measles vaccine and they're going to have significant mortality in Africa.

Senator CAPITO. Thank you.

Senator BLUNT. Thank you, Senator Capito.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman.

VACCINES IN DEVELOPMENT

I have a couple of, I hope, quick questions. Dr. Disbrow, can you just quickly list for me the vaccine prospects that are being invested in right now? You know, you've narrowed it from many, many who have come forward to I think it was first 14 and now fewer.

Can you just list those for me and what type of vaccine it is?

Dr. DISBROW. So I appreciate the question, Senator. I cannot specifically mention some of the companies. We're in active negotiations with many of them. One that I can mention is AstraZeneca, where we already have a very large contract that covers both advanced research and development and procurement.

We are in the process of moving forward with large manufacturing contracts and acquisition of the vaccine for multiple other candidates.

Senator BALDWIN. So those company names in terms of the vaccine prospects are not public?

Dr. DISBROW. So some of the companies that were originally funded by BARDA for advanced research and development, those are public, who we've invested in.

I think your specific question may be the composition of the portfolio under Operation Warp Speed. That I cannot today talk about, but we are very quickly moving and negotiating contracts and hopefully in the very near future we will be able to make an announcement with the entire portfolio under Operation Warp Speed.

Senator BALDWIN. How many have been finalized right now versus how many are you still in negotiations with?

Dr. DISBROW. So I already told you about the one which is the AstraZeneca, and we have multiple other candidates that we're working with.

Senator BALDWIN. How many do you think you'll have in total?

Dr. DISBROW. More than one. Sorry. It really is procurement-sensitive. These are market-moving negotiations that we're having with these companies, you know. So I just need to be very careful about that, but again we are happy to publicly announce. You will see the press releases when we award these contracts so that everybody is aware of what's being supported.

Senator BALDWIN. So you have the intellectual property prospect. You also have the manufacturing. You want to make sure timewise that you'll be able to have [technical glitch] are U.S. based?

Dr. DISBROW. So, I'm sorry, you cut out for a little bit, but you're asking is manufacturing going to be U.S.-based?

Senator BALDWIN. Yes.

Dr. DISBROW. Correct. 100 percent.

Senator BALDWIN. Okay. And are you looking at any vaccine prospects that you [technical glitch].

Senator BLUNT. Let's go to Senator Kennedy, and we'll come back to Senator Baldwin once we think that we've got this technical problem worked out.

Senator Kennedy.

Senator KENNEDY. Thank you, Mr. Chairman, and thank you, gentlemen, for being here.

MASK GUIDELINES

Gentlemen, I'd like your opinion on something. When the pandemic first became apparent in the United States, a number of busy and important people, smart people in the Federal Government, also in State and local governments, told us, the American people, that we shouldn't wear a mask, that a mask would not protect other people, it wouldn't protect us, and, in fact, in some cases it might actually hurt us.

When I heard that, I thought to myself, you know, this is odd because I turn on television and I see doctors and nurses wearing masks when they're treating coronavirus patients. I remember thinking this is odd. Wonder where they went to med school or nursing school.

Next, we were told, well, by these busy, important people, we were told, well, you should wear a mask, but the reason you should wear a mask is not for yourself but to protect other people who might get the coronavirus from you.

And then I turned on TV again and I saw these doctors and nurses wearing masks treating people with coronavirus and I thought to myself this is odd. Why are they trying to protect the patient? The patient already has coronavirus, for God's sakes.

And then it occurred to me that maybe these busy and important people were wrong and are wrong. So I talked to a lot of doctors and nurses, not the ones I saw on TV but others whose judgment I respect, and I've read a little bit, and I came to the conclusion that a mask is very helpful and it will protect us. It will protect other people and it will protect you and that's why I wear a mask because I don't want other people to die and I don't want to die.

Now how come these busy, important people who are smart people in the Federal Government told the American people this?

Dr. COLLINS. Well, may I? As a busy person, I don't know if I'm important, but let me try as a physician to explain the history here.

A mask is not a mask is not a mask. The kind of mask that I'm wearing, that most people in this room are wearing, cloth masks or something like that are pretty good at capturing any kind of droplets that might be coming out of your mouth while you're speaking because I'm producing them right now.

If I happen to have SARS–CoV–2, you don't want those droplets getting anywhere near you.

Senator KENNEDY. I get all that.

Dr. COLLINS. So but we didn't really know that, Senator, until March or thereabouts. This is a very unprecedented way for a virus to spread, to have asymptomatic people spewing out virus like this——

Senator KENNEDY. Excuse me for interrupting, Doctor, because I don't have a lot of time.

Then why were the doctors and nurses wearing the mask?

Dr. COLLINS. They were not wearing these kinds of masks. They were wearing N95s which have the ability to protect them.

Senator KENNEDY. They didn't all have N95s. Some of them, we didn't have enough N95s to go around.

Dr. COLLINS. Well, they should have had N95s and face masks and other means to protect them.

Senator KENNEDY. Well, would have, could have.

Dr. COLLINS. This kind of a mask doesn't do a great job of protecting me against somebody else who's near me. It still allows enough air flow around the edges——

Senator KENNEDY. Well, isn't some mask better than no mask?

Dr. COLLINS. I'd say this is better than no mask in part because——

Senator KENNEDY. How come we didn't tell the American people from day one that, look, you may not be able to get an N95 but some mask is better than no mask? Don't you think it would have been better if we had gotten it right initially to convince people now to wear a mask?

Dr. COLLINS. Again at the beginning——

Senator KENNEDY. I'm not just picking on you but you happen to be here.

Dr. COLLINS [continuing]. Senator, I don't think we realized the risk of asymptomatic people spreading this and we thought that if you were around people who were healthy, you weren't going to catch this. If you went into a sick bed, you might need to worry about it and then we learned otherwise.

Senator KENNEDY. The doctors and nurses on the front lines got it.

EXPEDITED VACCINE TRIAL SAFETY

Let me ask you one other quick question. Just give me a yes or no. I think you're all going to say yes. Is the expedited process for developing and testing therapeutics and vaccines safe that we're using right now?

Dr. REDFIELD. Yes.

Dr. DISBROW. Yes.

Dr. COLLINS. Yes, I would roll up my sleeve.

Senator KENNEDY. Well, how come we don't always use it then?

Dr. COLLINS. I think we do. I'm not sure of the question. I'm sorry.

Senator KENNEDY. Well, we're going faster than we normally do, right?

Dr. COLLINS. Yes.

Senator KENNEDY. How come we didn't always go faster and will we go back to doing it the old slower way once we're past the pandemic?

Dr. COLLINS. I think we talked about we are spending a heck of a lot of money by going really fast and doing things that are probably ahead of where they should be and running the risk therefore of needing to throw out a lot of materials that we don't use. We can't usually afford to justify billions of dollars in this circumstance but this time, we can, given the public health emergency and people are dying.

Senator BLUNT. Thank you, Senator Kennedy.

Senator KENNEDY. Thank you, sir.

Senator BLUNT. Let's go back to Senator Baldwin and about half of your time is still left, Senator.

Senator BALDWIN. I'm not sure what happened. So this is my question with Dr. Disbrow and perhaps also address it to Dr. Collins.

Are we considering any vaccine candidates where the delivery method would be something other than syringe and needle?

Dr. DISBROW. So not at the current time but there are products——

Senator BALDWIN. Okay. Thank you.

VACCINE DEVELOPMENT AND SMALL BUSINESSES

Let me move to Dr. Collins. I know that a lot of the companies that are catching the most attention are very large scale with the capacity to produce in large quantities, but some innovation comes from very small companies. I know Wisconsin has a number of small biotech companies that are working both in the vaccine space and in the treatment space.

What can you tell me about their opportunities to participate?

Dr. COLLINS. Senator, there were more than a hundred vaccine opportunities coming forward and, of course, we had to because of the public health emergency choose the ones that had the best chance of being able to scale up really rapidly, but there are lots of great ideas out there about vaccine development which might not be the ones that you want to bank in for SARS–CoV–2 right now because we have such a sense of urgency but this is not the last time we're going to face an infectious disease and so I hope all of those ideas will continue to be developed for whatever comes next or perhaps if we end up in a circumstance where this vaccine is needed to have a booster down the road, this virus doesn't seem to be completely vanquished, some of those ideas could be helpful. We just had to prioritize in this circumstance.

Finally, I would say in terms of small businesses, Senator Alexander was asking earlier about diagnostics for the RADx Program, which aims to try to bring on some great ideas about new ways to do diagnostics at point-of-care, of the more than 560 applications we've gotten, two-thirds of those have been from small businesses virtually from every State in the country. So in that space, there's been a wonderful opportunity for innovators to come in and have a chance to be scaled up rapidly.

VACCINE DISTRIBUTION PUBLIC PLAN

Senator BALDWIN. And final question for Dr. Redfield. With regard to a master plan for vaccine development and production and prioritizing initial delivery, can you let me know how far along we

are on a plan that all of us will be able to review in writing, particularly with regard to the tail end of when it is available, who will it first be made available to, because I think that is something that we really need to see.

I know there's an ongoing set of panels and experts who are tying themselves to these decisions, but I want to know the timeline for such a written plan.

Dr. REDFIELD. Thank you very much, Senator. You are right that a number of us are working on this plan. Unfortunately at this moment, I can't tell you exactly when we're going to have a plan released, but I can commit to you that we will, when we've completed the plan, have a plan that will be released, and as I said, part of the nuances of it is going to depend upon the actual vaccines, but the background plan independent of that is definitely being developed and working through and being coordinated through Operation Warp Speed.

But as I mentioned, CDC does have the lead on this distribution and as we get it completed, we will make it available.

Senator BALDWIN. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Baldwin.

I'm going to ask a question on the ethics and that discussion later. So you all might be thinking about that as you try to determine a priority of who gets access as access is available.

I'm going to go to Senator Murphy, Senator Schatz, and Senator Manchin, in that order, and then we'll start a second round.

Senator Murphy.

Senator MURPHY. Thank you very much, Mr. Chairman. Thank you all for being here and being so attentive to our concerns and questions.

First, let me just follow up on a series of questions that Senator Merkley raised. I don't have a question connected to it. It always puts me in an uncomfortable position to disagree with Dr. Collins and maybe I'm more disagreeing with your lawyers, but the United States Government has never exercised march-in rights under a contract and so it is true that there is a lot of question and dispute regarding exactly what the government is allowed to do but the language in the underlying statute is in fact very broad.

It requires companies who sign contracts with the U.S. Government to provide these drugs upon reasonable terms and there are plenty of legal scholars who read into that term price, that if you are gouging consumers, then you aren't offering the drug on reasonable terms, and so I would disagree with any guidance that's being given that says the government cannot use that underlying statute, the Dole-Bayh statute, as a mechanism to prevent price gouging, and I frankly think it's been a real success of the pharmaceutical industry to get lawyers to make recommendations that provide that kind of limitation. I think it's really concerning that that language is not in many of these contracts that are being signed by the government today.

That's, I think, important to say, but, Mr. Disbrow, I had one particular question that arises out of concerns that have been presented to be by smaller and medium-size drug discovery companies in and around the Northeast.

BARDA CONTRACTS WITH SMALL BUSINESSES

I've had a number of smaller companies, but companies with track records of success, who have tried to be in contact with BARDA and have received absolutely no response and given these concerns about cronyism and the potential track record that I think deserves investigation regarding companies that are big and multinational and have connections to people inside BARDA getting preference, do you think you have the resources to field inquiries and respond adequately to every company that may have a promising proposal to make to you because it does concern me to have heard from many very good companies in my State and my region who have been, frankly, completely unable to get any response from BARDA.

Dr. DISBROW. Thank you, Senator. I appreciate the question and also the comment.

So as the new Acting Director of BARDA, I am committed to doing a much better job. In a typical year, we are able to interface with multiple companies. We hold approximately a 150 to 200 Tech Watches each year where companies can actually come in and speak with us about their technologies.

As I mentioned in my opening statement, to date we have received 3,394 submissions that we are trying to get through so that they receive a fair evaluation and we are working as quickly as possible.

So under normal circumstances, I think the answer is yes, we are always looking to bring on new and bright and talented people, but we are a bit overwhelmed right now, but we are still working through the process. We have had over 391 Tech Watches, our Corona-Watches, where companies—it's a virtual Tech-Watch now, not an in-person Tech-Watch, but we continue to strive to improve our best business practices.

Thank you.

Senator MURPHY. Well, I appreciate that answer, and I hope that you will make recommendations to us on what additional resources we can give you because it would be absolutely tragic for a small or medium-size company who might have the key that unlocks a treatment or a vaccine to be left on the outside here.

CDC GUIDANCE ON SPORTS EVENTS

In the remaining time, I'm going to take the bait from Senator Alexander. As he knows, I care a lot about college sports as a fan but also as someone who wants to make sure that we start playing games in a way that's safe for especially college athletes who receive no compensation to go out there and frankly make billions of dollars for other adults and so my question is to you, Dr. Redfield.

Has the CDC given recommendations regarding whether it is appropriate to have fans in attendance at either college sports games or professional games this fall? I can see having enough resources to be able to test athletes, but we certainly don't have the resources to test every fan that walks into a crowded stadium and even a college stadium that's one quarter full still has tens of thousands of people in close proximity with each other.

Has CDC released any guidance with respect to attendance at sporting events?

Dr. REDFIELD. Not directly, Senator. We have had interactions with most of the sports industries, both at the professional, collegial level.

Senator MURPHY. Why not? Why not? That's a really important question. Should we put 20,000 people in a college football stadium? Why haven't you released that information?

Dr. REDFIELD. Well, I guess I misspoke then. I thought if you thought we directly recommended that we have fans. We have put out our guidance several weeks ago on mass gatherings, which would include obviously those events, and we have obviously commented directly in our guidance over the last 3 or 4 months on gathering size and precluded fans from going to—being recommended in these sporting events.

I was looking at the other way around. Did you think we made a positive recommendation to include them? So clearly in our mask guidance and clearly in all of our previous guidance to slow the spread and for the 15 and then 30 days, we've not recommended these gatherings to be such that you would have fans in the stands.

Senator BLUNT. Thank you, Senator Murphy.

Senator Manchin.

Senator MANCHIN. Thank you all for being here. It's good to hear from you.

I'm just trying to—Dr. Disbrow, just a simple explanation. Of the money that we've invested so far, and I know—my tally shows Johnson & Johnson got 456 million, Moderna's got 483, AstraZeneca was 1.2 billion, Emergent BioSolutions 628. That was all for developing vaccines. That comes out to about $2.76 billion, and then for distribution and manufacturing, ApiJect got a 138, Corning 204, Valor Glass 164, SIO2 Materials Science 143, for a total of about $650 million. So when you put it all together, you're up at around 3–34, in that neighborhood so far.

TAXPAYER INVESTMENT INTO VACCINE

What do we get back as taxpayers when this vaccine, when one of these companies or all these companies have a proven vaccine? Are we like a private investor from the Federal Government? Do we get something in return? Do we get this value back as far as in the vaccine that can be distributed to all of our health centers or do now we have to buy it back?

Dr. DISBROW. So there will be future procurements of the vaccine, but to address your specific point, yes, we do receive—so when we are doing contracting for acquisition, we seek consideration to the U.S. Government for our previous investment and it's more than just a dollar-per-dollar investment. It is also the cost of capital because the U.S. Government took the risk to make that investment.

Senator MANCHIN. Right. I mean, we're taking the risk the same as the private sector. We're taking the risk, right?

Dr. DISBROW. Correct.

Senator MANCHIN. So private citizen would take this type of risk, they get a bigger return for the risk——

Dr. DISBROW. Right. So our investments would be taken off the——

Senator MANCHIN. Our investments are part to what the private would make as far as the return back?

Dr. DISBROW. No. So if the company was going to charge $10 for a dose of vaccine, this is just an arbitrary number, I'm not saying anybody's charging $10 a dose, for, you know, sale outside the United States, in the United States, the U.S. Government would buy it at a reduced price because we've already invested $450 million, you know, to support the research.

Senator MANCHIN. Okay. So basically we're going to get our value back?

Dr. DISBROW. Correct.

Senator MANCHIN. Okay. And are we able to control any of the pricing on this, too, or be able to put pressure on them not to gouge?

Dr. DISBROW. So again whenever we are negotiating, we always negotiate best value to the U.S. Government. We seek consideration. I mean, these are hard negotiations we have.

Senator MANCHIN. Sure.

Dr. DISBROW. But, yes, we seek best value to the U.S. Government.

Senator MANCHIN. Well, and I know you already touched on basically how we're going to get—PPEs didn't get out the way they were supposed to get out as far as we still have a few problems there, and we're concerned about getting distribution, and I know you all spoke about the community health centers, Dr. Collins and all that, and I appreciate what you all have done there.

But I can tell you they're still hurting very much so because a lot of the States have not distributed the money that they received as help from the CARES package to keep them viable and there's money there that hasn't been distributed properly and we all should be putting pressure on our governors to do their job to make sure our first responders and our county health departments have the necessary funds and they're not getting it, I can assure you.

RURAL DISTRIBUTION OF VACCINE

Rural health. Rural providers have been hit particularly hard by the epidemic across the United States. COVID–19 are growing faster in rural areas at 13 percent than the national rate of 9 percent for the second week in a row. Rural counties have had the highest number of new cases of COVID–19 in a 7-day period since the pandemic began. West Virginia saw its single-day high just yesterday.

So we have 12 hospitals and all of our hospitals are rural. 12 hospitals already closed, three in West Virginia, and we're concerned about the rural healthcare that we have to distribute.

How's the vaccine going to be distributed in the rural areas to make sure that we're able to meet the rising challenges that we have there, rural providers have the necessary equipment or they have the personnel to administer the vaccine?

Dr. REDFIELD. Thank you, Senator. Really, really important question, as you know, in the broader question of how we maintain health capacity in Rural America.

As I said, there's going to need to be a variety of innovative strategies to ensure that we can get broad distribution, particularly the groups that have been under-vaccinated. You mentioned the rural. We've also had under-vaccination historically in African American and Hispanic populations, and, you know, we need to more aggressively—in the H1N1, there was reluctance to fully engage the pharmacies and those opportunities as vaccine outlets. Clearly we need to expand that in this distribution.

There is going to need to be clear inter-linkages, as you mentioned, with the community health centers that are there and augment them to be part of it, along with the local health departments, but, in addition to that, I think there's going to need to be mobile units that are going to be able to go and provide broader vaccination access, particularly in Rural America.

Senator MANCHIN. Let me just say—my time is up—Rural America basically is getting hit hard now. We knew it would be a delayed reaction of how they're getting hit, but we have the most vulnerable population in the country in West Virginia because of our age and the type of hard work that they've done. So they have underlying health conditions, too, and if it hits, it's going to be of disastrous proportions.

So we need to stay ahead of that and right now we had a hard time getting everything else. If we have a hard time getting a vaccine or an antibody when it comes, we're really up the creek. So we hope that you put the attention towards rural and make sure that your associates understand the need for rural.

Dr. REDFIELD. We're committed to make sure that all those in need get access to this vaccine.

Senator MANCHIN. Okay. Thank you.

Senator BLUNT. Thank you, Senator Manchin.

PRIVATE PARTNER OBLIGATIONS

Dr. Disbrow, let's talk a little more about any obligation these companies we've partnered with have to be sure that the vaccine is available at a reasonable price. If they fail, we underwrite their failure for that. I want to get plenty of opportunities out there on the field advancing forward so that we have as many vaccines as we can have available as soon—as many of the individual vaccines available as soon as we can, but if we're successful, we basically get our money back, plus interest.

Are there—surely there are other obligations here in that partnership of the private partner to make the vaccine available in a reasonable way. Would you expand on that a little bit?

Dr. DISBROW. Sure. And thanks for the question, Senator.

So also remember that, you know, each of the companies that we're working with, it's a true partnership. The U.S. Government has assumed risk. Many of the contracts that we have are cost share contracts, meaning that the company also assumes risk.

The companies, while we're working on, you know, awarding the contracts that I mentioned earlier, are agreeing to proceed at risk under Operation Warp Speed because, you know, they're committed to developing a vaccine, but, yes, the goal is to negotiate the best price for the U.S. Government.

We would probably have to pay a slightly higher price for industry partners who chose not to receive government funding because they assumed a hundred percent of the risk.

VACCINE DISTRIBUTION AND HEALTH PRIORITIES

Senator BLUNT. All right. Dr. Collins, so what's going on, and others can enter into this discussion if you want to, but in terms of determining the health priorities—or we should be doing this right now. We know we're eventually going to have a vaccine. We know we'll have therapeutics.

Let's focus on where we're going to be with the vaccine in terms of distribution and accessibility. Who's talking about health priorities or ethical issues that relate to the rapid opportunity for people who want a vaccine to get a chance to have the vaccination?

Dr. COLLINS. So a very important question and one that is occupying the minds of a lot of us, thinking about this future that we hope to have as soon as possible.

You've heard Bob Redfield talking quite a bit about what CDC's role is, which is absolutely central in terms of this distribution effort, but I think there may also be an opportunity before we get to that moment where we actually have a vaccine that has been proven safe and effective to have a broader discussion that brings into this ethics experts in public health, people who are particularly aware of the challenges for reaching out to those who've suffered from health disparities for a long time and are being hit particularly hard by COVID–19 is another area where we want to be sure as far as priorities. That is considered in a big way.

Bob Redfield and I have talked a bit about this. This may be a moment to actually bring together a group of such big thinkers who could take a high-level view of this and lay out a foundation of principles that then could be utilized by his CDC committee, the ACIP, when the moment comes to actually turn that into an implementation plan.

We think that that might be something best done in a circumstance by an organization that is not itself governmental because it's still the case, I think, that people are a little uneasy about the government calling the shots here and so we are having a conversation very early on with the National Academy of Medicine about whether they would be the place to convene such a discussion.

We can keep you posted on that. It looks pretty promising. I personally think that would be a really good step right now and to do that quickly and have those principles laid out, say, before Labor Day.

Senator BLUNT. I'm confident we'll hear from others about whether the National Academy of Medicine is the best place to do this or not and that's good. That input will be good and we'll share it with you as we hear it and you may hear it even before we do, but it does seem to me that this should be happening right now.

Just like every other plan about distribution of the vaccine, of therapeutics, of testing, but particularly the vaccine, I would think if we're going to have this discussion, let's not have it after we have a vaccine and we're waiting to distribute it because we haven't had a discussion of the ethics or healthcare priorities.

Dr. Redfield, do you want to talk about this?

Dr. REDFIELD. I just wanted to make one comment, Mr. Chairman, because I couldn't agree with you more, but I do also want to say how important it is that we have it now because it's not just about who's going to get the vaccine. It's also about we have a requirement to study the safety and efficacy of the vaccine in these populations.

Historically, if you have underlying medical conditions significant, you don't get into vaccine trials. If you have pregnancy, you don't get into vaccine trials. If you're a child, you don't get in vaccine trials, and I know Dr. Collins and I have discussed this, and I know they're planning to make sure these populations are included because the last thing we want to be is trying to recommend who gets the vaccine and we don't have any data on how the vaccine works in the population that we really think this vaccine needs.

So clearly right now, there's really thoughtful thinking among the vaccine trialists how do we make sure that we have good representation of African Americans, Hispanics, children, pregnancy women, individuals that are elderly that have multiple chronic medical conditions, because that's where this vaccine needs to go, and so I don't know if Francis wants to comment any more on it, but I know that they are thinking how to move those populations into the Phase 3 trial efforts so that we'll have that data when we need it.

Senator BLUNT. Dr. Collins, and then we'll go to Senator Murray.

Dr. COLLINS. Well, Dr. Redfield has said it well. This has got to be a really high priority. This may make it more challenging to run a Phase 3 vaccine trial when you're trying to enroll a very diverse set of volunteers.

It would be much easier just to line up a whole bunch of 20 somethings who happen to be from the white population, but that is not the only answer we need. We need to really have this diversity and many of us are working hard to make sure that as those trials get launched in the very near future that they have that kind of outreach.

Senator BLUNT. Yes. Well, let's be sure that the trials aren't needlessly waiting because we haven't had this discussion as quickly as we need to have it.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman, and that's exactly what I've been talking about, why we need to plan and why we need to see that plan and specifically the public needs to see this plan because even if everything goes well and we have a vaccine and it is safe and effective and to the best of everybody's knowledge, it isn't going to be available for everybody September 1st, and we need to know how it's going to be distributed, where it's going to go, what the priorities are.

The public is good at dealing with facts. They're not good at dealing with very high expectations that have no chance of being met and then we run into all kinds of problems. So that's why I have been pushing for a public plan for us to see it and for us to be able to know how this is going to happen. So I'm in that game.

BARDA CLINICAL TRIALS FOR THERAPEUTICS

Dr. Disbrow, let me ask you. Experts are saying that clinical trials for treatments can move more quickly than vaccine trials and that an effective drug that renders the virus less deadly could allow us to begin to return to normal faster.

So I was concerned last month that BARDA abruptly notified researchers that it was halting funding for treatments for severe lung ailments that were associated with the virus as well as treatments that dampen the overactive immune response that causes the body to actually turn on itself.

I wanted to ask you why did BARDA decide that the development of therapeutics for severe forms of COVID–19 is not a priority and how did it communicate that change?

Dr. DISBROW. Right. So thank you for the question, Senator. Two-part response and I promise to be very quick.

So BARDA continues to invest heavily in therapeutics. We are investing in a collection of convalescence plasma supporting the very large expanded access protocol that you heard about before. Over 25,000 people have been transfused.

We're further supporting hyper immune globulin which is where you take pooled plasma and further process that to concentrate the antibodies, and we're also supporting neutralizing monoclonal antibodies. All of that is being done under Operation Warp Speed, similar to what we're doing for vaccines.

We did close the immunotherapeutics portion of our broad agency announcement because at the same time, under Operation Warp Speed and in collaboration with Dr. Collins' active program, what we were receiving were individual proposals with no clear identification that the products would work as an immune modulator but requesting very large Phase 2/3 studies.

So under the active partnership and with OWS, the decision was made to stand up large clinical trials, a clinical network, under a master protocol where you can evaluate multiple candidates for immune modulators and they will also be looking at anticoagulants, as well, in a smaller cohort to determine if there's clinical benefit.

If any of these drugs that are run through the active protocols show clinical benefit, we are happy to engage with those developers to help them with manufacturing.

Senator MURRAY. So it was also reported that BARDA's suspending applications for the development of preventive treatments for COVID–19. Can you explain that?

Dr. DISBROW. I'm sorry. I didn't hear the question, the last part.

Senator MURRAY. It was reported recently that BARDA is suspending applications for the development of preventive treatments for COVID–19. Explain that.

Dr. DISBROW. So preventive therapeutic treatments?

Senator MURRAY. Correct.

Dr. DISBROW. So I will have to look into that and get back to you. I apologize.

Senator MURRAY. Okay. Well, vaccines are important. We all want that, but I think that we can't put all of our eggs in one basket, especially since we know there's no effective vaccine yet and we've seen issues in the past where it's hard to develop. We all

want it, but we can't put all of our eggs in one basket. So I am concerned and I will be following that.

NIH CLINICAL TRIAL DIVERSITY EFFORTS

Dr. Collins, I want to direct a question to you. Given the devastating impacts of COVID–19 on black, Latino, Tribal communities, it's so important that we ensure equitable representation in our clinical trials for vaccines and therapeutics.

There was an internal analysis on inclusion that showed that only 29 percent of participants in NIH-funded clinical research were members of racial minority groups, only 9 percent were ethnic minorities, and initial reports suggest we're still not achieving adequate enrollment for these groups in clinical trials for potential COVID–19 treatments and vaccines.

Can you tell us what NIH is doing to reduce the barriers for participation and recruit people for these?

Dr. COLLINS. Senator, I really appreciate this question. This is an extremely high priority. As has already been pointed out at this hearing, the burden that has been laid upon the shoulders of minority groups, particularly African Americans, Latinos, and Native Americans from COVID–19 has been extreme with much higher rates of hospitalization and death in those groups and that means that the health disparities that we have known, been around for a long time, have a very bright light now being shown on them, and this is our opportunity and our responsibility to take this on with the greatest seriousness.

Certainly when it comes to running the clinical trials, both for vaccines and for therapeutics, this will be the highest priority. We want to work with the parts of NIH that have expertise in this space, like the National Institute of Minority Health and Health Disparities, but we also want to work with the institutions out there, like the HBCUs (Historically Black Colleges and Universities), that have that kind of credibility and capability.

There's an irony here in that we're also at a moment, I think, where there is perhaps more suspicion about government involvement in such things and yet this is the very moment where we need to have the trust of those communities to reach out to them and that means we need to engage community leaders in that space. That means the churches. That means the heads of various organizations that represent these underserved populations.

We are building all those bridges as fast as we can and I totally agree with you. If we fail at this at this moment where health disparities have emerged in such a dramatic way, we will have really failed to live up to our responsibility as stewards of the public trust.

PREGNANT AND LACTATING WOMEN IN CLINICAL TRIALS

Senator MURRAY. Mr. Chairman, let me just ask one quick follow-up on that because there was a recent report from CDC that pregnant women are more likely to be hospitalized with COVID–19 than non-pregnant women and despite a lack of data, it's clear women of color are disproportionately at risk. So I'm really concerned about the lack of inclusion of pregnant and lactating women in COVID–19 clinical trials.

Are you going to follow the FDA guidance by including pregnant and lactating women in clinical trials in COVID–19?

Dr. COLLINS. Absolutely, and you may know we've had this committee, the PRGLAC Committee, that has been looking at ways that we could have more inclusion of pregnant women and lactating women and it applies very strongly in this place.

This is another high priority at NIH. Dr. Diana Bianchi, who's our Institute Director for Child Health and Human Development, has been a leader in this space. We are trying to put together some additional research efforts to try to improve the ability to do successful outreach safely to pregnant women and lactating women. We have to have that included as part of this mission.

Senator MURRAY. Thank you, and thank you for indulging me, Mr. Chairman. Thank you.

Senator BLUNT. Thank you, Senator Murray.

Senator Alexander.

Senator ALEXANDER. Thanks, Mr. Chairman.

Dr. Collins, I believe you said that you're considering involving the National Academy of Medicine in determining the fairness of the distribution of vaccines, is that correct?

Dr. COLLINS. That is correct.

Senator ALEXANDER. The National Academy describes itself this way. If I remember, it was founded by President Lincoln, chartered by the United States Congress to attempt authoritative, objective, and scientifically-based answers to difficult questions of national importance.

The *New York Times* called the National Academy of Medicine, "The United States' most esteemed and authoritative advisor on issues of health and medicine."

So put me down as thinking that's a good idea to involve because as people across the country look up at what's happening here, they'll see agencies with alphabetical names and they may be greatly respected agencies or bodies, but I don't believe they have the prestige of the National Academy of Medicine.

So in terms of the fairness of the distribution, I think the only downside I can think of because I've worked with the Academies many times, you may have to speed them up a little bit because the Academies are accustomed to not moving at warp speed and you're trying to move at warp speed, but we're not talking about safety. We're talking about fairness. I think that's a good idea and I would endorse it.

Now let me move on to something else, Dr. Collins. I want to pick up words that either you or Senator Moran said, something like sustaining what we've built. We had a whole hearing about this in our committee that Senator Murray and I chair, the Health Committee.

For 20 years, we've had four presidents and several Congresses past nine laws and try to be prepared for pandemics and we thought we were and then we get assaulted with this sneaky, dangerous COVID–19 virus, and we find gaps that didn't happen.

Senator Frist, the former Majority Leader, testified before our committee. He pointed out that he made 20 speeches when he was the Majority Leader identifying exactly what needed to be done,

tried to do them, but in between pandemics we got our eye off the ball. We have other things to do and we don't do the hard things.

So it seems to me that I'm going to work hard with Senator Blunt, Senator Murray, anyone else, Senator Shelby, others, to try to make sure that we don't make that mistake this time and that while we've got our eye on the ball, while we're paying attention, while we have these lessons in front of us, that we deal with them.

For example, manufacturing. We're building up capacity. We're building up onshore capacity, BARDA says. Well, are we going to sustain that or are we just going to let happen to it what Governor Leavitt testified happened with the last manufacturing plant Stockpiles?

We know what happened with the stockpiles. They diminished. Hospitals and States sold them off. They didn't have the money to keep them up.

Data. We're not all happy with the way data is being aggregated by CDC and need to take a look at that. Are we going to wait until next year when we're worrying about something else? Are we going to do it now?

Hospital preparedness. We're getting our hospitals prepared again, but are we going to sustain that for the next pandemic? This is not the last sneaky, dangerous virus that's going to assault our people.

State and local support for public health. Governor Leavitt, the former Secretary of Health, former governor, said for 30 or 40 years, as Dr. Redfield has said, we've gradually underfunded public health. So we're not as prepared as we think we are when we're assaulted by a virus like this.

FUTURE PANDEMIC PREPAREDNESS

So I would like in my remaining moments, Dr. Collins, to have your comment on the importance of, in the middle of this pandemic, sustaining what we've built up for the next pandemic because I'm pretty sure, based on my experience, that if we wait 6 months and everything is over and we're back to normal, we'll be worried about something else and we won't make the difficult funding decisions, which most of them are, on manufacturing stockpiles, data, hospital preparedness, and State and local public health.

Dr. COLLINS. Well, I'd love to capture the words you've just spoken and try to be sure that we all look at those every month or so after we get through this current crisis, which we will, but our track record's not so good here.

We don't really think about this as sort of we need an insurance policy against the next pandemic. We would never think about going bare in terms of insurance for our homes or our cars, but we've gone bare too often in terms of insurance against pandemics, which requires that sustained investment.

You've enumerated quite nicely the areas that have been allowed to slip in between these episodes. We might have a COVID–23. Who knows what the next coronavirus is. Or we might have an influenza that comes, which is sort of overdue now, and my sincere hope would be, given that this has been, after all, the most serious infectious threat in the lifetime of any of us, that this time we

would have a little sustained memory and I for one would very much like to help with that, too.

Senator ALEXANDER. Thank you. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Alexander.

Senator Moran.

Senator MORAN. Mr. Chairman, thank you very much, and I have been listening in my office to all of the hearing today, but I'm glad I was here in person to hear what Senator Alexander just said and, Lamar, while your tenure in the United States Senate is coming to an end, I hope your voice on this and many other things does not cease.

Senator ALEXANDER. Thank you.

Senator MORAN. What you just said is important for us and for the American people to hear and I appreciate how you've conducted yourself always, but what you had to say today was especially valuable.

ONGOING RESEARCH DURING THE PANDEMIC

Dr. Collins, I promised I'd come back to ask you a question. It deals with the consequences of the pandemic on research that was ongoing pre-pandemic and so I'm worried. This subcommittee, this Appropriations Committee, NIH, our colleagues in Congress have highlighted the importance of NIH research and in many instances have put our money where our mouths are, and I'm worried that we have set the stage for a step backwards rather than a step forward as a result of the virus.

And so my question is, that you can discount that if that's not true, but my impression is that research that should be ongoing today is not, that laboratories are not at capacity, many are shut down. People have not been able to come to work.

I don't know prevalent that is in university research versus in institutions in Maryland, but what is it that we need to know to make certain that we provide the resources perhaps in a Phase 4 that would quickly restart the capabilities of NIH to be on the path toward finding the cures to all the things we want to cure?

Dr. COLLINS. Senator, I really appreciate your asking the question. This is very much on my mind as I see the way in which, by necessity for safety reasons, so much of our research enterprise, not just at NIH and our laboratories in Bethesda but all over the country since that's where most of NIH's dollars go, has been very much scaled back.

Any research that involved something other than COVID–19 was pretty much put into a very slow pace because people needed to head home to protect against the further outbreaks and people were still able to do science and many of them have worked incredibly hard doing what they can do, but if you need a lab bench and you need some equipment and some supplies, you can't do that in your dining room.

So it is fair to say we have lost a lot of time with research that required that kind of action, whether it's in cancer research or something to do with gene therapy or a diabetes project, like in my lab because all of my people had to go home, too. This has been a major negative consequence among many others of COVID–19.

We do not want to see that have a lasting impact. I will tell you the universities who are our major grantees are hurting bad right now because of the way in which this has hit them financially. They both had the difficulty of not being able to conduct research that they thought they were doing but, of course, many of them have medical centers that have been hemorrhaging money because of the inability to do elective surgeries and other procedures that would normally allow them to balance the books. They're in deep trouble.

We have estimated just on the basis of the research that's been lost something in the neighborhood of $10 billion of Federal funds that may be necessary to recoup if we're going to bring these institutions back up to where they need to be.

On top of that, I think there's a wide variety of areas that NIH—my watch is talking to me, thinking I'm talking too long—a wide variety of areas that NIH really would like to also put more efforts into to compensate for this in terms of our efforts in COVID–19.

So, yes, we have been very interested in hearing what might be possible in terms of that compensation and I know the institutions who are grantees are particularly so, probably including in Kansas. I would be surprised if you've not heard from the leaders there about the situation they're in.

Senator MORAN. Doctor, thank you. You know, I don't know how many times I've asked you when are we going to be able to delay the onset, when is the research going to be sufficient to delay the onset of Alzheimer's? When are we going to be able to rid ourselves of diabetes, and you have in your ways tried to tell us the timeframe on which things seem to be on, and I worry that if we ask the question today it would have to be a timeframe that is much shorter and while the pandemic is certainly severe and serious, a crisis in many ways, the cure for cancer, the ridding ourselves of diabetes and Alzheimer's is so significant, as well,——

Dr. COLLINS. It is.

Senator MORAN [continuing]. That we cannot now allow this circumstance to keep us from being on the path necessary to do the things that we've set out to do.

Dr. COLLINS. And, Senator, I want to assure you NIH is doing everything within our power to allow flexibilities amongst our grantees in terms of ways that they can keep things going. Young investigators can have an extension on the time-table for their career next step and all of that. But it is still a heartbreaking situation to see the consequences.

Senator MORAN. Since I used most of my time to brag on Senator Alexander, I'm going to try to get another question in and that is, we see and hear Dr. Fauci regularly, and tell me about the other institutes at NIH. What else—I didn't mean to discount him.

THE ROLE OF INSTITUTES AT NIH DURING THE PANDEMIC

My actual question is, what do the other institutes have to do with the pandemic? It wouldn't just be Infectious Diseases that are trying to help us solve this problem. I assume NIH across the board is engaged fully.

Dr. COLLINS. Absolutely. I convened all of the institute directors back in March and said what could we do collectively that just one

institute can't do, although certainly Tony Fauci's institute is in the lead, and every single one of our 27 institutes and centers has a significant role they would like to play, some of which they don't have resources for but hope that perhaps it might be possible to obtain them, such things as the Heart, Lung, and Blood Institute.

Since this is a lung disease and they're actually running a trial right now of anticoagulants because that is the place, Heart, Lung, and Blood, where they have their greatest expertise to be able to see if that can help people who are the most ill patients on ventilators and ICUs.

The Genomics Institute is trying to figure out what's the difference between individuals that predicts who's going to get really sick after an exposure and who kind of shrugs it off. There's probably some big story to be learned there that could be useful even in terms of figuring out who ought to be the highest priority to get a vaccine.

I mentioned already Child Health and the importance of worrying about kids but also about pregnant women. Certainly the Health Disparities issues that you've heard about are absolutely pressing and we have expertise in that space, as well.

So it is all hands on deck with people designing programs, trying to figure out if there are ways that they can reallocate dollars in the very rapid turnaround and hoping there's a way that they can expand that because of the great needs.

So thanks for the question. It is very important and very much on everybody's minds at NIH.

Senator MORAN. I've utilized more than my good will. So I can't ask anybody else any other questions, but, Dr. Disbrow and Dr. Redfield, I have issues and things I'd like to discuss with you and I look forward to doing that when it becomes possible.

Senator BLUNT. Senator Kennedy.

Senator KENNEDY. Thank you, Mr. Chairman.

Gentlemen, I want to thank you for being here today. I want to thank you for your hard work. I know you've been under a lot of pressure, and I know this has been a learning process and we're learning more each and every day.

I don't know whether we're in the middle of a new surge or the first surge never ended. It doesn't really matter. But the American people are scared. They're scared not just about their health and their families' health. They're not just scared about dying. They're scared about their job. They're scared about their country. They're scared about their world. They're scared about their church.

This is overwhelming for all of us, but they are really overwhelmed, and they're not morons. They're very intelligent. They don't have time, of course, because they're too busy earning a living to read every day on the latest information.

I want to echo my colleagues and strongly encourage you at some point to, if you haven't already, prepare a report but also with your other colleagues, perhaps Dr. Birx, Dr. Fauci, set aside some time to talk straight to the American people, tell them the truth, as I know you will.

Under promise, over deliver, no spin, explain where we are on vaccines. I'm encouraged by the progress that's been made. I think the speed is breathtaking. I'm impressed that the whole world's

working together and explain where we are in terms of delivering that vaccine, if we develop it.

You may have to do this in several different reports or press conferences. I know this is an easy thing for me to suggest. There are others that will have input in terms of you holding a press conference, but I would do the same thing about therapeutics.

As I've said a number of times, people aren't afraid of getting sick, they're afraid of dying, and nobody wants to get sick but people would feel a lot better if they knew if they got sick they're not likely to die, and I know they're not likely to die but many people don't understand that and that's where the therapeutics comes in.

I would also encourage you to talk frankly to the American people about what they can do to make themselves as safe as possible. It's been a lot of misinformation about social distancing and masks. I think the information has been pretty consistent about good hygiene, but you gentlemen and others have credibility and I would strongly encourage you to do that.

I want to thank you for your service. I mean that. Give the American people some hope but tell them the truth, and I think there is hope out there.

The other issue I wanted to talk about but I'm not, will save it for another day, we've got to get our kids back to school. We've got to do it and we need your help figuring out how to do it safely.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Kennedy.

I did notice a major pediatric group came out yesterday talking about for nutritional reasons, for socialization reasons, for the sanity of their parents, kids need to get back to school. It'll be the most likely touchstone that things are returning to normal if we can get that done.

TESTING FOR SCHOOLS TO RE-OPEN

So, Dr. Collins, on the testing area, I'm concerned the dates I'm hearing don't seem to quite match up with the millions of school kids and college kids taking tests multiple times when school starts that would be easily taken and quickly responded to. Do you want to talk about that for me just a little bit more?

Dr. COLLINS. I'll try. So currently the way that testing has been progressing, you've seen substantial increases across the country now to the point where there are more than 30 million tests have been administered and we're at the point now where between half a million and a million tests are happening each day.

But as I said earlier, many of those are circumstances that require a central laboratory and where the results may not come back for a day or two or three.

What we're trying to do with RADx is to greatly enhance the ability for those kinds of point-of-care tests to be there. We are both looking at platforms that go into the Shark Tank and then have the opportunity for rapid expansion.

We're also looking at a few things that are a little bit more advanced but not advanced enough. They sort of bypassed the Shark Tank and go to the next phase in a program called RADx ATP for Advanced Technology Program.

Some of those are also looking promising and we are doing everything we can to pull them up into a higher throughput space. Again, we had said if this went really well, we'd have millions more of tests per week by the end of the summer, beginning of the fall.

I'm talking to Bruce Tromberg, who's the Director of RADx and a very gung-ho engineer, as you know from having met with him. He believes that we could get to the point of an extra one million tests per day just from the RADx Program by the first of September, by Labor Day. That is a heck of a stretch since we started this program at the end of April but that's the trajectory we're on.

But that would go fairly steadily upward then over the course of the next 2 or 3 months. So it might be more in the neighborhood of five to 10 million additional tests per day by December. That's our current projection, again taking the exhortation from Senator Kennedy about sort of under promise and the over deliver.

I'm not trying to tell you what I think the absolute most amazing outcome would be. I think I'm trying to tell you what we could achieve and then hold us accountable and see if we can do it.

COST OF TESTING

Senator BLUNT. From elementary school to big university to an employer, are you thinking about cost as one of the things you're looking at? I don't think these can cost $50 a test or a $120 a test. I think we've got to be very cost conscious here in what we encourage.

Dr. COLLINS. That is absolutely part of the way each one of these platforms is being assessed and if you have something that's like really cool technologically but it costs a hundred bucks, it's not clear to me that that's what we should be investing in right now.

Now, of course, there are oftentimes where somebody says it's going to cost a hundred bucks and once you actually get the Shark Tank folks involved, you find you can drive that price way down.

VACCINE DISTRIBUTION MANAGEMENT

Senator BLUNT. Right. Dr. Disbrow and Dr. Redfield, I heard Dr. Disbrow, in responding to another question, brought up the reality that when you have a vaccine, you have to have a package that will house that vaccine to be administered.

I can't imagine the outrage if we had a vaccine and we need, let's say, a handful of items to be able to give that vaccine and we only have four of them. I can't imagine how aggravated people would be starting right here if somehow we're not totally prepared for that.

Tell me whose job that is to be sure that we have all of that in line so that not only can the vaccine be developed and delivered but we have everything we need to be sure it can be administered.

Dr. DISBROW. Correct. Thank you for the question. It is important to have an end-to-end plan for vaccine development and delivery and so right now under Operation Warp Speed, the Strategic National Stockpile is working on the kitting of the vaccine—sorry—the——

Senator BLUNT. I understand.

Dr. DISBROW [continuing]. Components.

Senator BLUNT. Go ahead.

Dr. DISBROW. They are the ones that are doing it, but again under Operation Warp Speed, it is a continuum. So the people who are developing the vaccines, those working groups are letting them know, you know, it's going to be a five-dose vial, so you would need to send out, you know, seven, you know, needles, seven syringes, seven band-aids, seven alcohol wipes because you have to have excess, overage, and we are all working together on that, but the SNS is putting together those kits.

Senator BLUNT. And who's responsible for that?

Dr. DISBROW. The Strategic Stockpile——

Senator BLUNT. The Strategic Stockpile.

Dr. DISBROW. Correct.

Senator BLUNT. Is it part of BARDA?

Dr. DISBROW. So it's part of ASPR, the Assistant Secretary for Preparedness and Response, but again under Operation Warp Speed, they are at the table as part of Operation Warp Speed.

Senator BLUNT. All right. We're going to ask some questions of them about this topic then.

Dr. Redfield, do you want to add anything to that?

Dr. REDFIELD. Thank you, Mr. Chairman. The only thing I would add because it is important, we've done pandemic exercises, you know, to prepare for pandemics, and we have identified, as you pointed out, that everything was fine but we didn't have enough needles or everything was fine, we didn't have enough vials. So clearly that's been taken into account here with——

Senator BLUNT. I hope so.

Dr. REDFIELD. But the other area I wanted to just emphasize once again is don't underestimate the importance of making sure we have the cold chain capability, depending on what the restrictions are of the product, that that product needs to be handled within that cold chain for that distribution.

Senator BLUNT. Right. And as I believe I understand what we're trying to accomplish here, these various vaccines would have different levels of what they need to have to maintain their efficacy and——

Dr. REDFIELD. That's correct.

Senator BLUNT [continuing]. Then—okay.

Dr. REDFIELD. That's correct. Some of them that are there are going to require minus 80, you know, which is a higher level cold chain requirement. Some may require less. So I just think it's important that we are preparing to make sure we have redundancy in our cold chain capability.

FUTURE SUPPLEMENTAL FUNDING NEEDS

Senator BLUNT. Dr. Disbrow, there may be more than one more COVID bill, but I think we should assume that between now and some time very late this year, there's probably one more chance to get this right funding-wise. How much money do you need?

Dr. DISBROW. So I can't go on the record and say how much we need, but we will work with Congress and through our ASFR colleagues, our Budget Office at HHS, as additional needs are identified to bring them quickly to you.

Senator BLUNT. Well, so you're going to work that up through the Secretary?

Dr. DISBROW. Correct.

Senator BLUNT. All right. We need to know that number and we need to know that number pretty quick and then we'll have a discussion about whether it's appropriate or not, but we need to be thinking about that.

Dr. Redfield, do you want to talk about this topic? What do you need to enhance the flu vaccines at a level we haven't been able to encourage people to take them before? What do you need to use that network to see what your plan might be 60 days later for a vaccine network? What resources do you need that you will not have unless we provide them?

Dr. REDFIELD. Thank you, Mr. Chairman. I want to echo one of the sentiments of Chairman Alexander. Just to go back to my view that now is the time to make the investment in the core capabilities of public health that this Nation not only needs but is deserves. That's a broad issue in terms of data modernization, the ability to have predictive data analysis, laboratory resilience, and the public health workforce.

In terms of distribution of the vaccine, largely one of our key responsibilities, I think it's just important for people to realize that distributing a new vaccine to everyone in this Nation is a complicated process and it is going to take resources. It's not measured in the millions, it's measured in the billions. It's not like we're just going to send the vaccine off to a bunch of doctors' offices and it's all going to happen.

So I do think it's important that we make that investment so that just like we're developing the vaccine at risk right now, when it's finished, the company's going to have enough to actually start to give it to the American public. We need the exact same thing for the distribution strategy that was commented by Senator Murray and others. That process has to happen now and it is going to take resources to build it.

Senator BLUNT. Well, absolutely. We know we're going to have to—we have confidence we're going to have a vaccine. We know it's going to have to be distributed. We need to figure out what that plan is. There's no reason for that plan to wait any longer than we have to, you know. We ought to have that plan put together right now that has the flexibility that allows you to deal with different vaccines from different locations in different ways, but right now is the time that ought to happen and whoever you need to work through to get the information we need about what that's going to cost, we need to know that in the next couple of weeks.

Dr. REDFIELD. Yes, sir.

Senator BLUNT. Dr. Collins, I think we put a billion dollars in Shark Tank and put substantial money at NIH for all of these various institutions to be looking at what they need to be doing. What do you need next?

Dr. COLLINS. Well, I appreciate the question and I'll consider this that you're asking for my professional judgment.

Senator BLUNT. I am. I am.

Dr. COLLINS. So I already mentioned in response to Senator Moran's question the desperate need that our grantee institutions have for what's happened as a result of COVID–19 and that the

loss in research capabilities adds up to about $10 billion. That's part of it.

We do have these Trans-NIH initiatives that have been developed over the course of the last few weeks that I do think would make major contributions to our advances here. There's about $1.6 billion in those projects that involve multiple institutes and another $2.2 billion for specific institute initiatives that I think have very high value.

Then on top of that, we also are thinking about whether there are ways that we could help with the economic difficulties in the country because NIH, every dollar we give out we know has a big stimulus for the economy, and we have an additional set of ideas there about things that would be shovel ready that would add up to another $5 billion. Those are the things we've been thinking about.

Senator BLUNT. Okay. And I think on the grantee front, I know we've been talking about the grants that are going to run out this year. Basically, they lost this year. An extension of those grants, some money to start laboratories back up, and some absolute authority that the grants you didn't get to determine this year don't get lost in this process and you have more time to do that. Would those three things all be correct?

Dr. COLLINS. That is very much correct and appreciate your being so on top of those things. They're going to matter a lot.

Senator BLUNT. Senator Alexander.

Senator ALEXANDER. Thanks, Mr. Chairman. It's been a very helpful hearing for me. I've learned a lot.

Dr. Collins, Nashville Metropolitan Schools start August 4 and so do a lot of other schools in the South. I know in the North they think that's uncivilized but that's what we do and so the relevance of that is to tests and treatments.

As I said earlier, we've had a lot of talk about vaccines. They're down the road. Tests and treatments are upon us and I get a sense, I can't prove it, but that we're going to really need those point-of-care tests you're working on and we're going to need them quickly.

I hear lots of anecdotal stories about lab technicians that are overworked, machines that are overworked, about people even in our State where the governor has said if you want a test, go down to your public health department and get it. I get conflicting rumors that some public health departments say only if the doctor, you know, says so.

I hear stories of delays of 3, 4, 5 days before the diagnostic test comes back and, of course, it's not very useful when it comes back several days late.

So what I'm getting around to is I want to underscore the importance of your point-of-care tests and I hope you will let Senator Blunt and the rest of us know if there's anything that we can do to accelerate your RADx effort because creating millions of new tests a day that are point-of-care rapid, quick, reliable.

Senator Blunt said our surest path toward normalcy is when 75 million students go back to school and college and it will build a lot of confidence in those schools and colleges if the schools and colleges can test as frequently as they want to, randomly or every class or every floor in a dorm or as the Brown University president

said, she wants to test every student before they come back. Okay. Most campuses aren't going to do that, but she wants to.

So if that's what builds the confidence to come back, your project is the answer to that, it seems to me, and I have the same confidence in it that I did earlier when Senator Blunt and others worked on it.

My other question is treatments. We're talking about going back to school. Having the point-of-care tests so you can test any student, any class, any teacher, whenever you want is one thing.

A second thing would be able to say, as I mentioned earlier, and to say in the preliminary meetings that come back to school. We're going to try to be open 5 days a week and we want to assure the teachers and the administrators and the parents and the grandparents at home that when you come back, there are some specific medicines that are going to be available that will help make sure that your illness is not as severe and that you're less likely to die.

CURRENT TREATMENT OPTIONS AVAILABLE

Could you take a minute and just quickly list those, two or three of them are already approved, two or three like the "antibody cocktails" are very promising, and what would those things do? I mean, like the remdesivir, if I've said that right, that I hear someone say that decreases by 32 percent the amount of time to recovery. That's important specific information to someone.

Dr. COLLINS. Right. Well, I totally agree with you. This is critical and it's a major part of Operation Warp Speed and I'm glad to say Janet Woodcock is now the leader of the Therapeutic Workstream for Operation Warp Speed, a very experienced scientist who knows how to get things done. It's a privilege to work with her.

Yes, remdesivir has been approved and it does reduce hospitalization and it had——

Senator ALEXANDER. So if I get sick, if I'm a parent, my kid comes home sick, is that available to me to help make my hospital stay shorter?

Dr. COLLINS. Remdesivir is produced by Gilead. The U.S. Government has recently acquired large numbers of doses to make sure it's available. It is intravenous. So this is something that you save for people who are in the hospital and who are pretty sick but that's where we know it works.

Senator ALEXANDER. Okay. What else would reassure me?

Dr. COLLINS. Dexamethasone, which is a steroid, was shown in a study done in the U.K. but we've worked closely with the U.K. all the way along and knew they were doing this, basically showed a significant improvement in survival of people on ventilators and also people who were not on ventilators but who were on oxygen. So that's now become standard of care. So we have those two.

But that's not nearly enough. We need to be able to push forward all these other things quickly that look like they could have promise.

The ACTIV Partnership that I described, public/private partnership, looked hard to see what would be the most important therapeutics to get prioritized because there were hundreds of ideas out there and then try to get those into clinical trials.

There is a trial coming soon of other immunomodulators, basically things to try to damp down the overreaction of the immune system that seems to happen in people who are very sick, particularly those in ICUs.

There is a trial getting started very soon on anti-coagulants because it's clear that this virus does something to make the blood overly clottable and so it clots in the lungs and other places and that can end up being a fatal outcome. We need to figure out how that works.

And then there are all these immune systems, like the antibody cocktails, the convalescent plasma, the hyper-immune globulin, all of those now being subjected to rigorous testing this summer, as well, in the United States.

Senator ALEXANDER. And there's a possibility or a likelihood that some more of those will be available for parents, grandparents, teachers, administrators who might be infected?

Dr. COLLINS. We are going to push hard to get those trials to the point where you can draw a conclusion about their effectiveness by the end of the summer, early fall. That's really pushing the agenda, but it is the goal, and if I had to pick one, I think the monoclonal antibody cocktails have a lot going for them because we know they worked for Ebola and there's all kinds of reasons to think this is the kind of virus it should work for, too.

Senator ALEXANDER. And you have several companies making those, right?

Dr. COLLINS. We do.

Senator ALEXANDER. And if they work and are safe, you should be able to produce a lot of those, is that correct?

Dr. COLLINS. That will be part of the challenge is the manufacturing and here again, having Warp Speed involved, thinking ahead of time about the manufacturing so we don't get to the point of having a successful trial and then have to wait a long time to scale it up. These all have to be done in big fermenters and BARDA is very engaged in that as is NIH as is the whole Warp Speed Team. So we want to be sure if we have something that works there's a lot of it out there.

Senator ALEXANDER. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Alexander.

Thanks to our witnesses. We've taken a lot of your time today, but it's been very helpful to us. I think for those people at HHS who are here or who are following this hearing, I think we need more clarity in the next 2 weeks on specifically who's in charge of what, what are the deadlines, and what do you need to meet those deadlines and do the job that the country is counting on you to do, and we're going to help you do that, but we need answers to those three questions.

The record on this——

Senator ALEXANDER. Mr. Chairman, may I comment on what you just said?

Senator BLUNT. You can.

Senator ALEXANDER. It reminds me of Admiral Rickover who personally hired all of the commanders of the Navy nuclear subs from the 1950s and he said to them you've got two jobs. One is your ship

and one is your reactor and if anything happens to your reactor, your career is over, and he never had a problem with a reactor——

[Laughter.]

Senator ALEXANDER [continuing]. Because he put somebody on the flag pole. So I think that's what you just said.

Senator BLUNT. Well, we need to know and we need to know in a hurry and we can't be helpful if you don't tell us how to help and we need these questions answered.

So thank all of you. Thank you for sticking with me here. Senator Murray was with us right up until the end of this, as well.

ADDITIONAL COMMITTEE QUESTIONS

The record will stay open for 1 week for additional questions.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED TO FRANCIS S. COLLINS, M.D., PH.D.

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

VACCINE RESEARCH

Question. Dr. Collins, do you have animal models that are designed for high-throughput analysis of vaccine efficacy and safety?

Answer. The National Institutes of Health (NIH), through the National Institute of Allergy and Infectious Diseases (NIAID), develops and maintains a comprehensive suite of preclinical services for the scientific community. These services include in vitro and in vivo screening, assay development, product optimization, safety and toxicology testing, manufacturing process development, and good manufacturing practice (GMP) production of candidate medical countermeasures. As part of these services, NIH supports the development of animal models to enable safety and efficacy testing of candidate medical countermeasures (MCMs), including vaccines. Building on ongoing and longstanding research on related coronaviruses and a fundamental understanding of how SARS–CoV–2, the virus that causes COVID–19, infects cells, NIH was able to support the rapid development of small and large animal models and quickly evaluate their suitability for evaluation of COVID–19 candidate MCMs. In the case of candidate vaccines, these models can help identify and address any early concerns related to vaccine-induced immune enhancement. Small animal models are especially valuable for early rapid screening of MCMs. NIAID has supported development of a number of small animal models, including mouse and hamster models that facilitate infection by the virus by expressing human ACE–2, a protein on the surface of human cells that SARS–CoV–2 uses as a receptor to gain entry to the cells.

Evaluation of candidate MCMs in large animal models such as non-human primates is also crucial for advancing promising MCMs into early stage clinical trials. For example, results from non-human primate studies were crucial for the advancement of a SARS–CoV–2 chimpanzee adenovirus-vectored vaccine candidate, AZD1222, developed by researchers at NIAID's Rocky Mountain Laboratories and collaborators at the University of Oxford, to Phase 1 clinical trials. AZD1222 is being further developed through a partnership between the University of Oxford and AstraZeneca. A longstanding collaboration between the NIAID Vaccine Research Center and the biotechnology company Moderna, Inc., led to the development of mRNA–1273, a SARS–CoV–2 vaccine candidate that showed early promise in animal models. Moreover, interim results from a Phase 1 study showed this candidate vaccine was generally well tolerated and able to prompt neutralizing antibody activity in healthy human adults. Phase 2 trials of mRNA–1273 are ongoing and Phase 3 trials are expected to begin in late July 2020. Animal models developed with NIAID support also have been used to evaluate a wide range of additional COVID–19 candidate vaccines based on various platforms, including vaccine candidates developed utilizing DNA-, RNA-, protein/adjuvant-, and viral vector-based vaccine technologies.

NIAID is committed to supporting the development of improved animal models to help advance promising COVID–19 candidate MCMs through the development pipe-

line. NIAID will continue to make these valuable resources available to support the rapid development of vaccines and other MCMs for COVID–19.

Question. Are you supporting vaccines that are not totally dependent on the spike protein?

Answer. The NIH is taking a strategic approach to COVID–19 candidate vaccine development. Through the Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH has moved quickly to accelerate progress by conducting a scientific review of more than 50 vaccine candidates already identified. The vast majority of COVID–19 vaccine development efforts across the globe are focused on the SARS–CoV–2 spike protein. This is because the SARS–CoV–2 spike protein is how the virus binds with and gains entry to human cells. In addition, studies of related coronaviruses that cause Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS) have demonstrated that neutralizing antibodies against coronavirus spike proteins have protected animal models from coronavirus challenge. However, not all NIH COVID–19 vaccine development efforts are focused solely on the SARS–CoV–2 spike protein. For example, NIAID is supporting Codagenix to develop a live-attenuated vaccine candidate based on the same technology used to develop their influenza vaccine candidate currently in Phase 1 clinical trials. NIAID-supported researchers also are exploring vaccines that target other proteins encoded by the virus, as well as identifying and targeting specific regions of viral proteins to stimulate both an antibody and a T-cell response. NIAID intramural scientists are conducting early stage research to explore "universal" coronavirus vaccine approaches using an assortment of chemically inactivated coronaviruses or virus-like particles. These approaches also are being used by NIAID scientists to develop universal influenza vaccine candidates. NIH and Operation Warp Speed will continue to pursue development and manufacture of the most promising COVID–19 vaccine candidates.

Question. Are you supporting vaccine candidates in vectors that have already been used safely in humans?

Answer. Developing safe and effective vaccines against COVID–19 continues to be a top priority of the Administration. Operation Warp Speed (OWS) is the Administration's national program to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics. There are a number of NIH and OWS-supported investigational COVID–19 vaccines at various stages of development that use protein/adjuvant platforms that have been used against other viral respiratory pathogens such as influenza and RSV or viral vector platforms whose safety has been demonstrated through past clinical trials evaluating vaccine candidates for Middle East respiratory syndrome and Ebola virus disease. These include chimpanzee adenovirus-vectored, adenovirus 26-vectored (Ad26), and vesicular stomatitis virus- vectored (VSV) vaccine candidates. Both the Ad26 and VSV platform technologies have been used to develop approved vaccines for other infectious diseases in either the U.S. or Europe. In addition, there have been a number of Phase 1 studies assessing the safety and immunogenicity of RNA vaccines against various viral pathogens. NIH will conduct clinical trials to assess safety and efficacy of OWS-supported vaccine candidates using the COVID–19 Prevention Network (CoVPN), in partnership with the Department of Defense. NIH and OWS will continue to pursue development and manufacture of the most promising COVID–19 vaccine candidates, including those that use existing viral vector platforms.

Question. Are you supporting vaccine candidates in vectors that can be easily scaled in production?

Answer. Developing safe and effective vaccines against COVID–19 continues to be a top priority of the Administration. Operation Warp Speed (OWS) is the Administration's national program to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics. Among its objectives, OWS aims to have substantial quantities of a safe and effective vaccine available for Americans by mid 2021.

OWS aims to speed the typical vaccine development and distribution process by initiating large-scale manufacturing alongside highly coordinated clinical research. This will ensure we will have sufficient quantity of vaccine to distribute as soon as we identify safe and effective candidates, including investigational vaccines using viral vectors. For example, OWS is supporting advanced clinical trials, regulatory support, and large-scale manufacturing to produce up to 300 million doses of Johnson & Johnson's Ad26-vectored COVID–19 vaccine candidate. OWS also is supporting development of a protein/adjuvant vaccine from Sanofi and GSK, companies which have extensive experience with large scale manufacturing.

OWS aims to build the necessary plans and infrastructure for distributing vaccines to hundreds of millions of Americans in a timely and equitable manner. This includes expanding the supplies of specialized materials and resources for distrib-

uting vaccines, such as cold-chain storage, glass vials, and other materials. The involvement of the Department of Defense in OWS, and its coordination with the Centers for Disease Control and Prevention, will enable faster distribution and administration than would have otherwise been possible using traditional vaccine distribution pathways. Ultimately, OWS aims for the rapid distribution of large quantities of a safe and effective vaccine to the majority of all Americans.

PHASE 3 CLINICAL TRIALS

Question. It is critical for the rapid approval of funding for the vaccine phase 3 trials for COVID–19. It is my understanding that some sites participating in this work are being told to begin in mid-July, but as of the first week of July, have not received any specific funding for the trial beyond an agreement for $250,000 starter fund. Without additional funding it makes it difficult to scale-up work. Dr. Collins, when do you expect institutions participating in Phase 3 will receive funding for the trial?

Answer. The NIH, as a component of Operation Warp Speed, is committed to advancing the development and testing of COVID–19 vaccine candidates as rapidly as possible. In early July 2020, NIH plans to provide grant funds to sites in the U.S. participating in the first Phase 3 SARS–CoV–2 vaccine trial through the COVID–19 Prevention Network (CoVPN), a network of NIAID-funded sites throughout the U.S. and the world. This trial will investigate Moderna's mRNA–1273, a vaccine candidate that was developed in collaboration with scientists at the NIAID Vaccine Research Center. Funding for additional NIH-supported Phase 3 candidate vaccine trials through the CoVPN will be made available to institutes participating in such studies as expeditiously as possible.

NIH would defer to BARDA to provide information on Phase 3 clinical trials not supported through NIH.

Question. What are the specific recruitment strategies institutions participating in Phase 3 trials need to implement? Specifically, what are the targeted populations? Are you incorporating those from underrepresented groups, including from minority populations and those with co-morbid conditions?

Answer. NIH has established the COVID–19 Prevention Trials Network (CoVPN) by leveraging four existing NIAID-funded clinical trials networks: the HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN), the Infectious Diseases Clinical Research Consortium (IDCRC), and the AIDS Clinical Trials Group (ACTG), in partnership with the Department of Defense. The CoVPN aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines, monoclonal antibodies, and drugs intended to either protect people from COVID–19 or to effectively treat those with the disease. The CoVPN is a functional unit of the Operation Warp Speed (OWS) partnership led by HHS to invest in and coordinate the development, manufacture, and distribution of COVID–19 vaccines, therapeutics, and diagnostics. The CoVPN will participate in harmonized protocols, developed in collaboration with the Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, that will enable analyses across multiple trials of candidate vaccines. The network is expected to participate in numerous trials at more than 100 clinical trial sites across the United States and internationally. Phase 3 clinical trials overseen by the CoVPN will target populations at greatest risk from COVID–19, including individuals of older age, individuals with comorbid health conditions, and racial and ethnic populations disproportionately impacted by COVID–19. The CoVPN has developed an extensive community engagement framework to reach out to diverse groups of potential research volunteers and explain the specific details involved in participating in an investigational vaccine or monoclonal antibody clinical study.

QUESTIONS SUBMITTED BY SENATOR JOHN KENNEDY

Question. While we have the best minds in the world working on this vaccine, some may be concerned that every step in the research process is happening concurrently rather than sequentially. Can you assure us the vaccine will be safe and effective once it's finished?

Answer. Developing safe and effective vaccines against COVID–19 continues to be a top priority of the Administration. Operation Warp Speed (OWS) is the Administration's national program to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics. Among its objectives, OWS aims to have substantial quantities of a safe and effective vaccine available for Americans by mid 2021. OWS aims to speed the typical vaccine development and distribution process by initiating large-scale manufacturing alongside highly coordi-

nated clinical research. Clinical research trials will occur as expeditiously as possible without jeopardizing participant safety. The concurrent manufacturing will be conducted at financial risk as we will not know in advance whether these investigational vaccines will prove safe and effective and suitable for distribution, but we will be making investments in large-scale production of the vaccine candidates. This will ensure we will have sufficient quantity of vaccine to distribute as soon as we identify safe and effective candidates.

Safety and efficacy of the vaccine candidates will be evaluated by OWS through clinical trials conducted by NIH using the COVID–19 Prevention Network in partnership with the Department of Defense. The network will develop and execute a series of harmonized protocols to allow for the rapid, thorough evaluation of COVID–19 vaccine candidates. The use of established clinical trials networks and harmonized protocols will enhance efficiency and help ensure the consistency of data across OWS-supported candidate vaccine clinical trials. Moreover, all OWS trials are overseen by a common, independent Data and Safety Monitoring Board, whose specific purview is to protect the safety of volunteers enrolled in the trials. It is important to note that while the strategy described above increases the financial risk of developing these countermeasures, it does not affect the safety of any final product. Vaccines supported by OWS will not be distributed until they are shown to be safe and effective and are authorized for use by the U.S. Food and Drug Administration.

Question. There have been concerns regarding the transparency of Operation Warp Speed and a lack of up to date information about its progress and findings. Can you ensure that Congress and the American people will receive clear and transparent information from this panel and other respected public health experts moving forward?

Answer. NIH will continue to provide the Congress with clear and transparent information on the activities of the NIH, including NIH activities coordinated by Operation Warp Speed.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Dr. Collins, Dr. Redfield, and Dr. Disbrow, preliminary data suggests that secondary bacterial infections are prevalent amongst those infected with COVID, which raises concerns about increases in antibiotic resistance. Are you concerned by the ongoing decline in industry investment for novel antimicrobials?

What actions can be taken to support a sustainable pipeline moving forward?

Answer. Antibacterial resistance remains an important public health crisis. BARDA has provided over 241 million to support early stage product developers, via our CARB–X project. These resources have ensured product developers have access to the tools and support to bring innovative life-saving antibiotics from the bench to the market that overcome the evolving threat of antibiotic resistance. Importantly, with this funding, BARDA has established a robust portfolio composed of CARB–X, with over 30 candidates in development, and 16 advanced development public-private partnerships focused on the development of 16 novel, small molecule candidates.

Antibacterial resistance remains an important public health crisis. NIH is advancing the discovery, development, and clinical testing of novel antibiotics, monoclonal antibodies, and new antibacterial formulations, including therapeutics for difficult-to-treat infections. NIAID, the lead NIH Institute for research on antibacterial resistance, supports research to understand the fundamental biology of disease-causing microbes and to develop and test novel diagnostics, therapeutics, and vaccines to address drug-resistant infections. As part of broader NIH COVID–19 efforts, NIAID is supporting research at the intersection of SARS–CoV–2, the virus that causes COVID–19, and bacterial infections, including a study by NIAID intramural researchers of secondary staphylococcal infections in individuals with COVID–19. Additionally, several NIAID-funded cohort studies are evaluating the incidence and potential impact of secondary bacterial infections in hospitalized individuals with COVID–19.

NIAID also continues to provide research resources and reagents at no cost to scientists in academia and industry to help de-risk investment in antibiotic discovery and early-stage development. These resources are meant to lower the development costs of novel antimicrobial therapies, making it easier for both industry and academia to invest in this important area of research. NIAID also supports a clinical trials network overseen by the NIAID Antibacterial Resistance Leadership Group (ARLG) that is focused on evaluating potential solutions to the problem of antibacterial resistance. This network has initiated more than 40 wide-ranging clinical

studies of diagnostics, therapeutics, and treatment strategies for antimicrobial resistance.

As part of broader HHS efforts to address antimicrobial resistance, NIH is partnering with the Biomedical Advanced Research and Development Authority (BARDA) to support the "AMR Rapid, Point-of-Need Diagnostic Test Challenge" a $20 million prize competition seeking innovative, rapid point-of-care laboratory diagnostic tests to combat the development and spread of drug resistant bacteria. The Challenge calls for new, innovative, and novel laboratory diagnostic tests that identify and characterize antibiotic resistant bacteria and/or distinguish between viral and bacterial infections to reduce the unnecessary use of antibiotics, a major cause of antibiotic resistance. On August 5, 2020, NIH announced that a rapid diagnostic for gonorrhea won the $19 million Federal prize.[1] NIH also supports the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB–X), a public-private partnership led by BARDA that has funded 65 research projects, including 16 focused on new antibiotic classes. CARB–X seeks to accelerate the development of tools to combat antibiotic resistance by supporting a robust pre-clinical and early developmental pipeline of antibiotics and other therapeutics, diagnostics, and vaccines. NIAID remains committed to supporting this important area of research and will continue to work with our partners across HHS to support a robust pipeline of discovery and development of antibiotic therapies.

Question. Dr. Collins, Dr. Fauci said that the National Institutes of Health is currently making challenge doses. Could you describe the NIH's current plans for producing the virus under good manufacturing practices as well as a rough timeline for its completion?

Answer. Safe and effective vaccines will be a critical tool to prevent infection with SARS–CoV–2 and help to end the COVID–19 pandemic. NIH is participating in a whole-of-government effort to pursue the development of safe and effective SARS–CoV–2 vaccines as rapidly as possible. NIH currently is prioritizing randomized controlled clinical trials to evaluate the safety and efficacy of SARS–CoV–2 vaccine candidates. A number of candidates have entered clinical trials, with several of these poised to enter Phase 3 randomized controlled clinical trials. These trials are designed to provide information that may support licensure of the vaccines and availability to the public, should they provide evidence that the candidate is safe, immunogenic, and protective. Controlled human infection (CHI) studies are one research approach that might help determine the effectiveness of a vaccine.

NIH has not yet made a determination about whether to support CHI studies. By the end of 2020, preliminary (and potentially final) data from Phase 3 SARS–CoV–2 candidate vaccine clinical trials should be available and will be used to inform the assessment of future SARS–CoV–2 human challenge studies. NIH has begun early stage investigations of the technical, ethical, and community considerations of conducting such studies. Although NIH is prioritizing assessment of SARS–CoV–2 vaccine candidates through clinical trials, these early stage investigations of CHI studies would allow us to be prepared should they be deemed necessary and safe and ethical to employ.

NIH also has begun to identify the research reagents and resources that would be required for potential CHI studies and to develop SARS–CoV–2 strains that could be used. The development of strains for use in human challenge studies is a multistage process. First, strains with a documented history must be identified, including their clinical source, their growth in different cell lines, and other characteristics. They must be purified in conditions consistent with clinical good manufacturing practice (cGMP) and determined to be free from microorganisms that may have unintentionally been introduced during the manufacturing process; for SARS–CoV–2, this manufacturing must be done in specialized biocontainment facilities. Clinical lots of challenge strains must then be characterized in animal model studies. NIAID is pursuing this process for 2–3 strains that may be available for further consideration by December 2020.

Question. Dr. Collins, according to reporting, NIH staff recommended the preparation of a challenge model back in early March. How have you since considered the role of challenge trials in the vaccine development process?

Answer. As discussed in the response above, CHI studies are one research approach that might help determine the effectiveness of a vaccine. NIH's position is that the best way to determine both safety and efficacy is through the conduct of adequately powered, randomized, controlled trials. NIH currently is prioritizing such trials to evaluate the safety and efficacy of SARS–CoV–2 vaccine candidates.

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[1] https://www.nih.gov/news-events/news-releases/rapid-diagnostic-gonorrhea-wins-19-million-Federal-prize-competition-combat-antibiotic-resistance.

Although NIH is moving forward rapidly with assessment of SARS–CoV–2 vaccine candidates through clinical trials, CHI studies could be an important and scientifically sound complementary strategy to more traditional vaccine development approaches. As described in detail above, NIH has begun early stage investigations of the technical, ethical, and community considerations of conducting CHI studies to be prepared should they be deemed necessary and safe and ethical to employ.

Question. Dr. Collins, we understand that there are a limited number of suitable quarantine units in which to run challenge studies—how many beds in these units exist that could easily be made available for challenge studies in the U.S. in the near future?

Answer. Clinical centers with isolation units (to prevent transmission of SARS–CoV–2 from human challenge study participants to others) and intensive care unit capability would be needed to conduct CHI studies with SARS–CoV–2. In addition, as live SARS–CoV–2 virus must be handled in biosafety level 3 (BSL–3) containment facilities, locations under consideration for challenge studies must have the requisite facilities and personnel trained to handle BSL–3 pathogens. The NIH Clinical Center in Bethesda, Maryland, is one location that would be able to provide the required capabilities and could be used to conduct SARS–CoV–2 human challenge studies. The NIH Clinical Center could dedicate up to 27 beds for CHI studies.

It is possible that additional isolation units operated by academic centers would be able to provide the capabilities needed for CHI studies with SARS–CoV–2. To date, NIH is aware of at least one academic center with an isolation unit that has expressed interest in conducting such studies.

Question. Dr. Collins, what are the benefits and weaknesses of using a challenge study model for vaccine development and testing? Separately, could a challenge study model be used to uncover information about how long immunity lasts in patients with COVID–19 antibodies in their blood?

Answer. When it is possible to conduct them safely and ethically, CHI studies can provide detailed information about the natural course of an infectious disease. They also can be used to assess the effect of interventions to prevent or treat an infectious disease. When there is low disease transmission in the community, a CHI study can in theory help to evaluate effectiveness of a vaccine candidate more quickly, as it is certain that the study participants will be exposed to the infection during the experiment. In these situations, a traditional clinical trial may require more participants over a longer period of time to generate a statistically valid signal of efficacy of the vaccine because the likelihood of any one participant being exposed to the infection in the community may be low.

CHI studies also present challenges. There are ethical concerns due to potential health risks to the participants who are experimentally infected. This is particularly true for infectious diseases such as COVID–19, where we do not fully understand the scope of disease or have effective treatments for all manifestations of disease. In addition, CHI studies typically target young, healthy participants to help reduce or mitigate potential health risks from experimental infections. This practice can raise concerns about whether the findings of CHI studies can be generalized to other populations, such as older adults or individuals with comorbid health conditions. For COVID–19, this is especially concerning because these other populations are at high risk for complications and therefore will be prioritized in testing and eventual distribution of vaccines. In addition, it is unknown how well intranasal administration of a SARS–CoV–2 challenge strain will reproduce aspects of natural infection, including viral replication, symptomology, and the quality and magnitude of immune responses. As any SARS–CoV–2 human challenge model is being developed, it will be important to understand the strengths and limitations of the model for informing candidate vaccine development and evaluation.

Separately, it may be possible to evaluate how long immunity lasts in patients with SARS–CoV–2 antibodies in their blood by recruiting such patients for CHI studies. However, it is important to note that the same challenges and limitations as described for CHI vaccine studies would apply to these types of studies. In addition, such a proposed study would introduce additional ethical considerations, as the health effects of repeated SARS–CoV–2 infections are currently unclear.

Question. To all witnesses, an antibody therapeutic to fight COVID–19 holds the distinct advantage over a vaccine in that the former can be used to treat currently sick patients, while the latter can only be used as a preventative measure on healthy people with immune systems strong enough to learn how to recognize and fight the novel pandemic coronavirus. The number of patient cases and deaths are of primary concern for the country at this time because it is this load that pushes our healthcare system to the brink and slows our economy to a halt. While a vaccine is important in the long-term, how is Operation Warp Speed ensuring additional

focus on antibody therapeutics since they hold the key to managing our current crisis?

Answer. The NIH, in collaboration with the Foundation for the NIH, recently launched an innovative public-private partnership, ACTIV, to speed the development of COVID–19 therapeutics and vaccines. As part of the ACTIV partnership, and in collaboration with other NIH Institutes and Centers, NIAID plans to launch a series of clinical trials supported by Operation Warp Speed (OWS), a Federal partnership led by HHS to invest in and coordinate the development, manufacture, and distribution of COVID–19 countermeasures, to evaluate the efficacy of monoclonal antibodies (mAbs) as therapeutics for COVID–19 in both outpatient and hospitalized settings. NIAID also is planning separate clinical trials to assess hyperimmune intravenous immunoglobulin.

As part of OWS, NIAID recently established the COVID–19 Prevention Trials Network (CoVPN), in partnership with the DoD, by leveraging four existing NIAID-funded clinical trials networks. The CoVPN aims to enroll thousands of volunteers in large-scale clinical trials to test a variety of investigational therapeutics and vaccines intended to treat or protect people from COVID–19. Through the CoVPN, NIAID is supporting additional trials to evaluate mAbs directed against SARS–CoV–2 as potential tools to prevent transmission and spread of SARS–CoV–2. One clinical study is evaluating the use of mAbs for prevention of SARS–CoV–2 infection in households where there is a confirmed case of COVID–19. A second clinical study is investigating the use of mAbs for prevention of COVID–19 disease in senior living facilities. The NIH ACTIV Therapeutics Clinical Working Group also has developed and openly shared master protocols for OWS-sponsored clinical trials to enhance trial efficiency of mAbs.[2] In addition to the evaluation of mAbs for prevention of COVID–19, ACTIV and CoVPN also are supporting OWS efforts to develop safe and effective COVID–19 candidate vaccines.

Developing safe and effective medical countermeasures against COVID–19 continues to be a top priority of the Administration. NIH will continue to support the development and evaluation of mAbs and other antibody-based therapies for treatment and prevention of COVID–19 as a component of OWS.

Monoclonal antibodies are one kind of therapeutic that show early promise in the treatment of COVID–19. So far, BARDA has invested in both Regeneron and AstraZeneca to develop monoclonal antibodies for COVID–19. Additional monoclonal antibodies are being evaluated for potential funding. Under the ACTIV Public Private Partnership, clinical trials will be established to assess safety and efficacy of multiple monoclonal antibody products under a master protocol. The trials are being supported under OWS and the companies can submit information about their product for evaluation and prioritization. If selected they simply need to provide their product and it will be evaluated in collaboration with the company under the clinical trial. A key criteria for moving each candidate forward is the timing of candidate therapeutic availability. Regeneron's monoclonal antibody cocktail entered clinical trials in June, and AstraZeneca's monoclonal antibody cocktail will be entering the clinic very soon. In addition, if the clinical trials demonstrate that the antibodies are safe and efficacious, it is important that the company can manufacture significant amounts of therapeutic.

Question. To all witnesses, can you detail the plans each of you has for pursuing medical treatments, antibody therapies, and potential cures of COVID–19?

Answer. NIH is the HHS agency leading the research response to COVID–19 and the novel coronavirus that causes the disease, SARS–CoV–2. NIH is building on previous NIAID-supported research on the closely related SARS and MERS coronaviruses to accelerate the development of COVID–19 candidate therapeutics. To further speed the development of COVID–19 therapeutics and vaccines, NIH has launched an innovative public-private partnership in collaboration with the Foundation for the NIH. The ACTIV public-private partnership brings together stakeholders from across the U.S. Government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID–19 pandemic. Other Federal partners include BARDA, DoD, the Department of Veterans Affairs, CDC, and FDA. NIAID, the NIH Institute responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID–19, also has developed the NIAID Strategic Plan for COVID–19 Research. This Strategic Plan details NIAID's plan for accelerating research to diagnose, prevent, and treat COVID–19.[3] NIH also is an active member of Operation Warp Speed (OWS), a Federal partnership led by HHS to invest in and

[2] https://www.nih.gov/research-training/medical-research-initiatives/activ

[3] NIAID Strategic Plan for COVID–19 Research: https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.

coordinate the development, manufacture, and distribution of COVID–19 vaccines, therapeutics, and diagnostics.

Effective therapeutics for COVID–19 are critically needed to treat patients who have been infected with SARS–CoV–2. Guided by the ACTIV and OWS partnerships, as well as the NIAID Strategic Plan for COVID–19 Research, NIH Institutes and Centers are taking a multi- pronged, coordinated approach to develop and test candidate therapeutics for COVID–19. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial, the Adaptive COVID–19 Treatment Trial (ACTT),[4] to evaluate the safety and efficacy of therapeutics for COVID–19. The adaptive design of this trial will enable the evaluation over time of additional promising therapeutics, in coordination with the ACTIV partnership. The initial iteration of this study showed that the antiviral drug remdesivir increased rate of recovery from severe COVID–19 in adults and may benefit survival (ACTT–1). The anti-inflammatory drug baricitinib has been added to the second iteration of the study (ACTT–2), currently underway. Additional promising therapeutics may be added to further iterations of the trial as appropriate. NIAID also is developing and testing other novel and repurposed therapies including direct-acting antivirals and monoclonal antibodies that target either SARS–CoV–2 or are meant to modulate over-exuberant immune responses to severe COVID–19. NIAID also is planning separate clinical trials to assess hyperimmune intravenous immunoglobulin for treatment of COVID–19 in both outpatients and hospitalized adults. As part of the ACTIV partnership, and in collaboration with other NIH Institutes and Centers, NIAID plans to launch a series of OWS-supported studies to evaluate monoclonal antibodies in both outpatient and hospitalized settings.

Institutes and Centers across NIH are working with partners in academia and industry to pursue the development and testing of mAbs, antiviral, and anti-thrombotic drugs for potential treatment of COVID–19. For example, the National Heart, Lung, and Blood Institute (NHLBI) is supporting research to evaluate the efficacy of the repurposed anti-inflammatory drug colchicine for treating COVID–19 in the outpatient setting and the use of anticoagulants to prevent life-threatening blood clots experienced by some COVID–19 patients. NHLBI also is leveraging the NIH-funded Strategies to Innovate Emergency Care Clinical Trials Network[5] to study whether blood plasma from individuals who have recovered from COVID–19 can help reduce the progression of COVID–19 in patients with mild symptoms. The National Center for Advancing Translational Sciences (NCATS) is leveraging the NCATS Pharmaceutical Collection,[6] a compilation of every drug approved for human use by major regulatory agencies worldwide, and other collections of small molecules and compounds to identify potential SARS–CoV–2 therapeutics for further investigation.

In addition to supporting the discovery and development of therapeutics for COVID–19, NIH also has convened the COVID–19 Treatment Guidelines Panel to provide up-to-date treatment guidelines for clinicians. The panel is comprised of representatives of NIH and five other Federal agencies along with representatives of eight professional organizations, academic experts, and treating physicians including providers from high COVID–19 incidence areas. The guidelines are updated regularly as new evidence-based information emerges.[7]

The goal of OWS is to develop safe and effective vaccines and therapeutics against COVID–19. In support of OWS project goals, HHS intends to carefully evaluate the safety and efficacy of both vaccines and therapeutics. OWS will ensure the American people are poised to receive safe and effective vaccine(s) and therapeutics as soon as possible

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QUESTIONS SUBMITTED BY SENATOR MARCO RUBIO

Question. If a vaccine isn't available by 2021, or is not 100 percent effective, what would herd immunity look like?

What factors would states and cities have to evaluate before we achieved herd immunity and how long would that take?

Answer. Herd immunity occurs when a large portion of the population becomes immune to a disease, which helps limit the spread of the disease from person to person. In order to achieve herd immunity to SARS–CoV–2, greater than 70 percent

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[4] https://www.niaid.nih.gov/clinical-trials/adaptive-covid-19-treatment-trial-actt.

[5] https://siren.network/.

[6] https://ncats.nih.gov/expertise/preclinical/npc.

[7] Coronavirus disease 2019 (COVID–19) Treatment Guidelines: https://www.covid19 treatmentguidelines.nih.gov/.

of the population likely would need to gain immunity either through recovery from infection or through vaccination. The length of time necessary to attain herd immunity is difficult to predict and will be dependent not only on the availability and public acceptance of a vaccine, but also the durability of the immune reaction induced by vaccination or natural infection. It is important to note that no vaccine is 100 percent effective, and even a vaccine with a moderate efficacy could significantly decrease the spread of COVID–19, in combination with other public health measures outlined by CDC such as social distancing, appropriate use of masks and face coverings, and increased handwashing. Prophylactic treatments such as monoclonal antibodies also could be used to protect individuals who may need immediate protection or may not be able to receive a vaccine.

NIH is supporting a broad portfolio of cohort studies to better understand the incidence and prevalence of SARS–CoV–2 infection and the immune response to SARS–CoV–2. This includes a longitudinal cohort study at the NIH Clinical Center of individuals who have recovered from COVID–19, a NIAID and NCI co-funded longitudinal cohort study of healthcare personnel and other high-risk populations, and an additional NIAID-supported observational study of adults and children diagnosed with COVID–19. These studies, scheduled to evaluate immune responses over periods of one to 3 years, will help us to better understand the types and quantity of antibodies elicited by SARS–CoV–2 infection, the potential for re-infection, and the durability of immunity following infection. This information may help inform vaccination strategies as well as improve our understanding of what herd immunity for COVID–19 may look like.

Question. Research indicates that vaccines tend to be less effective amongst elderly populations—the very population that's most vulnerable to the coronavirus.

If a coronavirus vaccine is less effective in seniors and only has a 60 percent effectiveness overall, will the elderly population still be highly vulnerable to COVID?

What long-term steps should we be taking to ensure to prepare for a scenario in which older Americans are still highly vulnerable to this virus?

Answer. The development of a safe, highly effective COVID–19 vaccine would be an invaluable tool in our efforts to control the COVID–19 pandemic. As older adults have been shown to be particularly vulnerable to this disease, it will be important to evaluate promising vaccine candidates in this group in order to understand their efficacy in this population. NIAID expanded an ongoing Phase 1 clinical trial of an mRNA-based vaccine candidate to include adults age 56 and older in April 2020 and plans to enroll older adults in additional studies of this and other vaccine candidates. NIH also has established the COVID–19 Prevention Trials Network (CoVPN), in partnership with the Department of Defense, to support large-scale clinical trials of COVID–19 candidate vaccines and therapeutics. Phase 3 clinical trials overseen by the CoVPN will target populations at greatest risk from COVID–19, including older adults, individuals with comorbid health conditions, and racial and ethnic populations disproportionately impacted by COVID–19.

The results of these studies will provide valuable information on the efficacy of vaccination in high-risk populations and may suggest the use of adjuvants or other strategies that could be used to boost the immune response. Adjuvants, which are added to some vaccines to improve vaccine efficacy, have been shown to be particularly effective in boosting immunity in older adults. NIAID is working with collaborators to provide synthetic and other adjuvants to the research community for use in COVID–19 vaccine candidates. NIAID also is conducting and supporting research into multiple adjuvanted vaccine candidates that may be good candidates for vaccination in older adults. Many of these adjuvanted vaccine candidates are currently being evaluated in animal models with plans for clinical trials in the near future. NIH also is supporting the development of prophylactic treatments such as monoclonal antibodies that could be used to protect individuals who are at increased risk of disease, need immediate protection, or do not mount an effective immune response to a vaccine.

Until a safe and effective COVID–19 vaccine is available, it is important that all individuals, especially those who are senior citizens or have underlying health conditions, take precautions to prevent infection by SARS–CoV–2. Precautions include maintaining social distance and limiting interactions with other people as much as possible, wearing a face covering when in public places or in situations where it is not possible to maintain social distance, washing hands often, and cleaning and disinfecting frequently touched surfaces daily. Individuals should also monitor their health on a daily basis and follow CDC guidance should they develop symptoms of

COVID–19. Additional guidance specific to older adults is available on the CDC website.[8]

Question. Last week, the Chinese Military approved the use of CanSino Biologics' COVID–19 vaccine.

What can you tell us about the safety and efficacy of this vaccine candidate?

Should we be concerned that the Chinese government has already approved a vaccine candidate for limited use?

What does this mean for the United States' status as a leader in medical innovation?

Answer. Currently there is no efficacy data for the CanSino Biologics vaccine candidate, a recombinant adenovirus type-5 (Ad5) vectored COVID–19 vaccine expressing the spike glycoprotein of SARS–CoV–2. A Phase 1 trial of a low, medium, and high dose of this vaccine candidate was initiated on March 16, 2020, in China. The trial enrolled 108 participants, and 50 percent of subjects who received the low or medium dose developed neutralizing antibodies, with an increase to 75 percent of subjects who received the high dose. Significant side effects were noted however, and side effects with the high dose were severe enough to eliminate that dose from future studies. Although more information is needed, it is possible that the low immunogenicity seen in the trial may be due to inhibition by pre-existing immunity to the adenovirus vector itself. A Phase 2 trial of this vaccine candidate was initiated April 12, 2020. Safety and immunogenicity data from this Phase 2 trial were published online in the journal Lancet on July 20, 2020.

The COVID–19 global pandemic has elicited an unprecedented global response from the world's biomedical research community. For its part, NIH is working with international partners to improve fundamental knowledge of SARS–CoV–2 (the virus) and COVID–19 (the disease) as well as to optimize the development and delivery of diagnostic tests, treatments, and vaccines to populations most in need. We are encouraged whenever progress is made domestically or globally on any of these fronts.

Numerous international efforts are currently underway to develop vaccines against SARS–CoV–2. Comparing the performance of independently derived vaccine candidates will enhance our ability to identify the most safe and effective vaccines to prevent COVID–19. One such effort involves an experimental vaccine co-developed by the Chinese military and CanSino Biologics. According to press reports, on June 30, 2020, the Chinese military issued a limited approval of the experimental vaccine for its military personnel. This limited approval was issued prior to the July 20, 2020, publication of the experimental vaccine's Phase 2 clinical trial results.[9]

The United States remains in the vanguard of the global effort to diagnose, treat, and prevent COVID–19. For example, NIH plans to launch in July 2020 a Phase 3 clinical trial of an experimental COVID–19 vaccine co-developed by Moderna, Inc., and NIH. The trial, which will be conducted at U.S. clinical research sites, is expected to enroll approximately 30,000 adult volunteers who do not have COVID–19.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

VACCINE DEVELOPMENT

Question. OWS seeks to condense the traditional vaccine development timeline by testing multiple candidates at once and evaluating safety and efficacy simultaneously, rather than in turn. Experts caution that truncated trials may put patients at increased safety risk. At present, five candidate vaccines have entered phase two trials. At least five other candidate vaccines have commenced phase one safety studies in healthy human volunteers. The time required to adequately scale-up vaccine production will depend on the technology chosen. It is critical this process be transparent and data driven-meaning that as clinical trials progress, the data should be made public and available to those in industry, academia, and government to analyze.

What are the selection criteria for determining which vaccine technologies are chosen and who within OWS makes these decisions?

Does the Administration plan to substantially invest resources toward investigating recombinant protein, VLP or inactivated virus vaccines for COVID–19. If so, how?

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[8] CDC Coronavirus Disease 2019 (COVID–19)—Older Adults: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html.

[9] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31605-/fulltext.

Answer. Operation Warp Speed (OWS) aims to deliver 300 million doses of a safe, effective vaccine for COVID–19 by mid 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures). To accelerate development while maintaining standards for safety and efficacy, OWS has been selecting the most promising countermeasure candidates and providing coordinated government support. 14 promising vaccine candidates have been chosen from the over 100 vaccine candidates currently in development-some of them already in clinical trials with U.S. government support. The 14 vaccine candidates are being narrowed down to the most promising candidates from a range of technology options, which will go through further testing in early-stage clinical trials. Large- scale randomized trials for the demonstration of safety and efficacy will proceed for the most promising candidates. Rather than eliminating steps from traditional development timelines, steps will proceed simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety as happens normally. This increases the financial risk, but not the risk of the product to the recipient, as vaccines supported by OWS will not be distributed until they are shown to be safe and effective and are authorized for use by the U.S. Food and Drug Administration.

OWS will support the most promising COVID–19 vaccine candidates with no preference for one specific vaccine technology over any other. OWS has supported several distinct vaccine platforms. These include nucleic acid RNA vaccines, such as the Moderna SARS–CoV–2 vaccine candidate, mRNA–1273 and viral vector vaccines such as the Johnson and Johnson Ad26 SARS–CoV–2 vaccine candidate and the AstraZeneca/University of Oxford AZD1222 vaccine candidate, with additional platforms under consideration. NIAID also is providing support for a candidate prime/boost vaccination strategy developed by the biopharmaceutical company Vaxine whereby a SARS–CoV–2 DNA or RNA vaccine candidate will act as a 'prime', followed by a 'boost' containing recombinant SARS–CoV–2 protein plus the Advax-CpG adjuvant vaccine candidate. In addition, NIAID intramural researchers are investigating the use of virus like particles (VLPs) for the development of a universal coronavirus vaccine. NIH and OWS will continue to pursue development and manufacture of the most promising COVID–19 vaccine candidates regardless of the underlying vaccine technology.

The criteria to select candidates for funding are driven by the science of the preclinical and initial clinical trials and the ability of the vaccine companies to do the following: (1) Provide a vaccine that has the potential to be determined by the FDA to be safe and effective vaccine, (2) Execute clinical trials and deliver the vaccine, ideally by end of the year 2020, (3) rapidly scale manufacturing from clinical trials to meet quantity and distribution required to deliver millions of doses to United States and territories ideally by mid 2021.

The Advisory Committee on Immunization Practices (ACIP) COVID–19 Vaccine Work Group has been established to help inform evidence-based approaches to COVID–19 vaccination policy, including an initial vaccine prioritization strategy. While the end goal is to offer vaccines to the entire U.S. population, identifying priority groups for COVID–19 vaccination is critical for implementation planning. ACIP has embarked on early planning in hopes of preventing distribution delays post vaccine approval. The framework developed during, and the lessons learned from, the H1N1 influenza vaccine implementation are being used to guide COVID–19 vaccine prioritization. Given that many decisions regarding the vaccine will depend on the vaccine itself, specifics are unknown at this time.

ADJUVANT USE IN VACCINE AND THERAPEUTIC DEVELOPMENT

Question. HHS officials have stated that the Department has made substantial investments in monoclonal antibodies for a COVID–19 therapy. According to the Infectious Disease Research Institute in Seattle, WA, the use of adjuvants as stand-alone countermeasures have a number of advantages over monoclonal antibodies including that they are (1) easier to mass produce, (2) less expensive to manufacture, (3) given as a prophylactic versus intravenously, (4) not specific to COVID–19 and can adjust as mutations occur, and (5) proven to be protective against future pandemics as well.

Has HHS looked into a similar investment in alternative therapies, such as the use of adjuvants as a stand-alone countermeasure?

Do modern, synthetic adjuvants currently, or will they in the near future, play a role in the Administration's pursuit of a COVID–19 vaccine, especially given their ability to maximize the manufacturing and distribution of a compatible vaccine(s)?

If so, please describe the strategic resources and planning. What type of funding could be provided to ensure manufacturing capabilities match population needs?

Has the Administration considered including synthetic adjuvants, which have a long shelf life and can be produced at scale when needed quickly, as part of the National Stockpile to ensure we are sufficiently prepared to pivot should COVID–19 mutate or we inevitably encounter a new infectious pandemic in the future?

Answer. Adjuvants are an important tool that can be used to enhance and optimize the immune response to current and future vaccines. NIH conducts and supports research on the development of novel adjuvants as well as research to learn more about how adjuvants work to stimulate specific immune responses. Adjuvants alone are unable to create a targeted immune response to a specific pathogen. In combination with targeted vaccine constructs however, adjuvants can greatly increase the efficacy of the vaccine leading to a more robust and protective immune response. Within the NIH, NIAID supports immunology research to better understand underlying immune mechanisms and inform the development of a robust adjuvant pipeline. In 2018, NIAID released a Strategic Plan for Research on Vaccine Adjuvants which provides insights and recommendations that guide the NIAID adjuvant research program.[10] The NIAID adjuvant research program aims to develop a "toolbox" of adjuvants that can be matched with candidate vaccine antigens to optimize vaccine efficacy.

NIAID already is working with a number of collaborators to provide adjuvants of different types to the research community for potential use to enhance the immune response to SARS–CoV–2 vaccine candidates. These adjuvants are in various stages of development and include compounds that specifically improve vaccine efficacy in older adults or modulate host immunity to increase protection while limiting or preventing harmful inflammatory responses. NIAID scientists are currently evaluating well established adjuvants, such as AS03 from GSK, or CpG and CpG/alum, in collaboration with Dynavax, combined with the SARS–CoV2 Spike protein in non-human primate animal models. NIAID also is supporting scientists at the biotechnology company Vaxine who are exploring the use of adjuvants to generate an enhanced immune response by 'priming' with a SARS–CoV–2 DNA or RNA vaccine candidate followed by 'boosting' with a recombinant SARS–CoV–2 protein plus the Advax-CpG adjuvant vaccine candidate. The efficacy of Vaxine's SARS–CoV–2 vaccine is being evaluated in non-human primates with NIAID support and recently entered a Phase 1 clinical trial for safety in humans. NIAID also is supporting projects to identify optimal adjuvants for a particular SARS–CoV–2 vaccine candidate, as well as a project to test the usefulness of a novel category of anti- inflammatory co-adjuvants for a COVID–19 vaccine candidate.

In addition, NIAID scientists are developing vaccines using platforms that have inherent adjuvant, or immune boosting, properties. An example of this type of technology is the lipid nanoparticle platform used in the mRNA–1273 vaccine candidate developed by scientists at the NIAID Vaccine Research Center and the biotechnology company Moderna, Inc. Interim results from a Phase 1 study showed this candidate vaccine was generally well tolerated and able to prompt neutralizing antibody activity in healthy human adults. Phase 2 trials of mRNA–1273 are ongoing and Phase 3 trials are expected to begin in late July 2020.

NIH will continue to support development of these vital resources. NIH defers to BARDA to provide information related to manufacturing capabilities for adjuvants as well as questions related to the Strategic National Stockpile.

Adjuvants alone are not under current development at BARDA for prophylaxis. To date none of the proposed immunostimulatory approaches have been shown to prevent infection.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

HEALTH WORKFORCE CAPACITY

Question. Two Fridays ago, the AAMC projected that our nation faces a shortage of 139,000 doctors by 2033. Of course, we also face gaps in nurses, mental health and addiction treatment, and dental care. Whether it is in urban or rural areas, these health workforce shortages harm patient access to care-and they have only been magnified by this pandemic.

In Illinois, Gov. Pritzker called in health reinforcements from other states and out of retirement, and the University of Illinois at Chicago graduated 4th year medical

[10] 2018 Strategic Plan for Research on Vaccine Adjuvants: https://www.niaid.nih.gov/sites/default/files/NIAIDStrategicPlanVaccineAdjuvants2018.pdf.

students early to go serve. As we deal with the crisis at hand, we must look to the future and ensure we have a pipeline of health professionals ready and the pandemic preparedness in place.

Today, we take our brightest students, put them through years of medical school and residency, rigorous training, and license them on one condition: an average student debt of more than $200,000. The sheer economics of this equation steers newly minted health providers into higher-paying specialties or communities, while leaving many rural and urban areas with shortages. Unfortunately, the alarming racial and ethnic disparities we are seeing in COVID–19 cases and mortality are in part a reflection of these existing gaps in healthcare access, provider capacity, emergency response, and the ability to reach minority populations. The same will be true for targeting these populations for vaccine uptake.

Two weeks ago, Senator Rubio and I introduced legislation (S. 4055, Strengthening America's Health Care Readiness Act) to restore the pipeline of health workers and boost our nation's emergency surge capacity by expanding scholarship and loan repayment through the National Health Service Corps, Nurse Corps, and National Disaster Medical System. It would provide billions in a supplemental, multiyear investment to address care gaps in underserved communities, bolster preparedness and deployment capacity for health emergencies, and make a commitment to recruiting health workers from communities of color and underrepresented urban and rural areas.

Dr. Redfield, Dr. Collins: can you please comment on the health workforce strains and shortages we have seen both prior to and during the COVID–19 pandemic, and the challenges that debt from graduate health education can have on our healthcare delivery and emergency preparedness systems?

Answer. Prior to the COVID–19 Pandemic, our colleagues at the Health Resources and Services Administration (HRSA) in the National Center for Health Workforce Analysis (NCHWA) (https://bhw.hrsa.gov/data-research/review-health-workforce-research) noted that, under current workforce utilization and care delivery patterns, the 2025 demand for primary care physicians is projected to exceed supply at the national level.[11] Aging and population growth account for most of the anticipated shortage of primary care physicians, but its impact varies by discipline. There is substantial regional variation in the estimates of both supply and demand for primary care physicians in 2025.[12] Even in states with estimated surpluses, localized shortages in primary care providers may exist, especially for rural and underserved communities. As of June 30, 2020, there are over 18,700 primary care, mental health, and dental health professional shortage areas (HPSAs) in the United States, the majority of which are in rural areas.[13,14]

While it is too soon for NCHWA to measure the impact of COVID–19 on the primary care workforce due to a number of factors, the Health Workforce Research Centers have developed many resources that may be found on their website at this address, https://www.healthworkforceta.org/covid-19-the-health-workforce.

The Council on Graduate Medical Education (COGME) has made several recommendations in light of COVID–19. With regards to the healthcare workforce, some portions of their recommendations include:

—Strengthen and modernize the public health workforce by continuing to invest in preventive medicine residency training,

—Address stress, fatigue, and burnout among healthcare providers, and

—Continue to support and accelerate Federal program flexibilities to sustain, prepare, and strengthen the existing, entering, and returning health workforce.[15]

In addition, COGME also addressed the issue of educational debt as it affects the health workforce in their Advisory Committee report published in 2017. In sum-

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[11] U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis. 2016. National and Regional Projections of Supply and Demand for Primary Care Practitioners: 2013–2025. Rockville, Maryland. https://bhw.hrsa.gov/sites/default/files/bhw/health-workforce- analysis/research/projections/primary-care-national-projections2013–2025.pdf.

[12] Id at page 4.

[13] Health Professional Shortage Area designations are used to identify areas, population groups, and facilities in the United States that are experiencing a shortage of primary medical care, dental, or mental health providers.

[14] U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Workforce. Third Quarter of fiscal year 2020 Designated HPSA Quarterly Summary. Available at: https://data.hrsa.gov/topics/health-workforce/shortage-areas. As of June 30, 2020.

[15] Accessed August 24, 2020 from: Council on Graduate Medical Education. Letter to DHHS Secretary and Congress Concerning Section 3402 of the Cares Act Amendment 2020. June 30, 2020. https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/graduate-medical-edu/letters/congress-letter-covid19-recommendations.pdf.

mary, although there will probably always be a dedicated group of students interested in the field of medicine, high debt burdens may suppress recruitment, especially from low-income or minority populations, and high debt may also skew interest toward higher-paying specialties.[16] It is to be noted that, although the debt burden of medical students is high, 39 percent of dental school graduates have debt exceeding $300,000—significantly more than medical school debt.[17]

Finally, Section 3402 of the CARES Act calls on the Secretary of Health and Human Services, in collaboration with the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) and COGME, to "develop a comprehensive and coordinated plan with respect to the healthcare workforce development programs of the Department of Health and Human Services, including education and training programs." The Department has begun working on this plan and is taking into account the recommendations from COGME noted above and the challenges of the COVID–19 pandemic.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

Question. The United States' lack of participation in global vaccine collaborations. What is the reason for not participating in the Access to COVID–19 Tools Accelerator? Why would the United States not participate in every possible effort to identify promising approaches and find effective therapeutics and vaccines?

Answer. While the United States Government has not joined the ACT-Accelerator officially, USG subject matter experts are integrated into the vaccine, therapeutic, and diagnostic pillars coordinated by CEPI, Wellcome Trust, and FIND, respectively, to advance the pre-licensure development, clinical trials, and manufacturing work streams to identify safe and effective medical countermeasures. In addition, HHS coordinates an interagency working group that engages the ACT–A access and allocation work streams working with CEPI and Gavi, to provide leadership, participate in the work, and influence outcomes on the Allocation Framework to be used on approved therapeutics and vaccines.

The NIH, along with the Foundation for the NIH, has launched the Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to speed the development of COVID–19 vaccine and therapeutic candidates. This effort is complementary to the Access to COVID–19 Tools Accelerator (ACT Accelerator), which is being coordinated by multiple organizations.

The ACTIV partnership has brought together stakeholders from across the U.S. government, industry, and the European Medicines Agency (EMA) to develop an international strategy for a coordinated research response to the COVID–19 pandemic. This effort is part of the Administration's whole-of-government, whole-of-America response to COVID–19. Other Federal partners include the Department of Defense (DoD), the Department of Veterans Affairs (VA), and sibling agencies in HHS, including the Biomedical Advanced Research and Development Authority (BARDA), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

Through the ACTIV partnership, NIH has moved quickly to advance the development of diagnostics, therapeutics, and vaccines by conducting a scientific review of the available diagnostic tools, approximately 170 therapeutic compounds, and more than 50 vaccine candidates already identified. The ACTIV Clinical Trial Capacity Working Group is focused on maximizing clinical trials capacity in order to test the highest priority candidates and standardize evaluation methods to assist FDA review. The Working Group aims to establish a coordination mechanism across clinical research networks to expedite trials, track incidence across sites, and project future capacity. The ACTIV Therapeutics Clinical Working Group and Vaccines Working Group aim to develop harmonized master protocols for adaptive trials of multiple SARS–CoV–2 candidate therapeutics and vaccines. Information gained in ACTIV partnership trials, such as the identification of biomarkers, could both speed up the authorization process and provide evidence to address cross-cutting safety concerns. Multiple candidate therapeutics and vaccines will be evaluated. All these activities will help inform ACT Accelerator efforts and other COVID–19 research activities worldwide.

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[16] Accessed August 24, 2020 from: "Towards the Development of a National Strategic Plan for Graduate Medical Education". Council on Graduate Medical Education. 23rd Report. April 2017. https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/graduate-medical-edu/reports/April2017.pdf.

[17] Accessed August 24, 2020 from: https://www.adea.org/GoDental/Money__Matters/Educational__Debt.aspx.

The NIH also has taken steps to ensure the ACTIV partnership is closely interconnected and complementary with other COVID–19 efforts, including those led by the FDA and BARDA's Medical Countermeasures Task Force, as well as international initiatives led by the Bill & Melinda Gates Foundation, the Wellcome Trust, the European Commission, the government of the United Kingdom, and WHO. Specifically, in relation to the ACT Accelerator, NIH and other U.S. experts provide advice and guidance on numerous planning, coordination, and oversight entities associated with the ACT Accelerator program. NIH also participates in regular coordination calls with WHO-affiliated scientific leadership to facilitate scientific cooperation and help avoid duplication of effort. Under the leadership of the White House Office of Science and Technology Policy, NIH also participates in regular SARS–CoV–2 research coordination calls with senior science advisors from approximately 20 countries. The NIH will continue to engage with international partners through bilateral, multilateral, and regional efforts, to coordinate SARS–CoV–2 research and to expeditiously advance the development and testing of medical countermeasures that will urgently address the clinical and public health response to COVID–19.

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

Question. Nanovaccines represent a new type of vaccine delivery technology that can enhance our future preparedness because they offer faster global impact, higher effectiveness, lower cost, and higher safety for medical staff. This approach has already been used to design effective vaccines against respiratory infections such as influenza, pneumonia, and respiratory syncytial virus and tested in multiple preclinical and clinical models, and is particularly suited for pandemic scenarios.

What efforts are underway through Operation Warp Speed to ensure new delivery technologies such as nanovaccines are in the pipeline to be readily adapted to develop a new COVID–19 vaccine?

Answer. Developing safe and effective vaccines against COVID–19 continues to be a top priority of the Administration. Operation Warp Speed (OWS) is the Administration's national program to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics.

OWS is coordinating existing HHS-wide efforts, including the NIH ACTIV public-private partnership goals of streamlining clinical evaluation of these vaccine candidates. NIH's role in OWS-led vaccine development will be to conduct clinical trials to assess safety and efficacy of COVID–19 vaccine candidates via the COVID–19 Prevention Network (CoVPN). In July 2020, the CoVPN is expected to begin a Phase 3 clinical trial of the investigational mRNA–1273 vaccine, which was developed by scientists at the National Institute of Allergy and Infectious Diseases (NIAID) and their collaborators at the biotechnology company Moderna, Inc. The mRNA–1273 vaccine candidate uses a lipid nanoparticle delivery system. OWS also plans to support mRNA-based vaccine candidates developed by Pfizer, Inc./BioNTech that use similar nanotechnology delivery systems. In addition, NIAID is in the early stages of exploring additional nanovaccine approaches, including the development of nanoparticles capable of displaying key SARS–CoV–2 surface proteins. NIH and OWS will continue to pursue the development and manufacture of the most promising COVID–19 vaccine candidates, including those that use nanotechnology delivery platforms.

QUESTIONS SUBMITTED BY SENATOR JOE MANCHIN, III

IMMUNIZATION PROGRAMS

Question. In your testimony you highlighted several vaccine candidates and your plan to test the vaccine across age groups. One of the key lessons we've learned from COVID so far is how it has affected different vulnerable populations. According to the Kaiser Family Foundation, West Virginia has the most vulnerable population in the U.S. with 51 percent of our population falling into that category. So far West Virginia has had 2,979 cases with 93 deaths. Do you have any initial plans for prioritizing essential groups or vulnerable populations initially?

What input have you sought to date from immunization program leaders in state and local public health agencies?

Answer. NIH has established the COVID–19 Prevention Trials Network (CoVPN) by leveraging four existing NIAID-funded clinical trials networks: the HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN), the Infectious Diseases Clinical Research Consortium (IDCRC), and the AIDS Clinical Trials

Group (ACTG), in partnership with the Department of Defense. The CoVPN aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines, monoclonal antibodies, and drugs intended to either protect people from COVID–19 or to effectively treat those with the disease. The CoVPN is a functional unit of the Operation Warp Speed (OWS) partnership led by HHS to invest in and coordinate the development, manufacture, and distribution of COVID–19 vaccines, therapeutics, and diagnostics. The network is expected to participate in numerous trials at more than 100 clinical trial sites across the United States and internationally. Phase 3 clinical trials overseen by the CoVPN will target populations at greatest risk from COVID–19, including individuals of older age, individuals with comorbid health conditions, and racial and ethnic populations disproportionately impacted by COVID–19. The CoVPN has developed an extensive community engagement framework to reach out to diverse groups of potential research volunteers and explain the specific details involved in participating in an investigational vaccine or monoclonal antibody clinical study.

MEDICAL RESEARCH

Question. Investment into medical research is key to finding COVID–19 treatments and vaccines. However, research universities across the country have had to suspend a majority of the work at their labs. In West Virginia, researchers at West Virginia University have stepped up in developing COVID–19 tests and work with public officials to distribute the tests. This work is critical to helping fight this pandemic. How are you working with medical research universities to develop a COVID vaccine?

Answer. NIH supports research at academic and research institutions through funding opportunities including grants, contracts, and cooperative agreements. This funding is provided through both supplemental awards that allow researchers to expand existing research projects to include research on COVID–19, as well as opportunities to apply for funding for new research projects on COVID–19. NIAID, the lead NIH Institute for infectious diseases research, conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. NIAID is actively developing new funding opportunities to provide the extramural research community with vital funding to support the development of COVID–19 candidate vaccines, therapeutics, and diagnostics.

NIAID currently is supporting vaccine development efforts at a number of research universities. This includes basic research to characterize antibodies that target the SARS–CoV–2 spike protein to better inform the design of candidate vaccines. NIAID-supported research at universities also includes the development of novel SARS–CoV–2 vaccine candidates based on a number of different vaccine technologies. The Ad26 viral vector platform, now being developed by Janssen, was originally a university-developed HIV vaccine candidate developed with NIAID support. In addition, NIAID intramural scientists are collaborating with university research groups to advance candidate vaccines for SARS–CoV–2. For example, researchers at the NIAID Rocky Mountain Laboratories collaborated with scientists at University of Oxford on the development of a chimpanzee adenovirus-vectored SARS–CoV–2 vaccine candidate, AZD1222. This collaboration built on longstanding work with the University on the chimpanzee adenovirus vaccine platform. University of Oxford has partnered with the pharmaceutical company AstraZeneca on this candidate, which currently is undergoing clinical trials supported by the University. Investigators at NIAID's Rocky Mountain Laboratories also are conducting animal studies for additional RNA-based and vesicular stomatitis virus-vectored SARS–CoV–2 vaccine candidates in collaboration with researchers at the University of Washington and Washington University, respectively.

In addition to monetary funding, NIAID and NIAID-funded groups make research support services available to scientists at medical research universities and other research institutions. These resources include preclinical support such as in vitro and in vivo screening, assay development, product optimization, safety and toxicology testing, manufacturing process development, and good manufacturing practice (GMP) production for the advancement of promising candidate medical countermeasures. NIAID also supports the development of small and large animal models to evaluate the safety and efficacy of COVID–19 vaccine candidates. These resources are available to researchers regardless of whether they currently have NIH funding. NIAID also is working to develop a toolbox of potent adjuvants that are being made available to researchers developing novel COVID–19 vaccines to help optimize vac-

cine efficacy. A comprehensive list of resources available to medical research universities and the rest of the research community is available on the NIAID website.[18]

NIH will continue to support university research to develop candidate vaccines for SARS–CoV–2 through the funding of meritorious research proposals, collaborations between NIH intramural scientists and university researchers, and the provision of preclinical support services to advance promising vaccine candidates along the development pipeline.

QUESTIONS SUBMITTED TO ROBERT R. REDFIELD, M.D.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Dr. Redfield, as we look at vaccine development with special efforts taken to increase vaccination rates among higher risk populations of Covid–19 and/or flu-related complications, what are CDCs plans to target higher risk populations for Covid and flu vaccinations?

Answer. CDC is enhancing communications efforts to target special audiences, including older Americans, people of any age with underlying health conditions, workers in long-term care facilities and other essential workers. Targeted communication and education efforts will be implemented for African American and Hispanic/Latino communities realizing that these groups have lower rates of flu vaccination, yet higher risk for COVID complications.

CDC will also be working with the National Association for Community Health Centers to implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations. In addition, CDC will be engaging in simultaneous individual expert consultation with 15 national leaders in the field of health disparities, health equity, and social determinants of health to develop strategies to address racial and ethnic disparities in adult immunization.

CDC is testing flu vaccine messages to learn what impacts the pandemic may have on the intent to vaccinate, including fears about getting vaccinated in a safe environment, and CDC will continue to work with our public health and clinical partners to eliminate barriers to vaccination.

Question. We have seen some troubling statistics about the low number of anticipated flu vaccinations in the fall. What is HHS doing to combat this anticipated trend and provide flu vaccinations to Americans if we are under stay at home orders?

Answer. As we expect SARS–CoV–2 to continue to circulate in fall, CDC is working to significantly increase flu vaccination coverage, particularly for populations most at risk. Increasing flu vaccine coverage is an important public health goal on its own , but this year, it will also serve to reduce the strain on the healthcare system that will need to address the COVID–19 pandemic at the same time as seasonal influenza.

We will be conducting flu message testing to learn what impacts the pandemic may have on the intent to vaccinate, including fears about getting vaccinated in a safe environment. Additionally, this year we are implementing a project designed to assess the quality of communications with patients about vaccinations; areas of focus will include communications about influenza vaccination in African American patients. We will continue to work with our public health and clinical partners to eliminate barriers to vaccination.

The ongoing COVID–19 pandemic may affect where and how flu vaccines are given, but CDC is working with health departments to develop logistical contingency plans for vaccine distribution, with the understanding that social distancing and extended vaccine distribution may be necessary. Additionally, CDC has purchased 7.1 million additional doses of influenza vaccine directly from vaccine manufacturers to help uninsured and under-insured Americans get their flu vaccines. These vaccines will be provided to State health departments to focus on adults at higher risk of COVID–19 infection. CDC is taking many considerations into account in its efforts to expand flu vaccine coverage and is focusing on specific efforts to address racial and ethnic disparities.

Question. Dr. Redfield, one of the key questions this fall will be how a potential Covid–19 and/or current flu vaccines will be distributed to the American people. What are the current plans in place to achieve the goal of a seamless and efficient distribution process?

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[18] Coronaviruses—Information for Researchers: https://www.niaid.nih.gov/diseases-conditions/coronaviruses?researchers=true.

Answer. Recognizing that demand may exceed supply at the onset, HHS plans for a tiered approach to vaccine distribution. The approach builds on allocation methodology developed as part of pandemic flu planning and will be adjusted based on experience during the first wave of the COVID–19 response, data on the virus and its impact on populations, the performance of each vaccine, and the needs of the essential workforce.

CDC has a strong vaccine delivery infrastructure connecting public health departments, healthcare providers, community groups, pharmacists/chain drug stores, and others that can be used to efficiently reach the population. During an emergency, this proven system can be scaled up and expedited to manage and distribute many more doses of vaccine than in a typical year.

CDC has worked for decades with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure, which will help ensure effective distribution can occur once a safe and effective COVID–19 vaccine is available. CDC is working closely with our government partners in response to this pandemic, including with our sister agencies at HHS.

CDC will work with communities, government, and private partners to rapidly distribute vaccine. The ongoing COVID–19 pandemic may affect where and how vaccines are given, and we are working with health departments to develop contingency plans. Additionally, State, tribal, local and territorial health departments have hiring resources through supplemental funding for contact tracing. Jurisdictions can build on these recruitment pathways to support vaccine distribution.

Question. Supporting data exchange between States and community immunization providers is key for many reasons, in particular to ensure tracking of vaccination status for both flu and Covid–19. How much of a priority is this data sharing process and what needs to be done better moving forward?

Answer. Data sharing through vaccine tracking is a critical component of CDC's COVID–19 vaccination initiative. CDC is actively working to improve the data infrastructure needed to better track vaccines, vaccination, and related information. The Immunization Gateway is a data exchange hub that routes messages between State immunization registries and multi-State providers and allows consumers to access their immunization record. The support of the COVID–19 vaccine response requires significant enhancement of the Gateway's infrastructure and rapid onboarding of State immunization registries and multi-State providers. Enhancements and data exchange are critical for a multi-dose candidate, should one or more be approved, to ensure proper vaccine administration of the second dose.

Question. Dr. Redfield, the flu and Covid–19 look very similar and most public health experts believe that Covid–19 and influenza will circulate widely this upcoming fall and winter. What are your views on how medical professionals can further distinguish the flu from Covid–19?

Answer. Because some of the symptoms of flu and COVID–19 are similar, it may be hard to tell the difference between them based on symptoms alone, and testing may be needed to help confirm a diagnosis. CDC has developed a new diagnostic laboratory test (multiplex PCR assay) to assist with efforts to determine if an individual is infected with SARS–CoV–2, the virus that causes COVID–19. The diagnostic test can identify three viruses: Influenza A, Influenza B, and SARS–CoV–2. Although flu and COVID–19 share many characteristics, there are some key differences between the two. While more is learned every day, there is still a lot that is unknown about COVID–19 and the virus that causes it. This table (https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm) compares COVID–19 and flu, given the best available information to date.

Question. What is the government doing to expand sites of care?

Answer. Healthcare systems have adjusted the way they triage, evaluate, and care for patients during the COVID–19 pandemic, using methods that reduce exposure when appropriate. Telehealth services help provide necessary care to patients while minimizing the transmission risk of SARS–CoV–2 as well as other infectious diseases, such as influenza. These new methods help reduce staff exposure to ill persons, and preserve critical resources, such as personal protective equipment (PPE). They also minimize exposure in patients who may be at high risk for severe outcomes. Telehealth is not new, but new policies reducing barriers to access and endorsement by medical societies, has increased uptake and utilization during COVID–19. It has allowed access to acute, chronic, primary and specialty care without risking exposure. Telehealthcare can also improve compliance and patient outcomes.

Question. What is the administration doing to provide adequate reimbursement for telemedicine services related to diagnosis and treatment of flu and Covid–19?

Answer. Insurance payers and HCP professional associations have supported the transition to telehealth services during the pandemic. The Centers for Medicare & Medicaid Services (CMS) issued multiple waivers, providing flexibility (e.g., geographic location, type of health site) during the pandemic and granting payment parity between telehealth and in-person clinical care for Medicare. Medicaid programs are administered at the State level and States can choose whether or not to cover telehealth services as an alternative to traditional in-person methods of care. The HHS Office of Inspector General (OIG) is also providing flexibility for healthcare providers to reduce or waive cost-sharing for telehealth visits and other virtual care paid for by Federal healthcare programs, such as Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), during the public health emergency.

Question. Dr. Redfield, as reported by the CDC, routine vaccination rates have plummeted since the beginning of the pandemic. Are you concerned that this gap in immunization could lead to additional infectious disease outbreaks, particularly among pediatric populations, further exacerbating the existing public health crisis we're facing as a result of the pandemic?

Answer. During the COVID–19 pandemic, pediatric outpatient visits and routine childhood vaccination declined substantially. CDC observed notable reductions in the number of vaccine doses ordered through the Vaccines for Children (VFC) program. Corresponding declines were also observed in the number of measles-containing vaccine doses administered in eight U.S. healthcare organizations serving publicly and privately insured patients.[19]

To combat these trends and prevent outbreaks of vaccine-preventable diseases, CDC has been working with our immunization awardees and public health partners, including the American Academy of Pediatrics, to implement targeted intervention and communication strategies. We are supporting providers in the safe delivery of vaccines during the COVID–19 pandemic both through the development of guidance and support materials and by helping to support catch-up vaccination using reminder/recall systems for children who missed visits. We have increased communication efforts to remind parents, providers, and partners of the importance of routine vaccinations during the COVID–19 pandemic and expanding outreach to provide information about the VFC program to families, especially those who may have recently lost insurance coverage.

We are collaborating with our partners to encourage back-to-school vaccination activities during the summer and influenza vaccination in the fall. In addition, CDC's Vaccinate with Confidence strategic framework aims to strengthen public trust in vaccines and prevent vaccine-preventable disease outbreaks. Because of these efforts, we are starting to see signs of recovery with greater numbers of children presenting for preventive health services. For example, CDC's recent Morbidity and Mortality Weekly Report,[20] documents efforts taken by the NYC health department in response to reduced immunization visits; these efforts appear to have rapidly improved vaccinations, especially for children under 24 months of age, highlighting the key role that public health can play in conjunction with providers and the public. The majority of VFC providers are now offering vaccination services, and the number of vaccine doses ordered and delivered are increasing and trending towards prepandemic levels.

CDC also recognizes that the 2020–2021 flu season is fast approaching, posing a risk of serious complications, hospitalization, or death, even among otherwise healthy children and adults. As we expect SARS–CoV–2 to continue to circulate in fall, CDC is working to significantly increase flu vaccination coverage, particularly for populations most at risk.

Question. What actions should be taken now to address this and avoid adding additional stress to our already fragile healthcare system?

Answer. Dr. Robert Redfield, CDC Director and Dr. Nancy Messonnier, Director, National Center for Immunization and Respiratory Diseases, communicated a Call to Action to State Health Officers and key partners via a Dear Colleague Letter on June 22, 2020; the letter asked for help in protecting our communities through vaccination. CDC's Call to Action highlights several CDC resources, including Interim Guidance for Immunization Services During the COVID–19 Pandemic (https://www.cdc.gov/vaccines/pandemic-guidance/index.html). This interim guidance is intended to assist immunization providers in a variety of clinical and alternative settings for the safe administration of vaccines during the COVID–19 pandemic. The guidance will be continually reassessed and updated based on the evolving epidemiology of COVID–19 in the United States. Healthcare providers who administer vac-

[19] https://www.cdc.gov/mmwr/volumes/69/wr/mm6919e2.htm.
[20] https://www.cdc.gov/mmwr/volumes/69/wr/mm6930a3.htm?s__cid=mm6930a3__w.

cines should also consult guidance about immunization services options in their communities from State, local, tribal, and territorial health officials. Ultimately, we hope the guidance helps immunization partners reduce the burden on the healthcare system.

Question. Dr. Redfield, what actions is HHS currently taking to address misleading and inaccurate information about vaccine safety?

Answer. CDC's Vaccinate with Confidence framework aims to strengthen public trust in vaccines and prevent vaccine-preventable disease outbreaks. The framework emphasizes three key priorities: protect communities, empower families, and stop myths. CDC is working with local partners and using trusted messengers to establish new partnerships and contain the spread of misinformation. To advance this, we've recently collaborated with social media companies like Pinterest and Facebook to promote trustworthy information. To help protect them from misinformation, CDC seeks to reach new groups and stakeholders and provide clear information about vaccination and the critical role it plays in protecting the American public. CDC will continue to build upon the investments of our immunization program as it prepares both the Nation's public health system and the private sector to disseminate a COVID–19 vaccine once available.

Question. Does HHS have sufficient funding to support these efforts now, so that we are well prepared when an effective COVID–19 vaccine is available?

Answer. Vaccination will be a complex effort, because once available it will be an entirely new vaccine that will require broad distribution . Some variables that will impact cost and planning are unknown until the vaccine is licensed or granted Emergency Use Authorization. CDC will work with the department and administration to further examine needed resources.

Question. Dr. Redfield, once we have a proven vaccine or vaccines, efficient and seamless procurement and distribution will be critical to realizing the potential of a vaccine in a "return to normal." Following the H1N1 influenza pandemic, the CDC developed a series of pandemic planning guidances, which include information on the planned distribution of a vaccine during a pandemic.

How do you plan to distribute the vaccines to ensure high standards of equality, efficiency, and safety? What agency will have the lead? Will CDC's existing plans be utilized or are new plans under development?

Answer. CDC is working closely with the interagency staff to determine a path forward on critical issues related to a COVID–19 vaccine program through Operation Warp Speed. CDC stands ready to use its expertise in public health preparedness and response, along with its immunization infrastructure, to support Operation Warp Speed in vaccine promotion, distribution, administration, and monitoring.

The Advisory Committee on Immunization Practices (ACIP) Workgroup is evaluating safety and immunogenicity data of vaccine candidates as well as the epidemiology of COVID–19 to present to the parent ACIP for its deliberation, development of recommendations and presentation to the CDC for the CDC's consideration in order to target populations and priorities for vaccination.

Question. Will CDC's Advisory Committee on Immunization Practices be the recommending body for prioritization of populations to get the vaccine?

Answer. For COVID–19 vaccines, ACIP will review evidence on COVID–19 epidemiology and burden, vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for COVID–19 vaccine policy, including priority groups for vaccination. To prepare for potentially FDA-licensed COVID–19 vaccines, ACIP has established a workgroup that is evaluating safety and immunogenicity data of vaccine candidates, as well as the epidemiology of COVID–19, to identify target populations and priority groups for vaccination and will present its findings to the parent ACIP for its deliberation, development of recommendations and presentation to the CDC for the CDC's consideration in determining population prioritization. Lessons learned from the H1N1 influenza vaccine implementation are being used to guide COVID–19 vaccine prioritization.

While the end goal is to offer vaccines to the entire U.S. population, identifying priority groups for COVID–19 vaccination is critical for implementation planning. Among adults, the risk for severe illness from COVID–19 increases with age, with older adults at highest risk. However, people at any age with certain underlying medical conditions are at increased risk for severe illness from COVID–19.

Question. Dr. Redfield, the annual flu season is around the corner. Do you foresee and difficulties with distributing a flu vaccine along with a COVID–19 vaccine?

What is the potential impact of a low flu vaccination rate on the healthcare system?

Answer. CDC has worked for decades with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships, data systems, and other resources needed for sustaining a successful routine

immunization infrastructure. Each year, CDC safely distributes over 80 million doses of vaccines from every vaccine manufacturer to 40,000 public and private health providers across the country. CDC has a strong infrastructure that connects public health departments, healthcare providers, community groups, and others and can be used to efficiently reach every population. During an emergency, this proven system can be scaled up and expedited to manage and distribute many more doses of vaccine than in a typical year.

CDC has provided its immunization awardees $140 million in supplemental funding to support and enhance their immunization programs. This supplemental funding will be used to support awardee and local health department staffing, communications campaigns, pandemic preparedness, and mass vaccination. In addition to other COVID–19 vaccine response work, awardee activities will include a specific focus on significantly enhancing influenza coverage, especially in historically underserved populations, and enrolling and working with additional vaccinators like pharmacists.

Question. To Dr. Redfield and Dr. Disbrow, managing production capacity for therapeutics and vaccines is paramount to Operation Warp Speed's success. What challenges have you identified with respect to rapid manufacturing and distribution of multiple products that span a broad variety of technologies?

How do you plan to balance manufacturing capacity between antibody products, therapeutics, and vaccines?

How do you intend to engage companies with the necessary manufacturing capabilities, many of which would need to pause their work on other products to meet these accelerated timelines?

Answer. Antibodies, small molecule therapeutics, and vaccines all deploy different manufacturing technologies, and require different type of manufacturing capacity, not interchangeable between categories. For the vaccines, HHS has strived to maximize the amount of capacity available. In many cases, the limiting factor to the number of doses projected to be available by year-end is the timeline of the manufacturing process. OWS is expediting the overall development timeline by supporting development activities in parallel. For antibodies, HHS is maximizing the internal capacity of the manufacturers, while at the same time encouraging the transfer to contract manufacturers to further boost the production rate. For small molecules, the limiting factor determining the number of doses available by the end of the year is the availability of raw and starting materials, rather than the manufacturing capacity.

An effective influenza pandemic response includes developing, manufacturing, distributing, dispensing, and administering medical countermeasures, such as vaccines, in the shortest time possible, and monitoring their impact when used during a public health emergency. A safe and efficient vaccine distribution system (including storage and handling), tracking and monitoring systems, communication strategies, and technical assistance and analysis are integral components of a prospective pandemic vaccine program. CDC will work with HHS and the administration to coordinate COVID–19 vaccine allocation, distribution, and administration.

HHS has developed and refined tools and guidance over the past decade to help guide different aspects of pandemic planning and response, including processes for vaccines. Given that vaccine supply would likely increase incrementally as it is produced during the pandemic, targeting decisions may have to be made.

Additional efforts are underway to request that manufacturers produce additional needles and supplies to support the pandemic vaccination program. As part of this effort, HHS is taking care to avoid negatively impacting supplies used for routine and flu vaccination. Additionally, OWS is ramping up production of reagents and consumables to make sure that we have enough supplies to administer any vaccine as soon as it is ready.

QUESTIONS SUBMITTED BY SENATOR MARCO RUBIO

Question. The CDC recommends daily screening for COVID–19 symptoms before student athlete participation in practices and games.

Who is qualified to administer and record these screenings?

Should it be left to medical professionals, or should coaches and trainers have the ability?

Answer. Any sports program administrator may conduct screenings for symptoms. Steps should be taken to help ensure staff that are responsible for these screenings are able to employ mitigation strategies, such as maintaining social distancing or using physical barriers to minimize close contact with children who may have symptoms, so that they can stay healthy and avoid transmission. Additionally, encour-

aging parents to be on the alert for signs of illness in their children can be helpful in assuring that children who are sick don't come to practice or games.

Question. What action should be taken if one player tests positive for COVID–19? Should the entire team quarantine for 14 days?

Answer. Programs should ensure coaches, staff, officials, players, and families know that sick individuals should not attend the youth sports activity, and to alert the team if they have been exposed to someone suspected or confirmed to have COVID–19. If someone tests positive for COVID–19, programs should close off areas used by a sick person within the last 24 hours and avoid using these areas until after they are cleaned and disinfected. The organization should comply with any State or local law or regulation that requires notifying local health officials, youth sports program staff, umpires/officials, and families immediately of anyone with COVID–19 while maintaining that person's confidentiality in accordance with any applicable law or regulation. Last, if any coaches, staff members, umpires/officials, or players get sick, they should not return until they have met CDC's criteria to discontinue home isolation (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html#discontinue-isolation). In addition, individuals who recently had close contact with a person with COVID–19 should quarantine for 14 days since their last exposure to the individual.

Question. How can schools and sports programs utilize test result data while still complying with health privacy laws, like HIPAA?

Answer. Youth sports organizations should comply with any State or local law or regulation that requires notifying local health officials, youth sports program staff, umpires/officials, and families immediately of any case of COVID–19 while maintaining confidentiality in accordance with any applicable laws and regulations. Schools and sports programs can work with local health officials to develop a reporting system that youth sports organizations can use to notify health officials and close contacts of cases of COVID–19. They can also advise students and staff who have had close contact with a person diagnosed with COVID–19 to stay home and self-monitor for symptoms and to follow CDC guidance if symptoms develop.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

PLANNING A MASS COVID–19 VACCINATION CAMPAIGN

Question. Having an authorized vaccine is only the first step in a long process of actually distributing and administering that vaccine to the entire U.S. population—a task that will require significant coordination and planning. As Operation Warp Speed (OWS) races to develop a safe and effective vaccine for COVID–19, the Federal Government must fund the infrastructure to deliver vaccines and prepare for various vaccination needs and scenarios associated with a mass vaccination campaign. This effort must be led by the CDC, which has the expertise and experience in protecting communities from vaccine preventable diseases, responding to outbreaks, and ensuring a scientifically sound and robust immunization infrastructure.

Please provide a comprehensive list of the various activities that need to be fully accounted for and budgeted in planning for all aspects of a mass COVID–19 vaccination program across the country. What preliminary budget estimates are associated with each of these activities?

Answer. A pandemic places extraordinary and sustained demands on both public health and healthcare systems and on providers of essential community services. Vaccination for COVID–19 will be a complex effort, because it will utilize an entirely new vaccine that will require broad distribution. A safe and efficient vaccine distribution system (including storage and handling), tracking and monitoring systems, communication strategies, vaccination of individuals in settings that permit optimal social distancing, and technical assistance and analysis are integral components of a prospective pandemic vaccine program. However, some variables that will impact cost and planning are unknown until the vaccine is licensed or granted Emergency Use Authorization. CDC will work with the department and administration to further examine needed resources.

Question. Please include estimated costs for State and local vaccination infrastructure, cold chain supply, standing up additional vaccination sites, workforce recruitment and training, immunization information systems, reporting on coverage, effectiveness, safety and evaluation, targeting hard to reach populations, and any other relevant activities.

Answer. A pandemic places extraordinary and sustained demands on public health and healthcare systems and on providers of essential community services. Vaccination will be a complex effort because it is an entirely new vaccine, or multiple dif-

ferent new vaccines, that will require broad distribution A safe and efficient vaccine distribution system (including storage and handling), tracking and monitoring systems, communication strategies, and technical assistance and analysis are integral components of a prospective pandemic vaccine program. However, some variables that will impact cost and planning are unknown until the vaccine(s) is/are licensed or granted EUA. CDC will work with the department and administration to further examine needed resources.

There are many critical components to consider in implementation of a pandemic vaccine. Critical to success of the vaccine program is ensuring vaccine safety, effectiveness, and ultimately vaccine confidence. CDC is working closely with our government partners in response to this pandemic, including with our sister agencies at HHS. CDC stands ready to assist Operation Warp Speed to be successful in achieving its coverage goals by building on our long- standing immunization infrastructure and leveraging our broader public health partnerships to address this health emergency (www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html). Below are the major program considerations in developing and implementing a vaccine campaign:

—*Prioritization and Allocation of Vaccine:* The overarching aim of a national pandemic vaccination program is to vaccinate all persons in the U.S. who choose to be vaccinated. The vaccine supply needed to meet this goal will increase incrementally over time as vaccines are produced; however, initial supply is likely to not meet demand. Since most vaccines in development are expected to require two doses, and individuals will need to receive a second dose of the same type of vaccine given for their first dose, prioritization of limited supplies needs to incorporate this element (e.g., will available doses of a given product preferentially go to complete individuals' series or for first doses for additional individuals). Once priority populations are determined, guidance on vaccine prioritization will be disseminated to State, tribal, local, and territorial partners to inform planning and decisionmaking.

—*Support State Immunizations Programs:* State and local public health programs will be largely responsible for directing vaccine to target these federally identified priority populations. State and local public health programs will enlist providers to vaccinate the public who are eligible for USG VFC and section 317-purchased vaccine. State and local public health authorities will need to train providers in storage, handling, and administration of COVID–19 vaccine.

—*Distribution of Vaccine:* Each year, CDC safely distributes more than 80 million doses of vaccines to approximately 40,000 public and private health providers across the country. During the 2009 H1N1 pandemic, more than 70,000 provider sites participated in the expanded vaccination program. Distribution includes moving vaccines from manufacturer, to distribution center, to States, and/or to vaccination administration entity (e.g. doctor's offices, pharmacies, occupational clinics). Strong networks connect public health departments, healthcare providers, community groups, pharmacists/chain drug stores, and others that can be used to efficiently reach diverse populations. From these sites, vaccine may be transported in small quantities to clinical sites for immediate use while maintaining cold chain. During an emergency, this proven system can be scaled up and expedited to manage and distribute many more doses of vaccine than in a typical year.

—*COVID–19 vaccine distribution* will require scale-up of the existing centralized vaccine and ancillary supply allocation and distribution. Additional distributors are also under consideration for larger scale up. COVID–19 distribution will also require additional IT infrastructure and support of existing ordering systems.

—*Monitoring, Tracking and Data Infrastructure:* CDC is actively working to improve the data infrastructure needed to track vaccines, vaccination, and related information. The Immunization Gateway is a data exchange hub that routes messages between State immunization registries, multi-State providers, and allows consumers to access their immunization record. The support of COVID–19 vaccine response requires significant enhancement of the Gateway's infrastructure and rapid onboarding of State immunization registries and multi-State providers. Enhancements and data exchange are critical for a multi-dose candidate to ensure proper vaccine administration of the second dose.

—*Vaccine Safety Systems and Vaccine Effectiveness Studies:* Post-licensure (post-approval) vaccine safety monitoring is the continued assessment of a vaccine's safety after it has received U.S. Food and Drug Administration (FDA) approval and is being administered in the population; it is a Federal responsibility. Due to the compressed regulatory approval timeline, the anticipated vaccine administration of large numbers of doses during a short time window, and heightened

public concern about vaccine safety, enhanced monitoring will be an important component of a large-scale national SARS–CoV–2 immunization program.

—Post-approval monitoring can generate the large volumes of data necessary to detect and characterize rare adverse events following immunization. CDC uses multiple, complementary systems and processes to monitor and assess vaccine safety. In addition, CDC will work with partners to establish or develop systems to fill gaps in post-approval safety monitoring (i.e., in older age groups, the indigent, special populations, etc.). CDC systems will be especially important for monitoring new SARS–CoV–2 vaccines that are made using novel manufacturing techniques not previously used for other U.S. vaccines.

—*Communications and Outreach:* A strong and comprehensive communication strategy is critical to any vaccine initiative. Identifying the right messages, countering misinformation, and targeted outreach to vulnerable and at-risk populations will be necessary to achieve high coverage and herd immunity. CDC will build on its existing relationships with public health partners and health departments to effectively implement communication efforts.

Question. What are the plans to centralize the pricing, purchase, initial allocation, reallocation, and distribution of vaccines under one Federal agency?

Answer. CDC is working closely with the interagency staff to determine a path forward on critical issues related to a COVID–19 vaccine program through Operation Warp Speed. CDC stands ready to use its expertise in public health preparedness and response along with its immunization infrastructure to support Operation Warp Speed in vaccine promotion, distribution, administration, and monitoring.

Question. How is the Administration working to make sure States are not competing with each other to get access to a vaccine or vaccine supplies to deliver the COVID–19 vaccine broadly? Will the Administration make public a clear set of criteria and guidance to make initial allocation and distribution prioritization decisions for a vaccine or vaccines?

Answer. CDC has worked for decades with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure. Each year, CDC safely distributes over 80 million doses of vaccines from every vaccine manufacturer to 40,000 public and private health providers across the country. CDC has a strong infrastructure that connects public health departments, healthcare providers, community groups, and others and can be used to efficiently reach every population. During an emergency, this proven system can be scaled up and expedited to manage and distribute many more doses of vaccine than in a typical year.

The Advisory Committee on Immunization Practices (ACIP) COVID–19 Vaccine Work Group has been established to help inform evidence-based approaches to COVID–19 vaccination policy, including an initial vaccine prioritization strategy. While the end goal is to offer vaccines to the entire U.S. population, identifying priority groups for COVID–19 vaccination is critical for implementation planning. ACIP has embarked on early planning in hopes of preventing distribution delays post vaccine approval. ACIP meetings are open to the public, and committee records are required to be made available to the public, thereby increasing transparency and visibility of the recommendation-making process.

Question. What is OWS doing to work with CDC and State and local public health officials to ensure an adequate public health workforce to execute a nationwide vaccination campaign?

Answer. CDC stands ready to assist Operation Warp Speed to be successful in achieving its coverage goals by building on our long-standing immunization infrastructure. Each year, CDC distributes over 80 million doses of vaccines from every vaccine manufacturer to health departments and private health providers across the country. We have a strong vaccine delivery infrastructure connecting public health departments, healthcare providers, community groups, and others that can be used to efficiently reach the population. During an emergency, this proven system can be scaled up and expedited to manage and distribute many more doses of vaccine than in a typical year.

CDC has provided its immunization awardees $140 million in supplemental funding to support and enhance their immunization programs. This supplemental funding will be used to support awardee and local health department staffing, communications campaigns, pandemic preparedness, and mass vaccination. In addition to other COVID–19 vaccine response work, awardee activities will include a specific focus on significantly enhancing influenza coverage and enrolling and working with additional vaccinators such as pharmacists.

Question. What steps is OWS taking now to educate the American public about a possible vaccination campaign? How is it ensuring that the American people have

access to early, clear, and consistent information to make the best decisions about the health of their families?

Answer. CDC recognizes that effective communication is a critical component of any vaccine program, and CDC is working collaboratively within Operation Warp Speed to ensure that consistent and accurate information is at the foundation of the communication plan currently being developed. Understanding that public confidence in vaccines is necessary for vaccine uptake, CDC's strategic framework, Vaccinate with Confidence (https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html), aims to strengthen public trust in vaccines and prevent vaccine-preventable disease outbreaks. This framework emphasizes three key priorities: protect communities, empower families, and stop myths. Within this framework, CDC is working with local partners and using trusted messengers to establish new partnerships and contain the spread of misinformation. In addition to accurate communication of what we do and do not know, building confidence requires setting realistic expectations. CDC will continue to build upon the investments of our immunization program as the agency works with both the Nation's public health system and the private sector to plan and prepare for dissemination of a COVID–19 vaccine, once available.

Question. What steps is OWS taking to ensure access to vaccines for communities of color, high-risk populations, low-income populations, uninsured populations, and rural and frontier areas?

Answer. CDC is enhancing vaccination messaging to target special audiences, including older Americans, people of any age with underlying health conditions, workers in long-term care facilities, and other essential workers. Targeted communication and education efforts will be implemented for African American and Hispanic communities with the understanding that these groups have lower rates of flu vaccination, yet higher risk for COVID complications.

CDC will also be working with the National Association for Community Health Centers to implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations. In addition, we will be engaging in simultaneous individual expert consultation with 15 national leaders in the field of health disparities, health equity, and social determinants of health to develop strategies to address racial and ethnic disparities in adult immunization.

CDC is testing flu vaccine messages to learn what impacts the pandemic may have on the intent to vaccinate, including fears about getting vaccinated in a safe environment, and CDC will continue to work with our public health and clinical partners to eliminate barriers to vaccination.

Question. What is the role of CDC's Advisory Committee on Immunization Practices (ACIP) in developing recommendations for a COVID–19 vaccine? How does the planned study by the National Academy of Medicine that is being coordinated by NIH relate to, and not duplicate, ACIP's role?

Answer. The Advisory Committee on Immunization Practices (ACIP) was established in 1964 and is chartered as a Federal advisory committee that provides guidance to the CDC Director on the use of vaccines in the U.S. civilian population. For COVID–19 vaccines, ACIP will review evidence on COVID–19 epidemiology and burden, vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for COVID–19 vaccine policy, including priority groups for vaccination. ACIP meetings are open to the public, and committee records are required to be made available to the public, thereby increasing transparency and visibility of the recommendation- making process.

The committee convened by the National Academy of Medicine (NAM) will focus on developing a framework for equitable allocation of COVID–19 vaccines both in the United States and abroad. The findings from the NAM committee will be shared with ACIP and may help inform the committee's deliberations related to vaccine priority groups and ensuring equity in vaccination in the United States.

Question. Given that CDC recently disbursed $140 million to States and localities to assist with preparation for the coming flu season, what more is needed to scale up our vaccination efforts for the seasonal flu this fall and winter?

Answer. Funds from the recent CDC award of $140 million to jurisdictions will begin to support staffing and preparedness early this summer and focus on ensuring flu coverage for vulnerable populations. CDC has also increased communication efforts and has purchased 7.1 million additional doses of seasonal influenza vaccine directly from vaccine manufacturers to help uninsured and under-insured Americans get their flu vaccines. These vaccines will be provided to State health departments, and adults at higher risk will be prioritized to receive vaccine. CDC is taking many considerations into account in its efforts to significantly expand flu vaccine coverage and is focusing on specific efforts to address racial and ethnic disparities.

Specifically, CDC will be working with the National Association for Community Health Centers to implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations. CDC will engage in expert consultation to develop strategies for addressing racial and ethnic disparities in adult immunization by, soliciting simultaneous individual expert opinions from 15 national leaders in health disparities, health equity, and social determinants of health. The focus will be on African Americans, with similar activity focused on Hispanic populations under consideration.

CDC is also working with Vaccines for Children program providers to ensure they are prepared for a potentially increased number of eligible children, due to the economic impact of the pandemic. Children and adults with private insurance should be able to access the flu vaccine at no cost, if they are seen at in-network providers. The Affordable Care Act requires that all vaccines recommended by the Advisory Committee on Immunization Practices and adopted by the CDC Director are covered by insurance providers. CDC is also supporting efforts for school-located vaccination clinics to expand access to flu vaccines for children. Additionally, Section 317 Immunization program provides some vaccine to be used as a safety net for outbreaks and uninsured adults.

QUESTIONS SUBMITTED BY SENATOR JACK REED

VACCINE INFRASTRUCTURE FUNDING

Question. Once a safe and effective COVID–19 vaccine is approved, it will require a serious undertaking to launch a nationwide vaccine campaign, which would include vaccine distribution, safety monitoring, education and awareness campaigns, and tracking vaccine coverage rates. Do you think that more funding will be necessary for State and local health departments to do this critical work? Do you think that this funding is needed now so that when a vaccine is approved, systems will be in place to deploy the vaccine as soon as possible?

Answer. The cost and planning for vaccine distribution are contingent on multiple variables, many of which are unknown. CDC will work with the department and administration to further examine needed resources, as necessary.

LESSONS LEARNED FROM H1N1

Question. Is CDC leveraging its existing vaccine infrastructure to prepare a national COVID–19 vaccine distribution plan? What lessons were learned from the H1N1 vaccine strategy to help inform us now?

Answer. CDC has worked for decades with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure. This will help ensure that effective distribution can occur once a safe and effective COVID–19 vaccine is available. CDC is using both its expertise in public health preparedness and response and its immunization infrastructure to support Operation Warp Speed in planning for vaccine promotion, distribution, administration, and monitoring. As part of our influenza pandemic preparedness and planning we have developed guidance that is available online. The COVID–19 pandemic has likely accelerated a trend towards different ways of engaging with the healthcare system, and successful delivery of this vaccine will need to incorporate new types of sites and approaches for vaccine delivery. For example, during H1N1, once vaccines became widely available pharmacies played an important role in the vaccine distribution, and their role is even more critical today.

CDC learned several lessons from the H1N1 response and vaccine distribution. One relevant example is that there can be uncertainties in the pharmaceutical manufacturing process; we should anticipate delays and build flexibility into our planning process to respond to adapting circumstances. Another is that demand is likely to vary in different parts of the country and in diverse populations within a given geographic area. Equitable distribution, trusted communication, and nimble delivery strategies will be important.

NATIONAL VACCINE CAMPAIGN

Question. What work is underway on a national vaccine campaign? Once a vaccine is approved, how can we ensure that the public feels confident in the safety of the vaccine? What strategies will CDC employ to ensure that vulnerable communities, such as minority communities—who have been hit hardest by COVID–19 and historically have lower immunization rates—get the vaccine? How will CDC work to

combat misinformation about a COVID–19 vaccine and vaccines more broadly to increase confidence in a vaccine and therefore increase vaccination rates?

Answer. CDC recognizes that effective communication is a critical component of any vaccine program, and CDC is working collaboratively within OWS to ensure that consistent and accurate information is at the foundation of the communication plan currently being developed. Understanding that public confidence in vaccines is necessary for vaccine uptake, CDC's Vaccinate with Confidence (https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html) strategic framework emphasizes protecting communities, empowering families, and stopping myths.

—*Protecting Communities:* Immunization information system data will be important to help find and respond to pockets of low vaccine coverage and CDC will continue to help build immunization program capacity and leadership to effectively respond to outbreaks in vulnerable communities.

—*Empowering Families:* CDC will assist with strengthening parent-provider conversations about vaccination by developing a provider toolkit to address parents' vaccine questions during outbreaks; encourage early conversations about vaccination; and ensure vaccination resources are available to families throughout the Nation's community health centers

—*Stopping Myths:* CDC will work with social media companies to promote trustworthy vaccine information, provide accurate and accessible information to policy makers, and engage State and local health officials to advance effective local responses to misinformation

CDC is also working on developing its campaign strategy and messages for this fall. CDC will conduct outreach to those at higher risk for both COVID–19 and flu, such as those living and working in long-term care facilities, adults with underlying conditions, other essential workers, and certain racial/ethnic groups. CDC will enhance education and communication efforts related to flu by aligning with COVID messaging and targeting African American and Hispanic communities, given that these groups have lower rates of flu vaccination and higher risks for COVID complications.

In addition, CDC continues to update its Vaccine Guidance During a Pandemic, available on the CDC website. This resource provides the most up to date information for healthcare providers to properly prepare for vaccine planning and distribution in their area. In addition the CDC website (https://www.cdc.gov/vaccines/index.html) provides regularly updated information on vaccination guidance and immunization, including specific links for special populations and race/ethnic groups. As developments are made in COVID–19 vaccines, additional information will be available on the public website for healthcare providers and the general public.

FLU VACCINE

Question. Vaccination rates for the flu have always been low across the country, and still we experience shortages of the flu vaccine some years. It will be absolutely critical that more people get the flu vaccine this year and that we have sufficient supplies of the vaccine so that we keep people healthy and out of the hospital during a potential second wave of COVID–19 this fall and winter. How is the Administration working to improve flu vaccination rates this year? What are the plans for flu vaccine purchase and for ensuring sufficient supplies of the flu vaccine this year? How much funding will be needed to achieve these goals?

Answer. We will use a multipronged approach to increase the uptake of flu vaccinations this year:

—Implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations.

—Make additional influenza vaccine available to State health departments for uninsured adults at increased risk.

—Execute targeted communication and education efforts for under vaccinated and priority populations.

Through CDC's existing immunization cooperative agreement, CDC awarded $140 million from the Coronavirus Aid, Relief, and Economic Security Act to 64 jurisdictions to enable State health departments to scale up for influenza season given the increased risk of COVID–19. Funds will support staffing and preparedness this summer and focus on ensuring flu coverage for vulnerable populations.

The ongoing COVID–19 pandemic may affect where and how flu vaccines are given, but we are working with health departments to develop contingency plans. CDC is also looking at operational considerations such as potential need for social distancing measures in vaccination settings and prolonging seasonal influenza vaccine uptake from September through December. In addition to these efforts, CDC has purchased 7.1 million additional seasonal influenza vaccine doses directly from

vaccine manufacturers to help uninsured and under-insured Americans get their flu vaccines. These vaccines will be provided to State health departments to focus on adults at higher risk. We are taking many considerations into account in our efforts to significantly expand flu vaccine coverage and focusing on specific efforts to address racial and ethnic disparities.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

Question. Anti-vaccination attitudes and public confidence in a vaccine.

Even before the pandemic, public trust and belief in the importance of vaccines had been falling. When there is a safe and effective vaccine available, there are significant concerns that the public will not be confident enough in the vaccine to become vaccinated at a level to achieve herd immunity. What are the most important factors in increasing public confidence in a vaccine and improving vaccination rates?

Answer. To both increase the public's confidence in vaccination and enhance provider and policy makers' role in supporting improving vaccination rates, CDC's Vaccinate with Confidence strategic framework emphasizes the following important actions:

—Leveraging diverse data sources to find and protect communities at risk;
—Expanding resources for working with local communities;
—Building and fostering a culture of immunization in healthcare practices;
—Continually improving communication strategies; and
—Further investing in and collaborating with vital partners

Within this framework, CDC is working with local partners and using trusted messengers to establish new partnerships and increasing public confidence in vaccination. Building confidence is inherent to all our work, and CDC will continue to build upon the investments of our immunization program as it prepares both the Nation's public health system and the private sector to disseminate a COVID–19 vaccine, once available.

CDC is committed to ensuring the most up to date and accurate information is available to healthcare providers and the general public. The CDC website is updated regularly with the latest guidance and recommendations on vaccines and immunizations. CDC will continue to offer the latest information on vaccine preventable disease, including COVID–19, on the public website, which features resources and information to educate the general public on the safety and purpose of vaccination.

Question. For this pandemic, how will Operation Warp Speed both counter the reasons why people may be anti-vaccination and increase the general public's confidence in a vaccine?

Answer. CDC recognizes that effective communication is a critical component of any vaccine program. We are working collaboratively within Operation Warp Speed to ensure consistent and accurate information is at the foundation of our work, and a communication plan is currently being developed. Understanding public confidence in any and all vaccines is necessary for vaccine uptake, and CDC is implementing a new strategic framework, Vaccinate with Confidence, to strengthen public trust in vaccines and prevent vaccine-preventable disease outbreaks. The framework emphasizes three key priorities: protect communities, empower families, and stop myths. Within this framework, CDC is working with local partners and using trusted messengers to establish new partnerships and increase public confidence in vaccination. Building confidence is inherent to all our work, and CDC will continue to build upon the investments of our immunization program as it prepares both the Nation's public health system and the private sector to disseminate a COVID–19 vaccine once available.

Question. How will vaccine distribution be designed to improve public confidence in a vaccine?

Answer. CDC is using its expertise in public health preparedness and response and its immunization infrastructure to support Operation Warp Speed in planning for vaccine promotion, distribution, administration, and monitoring. We recognize that the pandemic has likely accelerated a trend towards different ways of engaging with the health system; thus, we will work closely with trusted State and local partners to deliver vaccines from new sites, using approaches that meet communities' unique needs.

One critical point that we will reiterate for public confidence is that safety and efficacy are of paramount importance. Operation Warp Speed will not allow for any risk with respect to the safety profile required of a vaccine intended for wide distribution.

The overall distribution plan will be designed working with HHS and other agencies

Question. It is critical that the public hears consistent, factual messaging about a vaccine. What are the plans and steps the CDC is taking now to establish a vaccination promotion campaign to ensure sufficient coverage of a vaccine, when available?

Answer. As part of CDC's Vaccinate with Confidence strategic framework, CDC will work to ensure availability of accurate and effective messaging and aim to dispel myths about vaccination by:

—Working with social media companies to promote trustworthy vaccine information

—Ensuring State policy makers have access to accurate vaccine information and support vaccine uptake in their communities

—Engaging State and local health officials to advance effective local response to misinformation and bring attention to credible resources

In addition, CDC will maintain accurate and up to date information on the CDC website which is accessible to the general public, healthcare providers, and policy makers, and contains additional resources that can be used for vaccine messaging, education, and promotion.

Question. What lessons from the H1N1 vaccination campaign is the CDC applying to the COVID–19 pandemic?

Answer. CDC learned several lessons from the H1N1 response, including that there can be uncertainties in the pharmaceutical manufacturing process of vaccines; we should anticipate delays and build flexibility into our planning process to respond to adapting circumstances.

During H1N1, CDC as a public health agency and providers who offer vaccination services already had a lot of experience and knowledge of flu vaccines, which provided a good base understanding when the H1N1 vaccine was rolled out. With COVID 19 being a novel virus, we do not have the same baseline. CDC recognizes the need to be out front talking to healthcare providers and State and local health departments about the vaccine(s) to help ensure that providers are comfortable with the administration of the vaccine, once available. CDC also learned with H1N1 that we need to be nimble about access to vaccine, keeping an eye on the disease and on differing levels of demand for vaccine in order to determine who we need to reach most quickly.

VACCINE DISTRIBUTION

Question. Does the Federal Government intend to coordinate vaccine allocation, distribution, and administration, including determining priority populations to receive the vaccine first?

Answer. CDC is using its expertise in public health preparedness and response and its immunization infrastructure to support Operation Warp Speed in planning for vaccine promotion, distribution, administration, and monitoring. This is a tremendous undertaking, and in anticipation of a vaccine, there is much to prepare for by the fall. Our goal is to effectively and efficiently implement a COVID–19 vaccination program immediately after FDA licenses and the Advisory Committee on Immunization Practice recommends, and the CDC Director adopts that recommendation for, a vaccine. While the end goal is to offer vaccines to the entire U.S. population, identifying priority groups for COVID–19 vaccination is critical for implementation planning. Specifically, CDC will be working with the National Association for Community Health Centers to implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations. We will be engaging in expert consultation to develop strategies for addressing racial and ethnic disparities in adult immunization by soliciting simultaneous individual expert opinion from 15 national leaders in health disparities, health equity, and social determinants of health. The focus will be on African Americans, with similar activity focused on Hispanic/Latino populations under consideration.

Question. Will the CDC or Operation Warp Speed have the lead on vaccine allocation, distribution, and administration? If the CDC is not the lead, what is the rationale for taking this key responsibility out of the CDC?

Answer. CDC is working closely with the interagency staff to determine a path forward on critical issues related to a COVID–19 vaccine program through Operation Warp Speed. CDC stands ready to use its expertise in public health preparedness and response along with its immunization infrastructure to support Operation Warp Speed in vaccine promotion, distribution, administration, and monitoring.

Question. Given cuts to the public health workforce and how overwhelmed State and local health departments are in responding to the pandemic, how will Operation

Warp Speed support State and local health departments in carrying out a vast vaccination program?

Answer. CDC has worked for decades with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure. This will help ensure that effective distribution can occur once a safe and effective COVID–19 vaccine is available. CDC is working closely with our government partners in response to this pandemic, including with our sister agencies at HHS. CDC has provided its immunization awardees $140 million in supplemental funding to support and enhance their immunization programs. This supplemental funding will be used to support awardee and local health department staffing, communications campaigns, pandemic preparedness, and mass vaccination. In addition to other COVID–19 vaccine response work, awardee activities will include a specific focus on significantly enhancing influenza coverage and enrolling and working with additional vaccinators (e.g. pharmacists).

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

Question. CDC currently distributes 80 million doses of vaccines every year. We will need at least 300 million doses of a COVID–19 vaccine to achieve herd immunity, in addition to tens of millions of doses of the flu vaccine and other needed vaccines to protect public health. We are months into this pandemic and the Administration has failed to secure the supply chain for COVID–19 tests, and I am not confident that we can count on the Administration to secure the supply chain for hundreds of millions of vaccines. Furthermore, we will face significant challenges and international competition in obtaining all of the needed supplies.

Does the CDC currently have a plan in place for the allocation, distribution, and prioritization of all vaccine supplies that accounts for severe supply shortages? Once the CDC has developed such a plan, will you commit to making it public?

Answer. An effective pandemic response includes developing, manufacturing, distributing, dispensing, and administering medical countermeasures, such as vaccines, in the shortest time possible, and monitoring their impact when used during a public health emergency. A safe and efficient vaccine distribution system (including storage and handling), tracking and monitoring systems, communication strategies, and technical assistance and analysis are integral components of a prospective pandemic vaccine program. CDC will work with HHS and the administration to coordinate COVID–19 vaccine allocation, distribution, and administration.

HHS has developed and refined tools and guidance over the past decade to help guide different aspects of pandemic planning and response, including processes for vaccines. Given that vaccine supply would likely increase incrementally as it is produced during the pandemic, targeting decisions may have to be made.

CDC has worked for decades with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure. This will help ensure effective distribution can occur once a safe and effective COVID–19 vaccine is available. The cost and planning for vaccine distribution are contingent on multiple variables, many of which are unknown. CDC will work with the department and administration to further examine needed resources, as necessary.

QUESTIONS SUBMITTED BY SENATOR JOE MANCHIN, III

VACCINE SUPPLY CHAIN

Question. Back in March of this year, we saw shortages of common necessary medical equipment for COVID–19 testing, such as swabs for sample collection and PPE. These shortages led to people rationing their tests and it slowed our ability to know where hot spots were happening. Once we have an approved vaccine, this vaccine will need to be widely distributed. That means: having personnel to administer the vaccine, supplies such as syringes and PPEs, and reliable refrigeration for the vaccine. Can you elaborate on how you plan to ensure health providers have the needed equipment to administer a COVID vaccine?

Answer. HHS is leading efforts to purchase needles and syringes for the pandemic vaccination program, and CDC is working collaboratively to provide technical assistance. Additional efforts are underway to request that manufacturers produce additional needles and supplies to support the pandemic vaccination program. As part of this effort, HHS is taking care to avoid negatively impacting supplies used for

routine and flu vaccination. Additionally, HHS is ramping up production of reagents and consumables to make sure that we have enough supplies to administer any vaccine as soon as it is ready.

Question. What is your vision of how COVID vaccine should be delivered to the American public?

Answer. CDC will continue to work with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure. This will help ensure effective distribution can occur once a safe and effective COVID–19 vaccine is available.

CDC will continue to use its expertise in public health preparedness and response and its immunization infrastructure to support Operation Warp Speed in planning for vaccine promotion, distribution, administration, and monitoring.

CDC plays an important role in ensuring success of Operation Warp Speed because of our expertise in the delivery of vaccines through a robust immunization delivery infrastructure. This infrastructure can and will be leveraged to deliver a COVID–19 vaccine and protect Americans from this novel health threat.

VACCINE DISTRIBUTION

Question. In your testimony, you highlighted the fact that in the 2018–2019 flu season, only 49 percent of the U.S. population was vaccinated. The Food and Drug Administration (FDA) has stated that we would need upwards of 70 percent of the population vaccinated to create immunity to COVID. Not only is this an incredibly high threshold to meet, but now we have the 2020–2021 flu season on the horizon, and will need to ensure supplies are available to vaccinate and treat the flu. What is your plan to ensure we have adequate supply to vaccinate the public against both the flu and COVID?

What is your plan for vaccinating the U.S. population for both of these viruses?

Have you developed a budget estimate on how much it will cost to vaccinate every American?

Answer. As we expect SARS–CoV–2 to continue to circulate in fall, CDC is working to significantly increase flu vaccination coverage, particularly for populations most at risk. Increasing flu vaccine coverage is an important public health goal on its own, but this year, it will also serve to reduce the strain on the healthcare system that will need to address the COVID–19 pandemic at the same time as seasonal influenza.

Through CDC's existing immunization cooperative agreement, CDC awarded $140 million from the Coronavirus Aid, Relief, and Economic Security Act to 64 jurisdictions to enable State health departments to launch an initial scale up for influenza season given the increased risk of COVID–19. Funds will support staffing and preparedness this summer and focus on ensuring flu coverage for vulnerable populations. In addition to other COVID–19 vaccine response work, awardee activities will include a specific focus on significantly enhancing influenza coverage and enrolling and working with additional vaccinators such as pharmacists, mass vaccinators.

The ongoing COVID–19 pandemic may affect where and how flu vaccines are given, but we are working with health departments to develop contingency plans. CDC is also looking at operational considerations such as potential need for social distancing measures in vaccination settings and prolonging seasonal influenza vaccine uptake from September through December. In addition to these efforts, CDC has purchased 7.1 million additional seasonal influenza vaccine doses directly from vaccine manufacturers to help uninsured and under-insured Americans get their flu vaccines. These vaccines will be provided to State health departments to focus on adults at higher risk. CDC is taking many considerations into account in our efforts to significantly expand flu vaccine coverage and focusing on specific efforts to address racial and ethnic disparities.

We will be conducting flu message testing to learn what impacts the pandemic may have on the intent to vaccinate, including fears about getting vaccinated in a safe environment. Additionally, this year we are implementing a project designed to assess the quality of communications with patients about vaccinations; areas of focus will include communications about influenza vaccination in African American patients. We will continue to work with our public health and clinical partners to eliminate barriers to vaccination.

LOCAL MEDIA

Question. Once we have a vaccine, the government will need to get critical information to the American public. Unfortunately, local newspapers and broadcasters—

which were already struggling—have been hard hit financially by the epidemic, losing much of the local advertising revenue they rely on to stay open. We will need to provide essential information to the American public, such as where they can get and where they can receive the vaccine. However, some of the most vulnerable newsrooms, which were already struggling prior to the pandemic, are located in the areas that rely on them the most. In rural areas like West Virginia, broadcast stations and local papers are the predominant or only form of localized information. Federal funding could ensure that this information reaches the American public while also providing a financial lifeline to our local media. Throughout this process, how will you work to keep the American public informed through local media?

Answer. A strong and comprehensive communication strategy is critical to any vaccine initiative. Identifying the right messages, countering misinformation, and targeting outreach to vulnerable and at-risk populations will be necessary to achieve high coverage and herd immunity. CDC will build on its existing relationships with local public health partners and health departments to effectively implement communication efforts. CDC is also convening a critical populations workgroup to work on innovative approaches to vaccinate hard to reach populations.

Question. Some of your agencies have extensive ad budgets. Would you commit—where possible—to increasing advertising in local newspapers and broadcast stations to ensure they are able to disseminate important information and continue to operate throughout the pandemic?

Answer. A strong and comprehensive communication strategy is critical to the COVID–19 public health response. Identifying the right messages, countering misinformation, and targeting outreach to vulnerable and at-risk populations are important elements of CDC's approach. CDC has made available a variety of communication resources including public service announcements, social media and communications materials, posted online (https://www.cdc.gov/coronavirus/2019-ncov/communication/index.html). CDC has collaborated with an advertising campaign that has been organized by the Ad Council (www.adcouncil.org). The Ad Council has developed public service ads, social media assets and more that has been seen in media around the nation since February. The entire campaign has aired utilizing donated media and digital platform time and space. The Ad Council has a number of ads and other assets that are available free to media to take and use http://coronavirus.adcouncilkit.org/.

CDC will partner with the necessary groups and individuals, such as local public health partners and health departments, to disseminate information through appropriate channels and effectively implement communication strategies.

QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

VACCINE AVAILABILITY AND RURAL DISTRIBUTION

Question. The rapid increases in cases of COVID–19 over the past weeks should be alarming to everyone. Congress has provided unprecedented resources to help the country address this public health crisis, including more than $5 billion in congressional appropriations to support research, development, construction, manufacturing and purchasing of vaccines. We must develop a vaccine that is safe and accessible to all.

Vermont has worked effectively to manage and control COVID–19 outbreaks. As a result, Vermont currently has the third lowest rate of cases per 100,000 people in the contiguous United States. Nonetheless, Vermonters shoulder the same risk as someone from Missouri, Washington State, New York, Texas or anywhere else around the country.

How is the Centers for Disease Control and Prevention (CDC) preparing to ensure that rural regions have adequate, equitable and timely access to a coronavirus vaccine?

Answer. CDC is committed to ensuring rural populations can access the vaccine. We have decades of experience working with public health partners addressing the needs of hard to reach populations. We will work with communities, government, and other local partners to identify the best places and times to reach this population and utilize strategic distribution points via community health centers, schools, workplaces, mobile clinics, and pharmacies. Our immunization programs have built a strong public health immunization infrastructure, including through the provision of a safety net for those with no health insurance and through response to outbreaks of vaccine preventable diseases and other urgent public health issues. This infrastructure can be leveraged to reach these populations.

Question. Will the CDC provide vaccines based on total populations, COVID-positive populations, or a combination of both?

Answer. The Advisory Committee on Immunization Practices (ACIP) COVID–19 Vaccine Work Group has been established to help inform evidence-based approaches to COVID–19 vaccination policy, including an initial vaccine prioritization strategy. While the end goal is to offer vaccines to the entire U.S. population, identifying priority groups for COVID–19 vaccination is critical for implementation planning. ACIP has embarked on early planning in hopes of preventing distribution delays post vaccine approval. The framework developed during, and the lessons learned from, the H1N1 influenza vaccine implementation are being used to guide COVID–19 vaccine prioritization. Given that many decisions regarding the vaccine will depend on the vaccine itself, specifics are unknown at this time.

Question. If based on total populations, can you assure this Committee that there will be an all-State minimum for the distribution of vaccines?

Answer. The Advisory Committee on Immunization Practices (ACIP) COVID–19 Vaccine Work Group has been established to help inform evidence-based approaches to COVID- 19 vaccination policy, including an initial vaccine prioritization strategy. While the end goal is to offer vaccines to the entire U.S. population, identifying priority groups for COVID–19 vaccination is critical for implementation planning. ACIP has embarked on early planning in hopes of preventing distribution delays post vaccine approval. The framework developed during, and lessons learned from, the H1N1 influenza vaccine implementation are being used to guide COVID–19 vaccine prioritization. Given that many decisions regarding the vaccine will depend on the vaccine itself, specifics are unknown at this time.

Question. Is the CDC preparing to provide the necessary resources, equipment and support to States to administer the vaccine?

Answer. CDC is working with State and local health department on preparing a detailed but flexible plan for vaccine distribution and administration which includes consideration of critical infrastructure workers, high risk individuals, health equity issues, and lessons learned from H1N1. CDC awarded $140 million using resources from the CARES Act to help immunization programs begin preparation for vaccine distribution and administration. The funding will be used to enhance capacity to support staffing, communications campaigns, pandemic preparedness, and mass vaccination.

Question. Are you working to manufacture and procure vaccination equipment, such as syringes and needles, in advance of approving a vaccine?

Answer. HHS is leading efforts to purchase needles and syringes for the pandemic vaccination program, and CDC is working collaboratively to provide technical assistance. Additional efforts are underway to request that manufacturers produce additional needles and supplies to support the pandemic vaccination program. As part of this effort, HHS is taking care to avoid negatively impacting supplies used for routine and flu vaccination.

QUESTIONS SUBMITTED TO GARY DISBROW, PH.D.

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

MANUFACTURING

Question. What is the current vaccine manufacturing capacity to manufacture vaccine by January 2021? What about by August 2021? What additional capacity is necessary to prepare for sufficient supply of multiple vaccine candidates?

Answer. To accelerate the development and subsequent production of a vaccine for COVID–19, in mid-May, President Trump announced Operation Warp Speed (OWS). OWS aims to deliver up to 300 million doses of a safe and effective vaccine for COVID–19 in early 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures). OWS is a partnership among components of the U.S. Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD), with the aim of a unified government approach to respond to the pandemic. OWS engages with private firms and other Federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. OWS coordinates with existing HHS-wide efforts, including the NIH's Accelerating COVID19 Therapeutic Interventions and Vaccines (ACTIV) partner-

ship, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA and the National Institute of Allergy and Infectious Diseases (NIAID).

Specific to manufacturing efforts, OWS continues to analyze and engage domestic pharmaceutical manufacturing and fill/finish capacity across the vaccines and therapeutics landscape. OWS is also identifying suppliers of secondary items for administration of any successful vaccines, and providers of pharmaceutical distribution to ensure sufficient capacity exists once products have been granted FDA emergency use authorization or licensure/approval. HHS is procuring secondary items (syringes, needles and other ancillary supplies) and investing in the expansion of domestic manufacturing capacity while countermeasures are still in clinical development to maximize domestic supply chains and ensure that the American people are poised to receive safe and effective vaccine(s) and therapeutics as soon as possible.

Question. What is the current therapeutic manufacturing capacity to manufacture therapeutics by January 2021? What about by August 2021? What additional capacity is necessary to prepare for sufficient supply of multiple therapeutic candidates?

Answer. In support of OWS project goals, DoD and HHS personnel are working with industry partners to ensure all of their available in-house capacity is immediately deployed to manufacture COVID–19 therapeutics. This effort will make available hundreds of thousands of treatment courses by the end of the 2020, should the candidate therapeutics demonstrate efficacy in clinical trials. Additionally, OWS is working to implement manufacturing partnerships among domestic antibody manufacturers, to make significantly more capacity available to developers of COVID–19 therapeutics. These combined efforts are expected to make hundreds of thousands of treatment courses available each month during the second quarter of 2021.

Question. What are the assumptions for price of vaccine in the research and manufacturing contracts?

Answer. There will be variations in the cost of each vaccine or therapeutic based on factors unique to each company and product.. Major factors impacting determination of a fair price are the cost of Active Pharmaceutical Ingredients (API)/raw materials, type of expression system, Contract Manufacturing Organization (CMO) costs, cost of fill—finish (to include vials and stoppers), and associated fees.

STRATEGIC NATIONAL STOCKPILE

Question. A critical part of the distribution plan will be an adequate supply of all the ancillary products such as syringes, bandages, alcohol wipes, etc. What efforts are being made to ensure adequate supply of these products is available? Who is responsible for this effort?

Answer. Supporting and securing an adequate supply of ancillary products is a collaborative, interagency effort.

Specific to securing needles and syringes, to date, BARDA has awarded four large task orders for such products. Going forward, BARDA will support additional solicitations, in coordination with the Strategic National Stockpile (SNS), to maximize the availability of needles and syringes toward the end of 2020. BARDA and the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO–CBRND) CBRND have awarded three agreements to increase needle and syringe capacity in the U.S. for the future, some of which will be available in time to support the COVID–19 vaccination in early 2021. Lastly, BARDA and JPEO–CBRND have awarded agreements with two domestic manufacturers of vials to increase production capacity of vials to support multiple vaccine candidates.

To specifically support domestic manufacturing efforts for active pharmaceutical ingredients and other essential medicines, on Tuesday, May 19, 2020, BARDA announced a $354 million 4-year contract with Phlow Corporation and its partners-including CivicaRx, Virginia Commonwealth University's Medicines for All Institute, and AMPAC Fine Chemicals. The partnership with PHLOW allows flexibility in selecting and prioritizing active pharmaceutical ingredients and finished drugs for manufacturing to allow for rapid response to situations such as the current COVID–19 public health emergency. Phlow's criteria for prioritizing APIs and finished drugs for early manufacturing are based on data on essential medicines shortages that have been exacerbated by COVID–19-associated increases in hospitalized patients.

QUESTIONS SUBMITTED BY SENATOR JOHN KENNEDY

Question. In May and June, HHS and DoD announced around $400 million in contracts for pre-filled syringes and glass vials for vaccine distribution, do you anticipate any potential domestic production shortages with this aggressive vaccine timeline?

Answer. HHS funded contracts with negotiated delivery dates and quantities sufficient to meet the Nation's needs for administering any FDA approved vaccine(s) as it becomes available. While HHS has endeavored to contract with domestic sources, in some cases the Department has been required to work with off-shore companies. In cases where HHS has awarded such contracts to non-domestic companies, HHS is funding additional contracts to ensure supplies are readily available to administer vaccine. HHS is working with DoD's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense office to expand domestic capacity for needles and syringes and vials that will be required for sterile injectable products.

Question. There have been concerns regarding the transparency of Operation Warp Speed and a lack of up to date information about its progress and findings. Can you ensure that Congress and the American people will receive clear and transparent information from this panel and other respected public health experts moving forward?

Answer. In recognizing this important relationship, the leadership of Operation Warp Speed is committed to remaining transparent with Members of Congress, their staffs and the American people. Accordingly, Operation Warp Speed will continue to provide written updates and announcements as OWS reaches new milestones. The offices responsible for interacting with Congress at both HHS and DoD are in close coordination to ensure Members are provided frequent updates on development milestones and other activities. Most recently, OWS provided briefings to Member of Congress on June 16, July 2, and July, 13, 2020. In addition, as products are brought under the OWS portfolio, public announcements will be made in a transparent manner.

Question. CARES provides BARDA with no less than $3.5 billion for the development and purchases of countermeasures, "including the development, translation and demonstration at scale of innovations in manufacturing platforms." In CARES, Congress prioritized funding of domestic platform-based technologies. How important is it to BARDA to invest in domestic platform technology companies which use continuous manufacturing?

Answer. The global pandemic has highlighted the vulnerabilities of the global supply chain for many products. It is critical that steps be taken to invest in expansion of domestic manufacturing capacity. BARDA has made an investment in PHLOW, a consortium of organizations that will expand domestic manufacturing of raw materials and active pharmaceutical ingredients for drugs. This effort includes support for continuous manufacturing. The efforts will target drugs on the FDA drug shortage list that have become even more critical during the COVID–19 response. BARDA is working with the FDA to identify which products to manufacture. Vaccine manufacturers are relying on proven technology platforms and other methods to provide for the large volume of vaccine doses being required in a short period of time.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Dr. Disbrow, Dr. Fauci has indicated that highly effective COVID–19 vaccines may take years to develop and may never result in total herd immunity. What is BARDA's position on continued development of monoclonal antibody therapeutics, a permanent way to make society work as a treatment? Are there funds currently available to support novel monoclonal therapeutics developed by small businesses? I understand that BARDA has funded large companies and their monoclonal antibody approaches. Are there funds currently available for smaller businesses?

Answer. Monoclonal antibodies are one kind of therapeutic that show early promise in the treatment of COVID–19. So far, BARDA has invested in both Regeneron and AstraZeneca to develop monoclonal antibodies for COVID–19, both large businesses. A key criterion for moving a candidate forward is the timing for availability of the candidate therapeutic. Regeneron's monoclonal antibody cocktail entered clinical trials in June, 2020, and AstraZeneca's monoclonal antibody cocktail will be entering the clinic very soon. In addition, if the clinical trials demonstrate that the antibodies are safe and efficacious, it is important that the company can manufacture significant amounts of therapeutic. BARDA's review criteria are independent of company size. The review criteria are based on the science and the company's ability to have an immediate impact on the pandemic. Any business that can meet the technical criteria are eligible for funding. If a small or large business has a monoclonal antibody that can enter the clinic before September and manufacture significant amounts of drug in the United States by the end of December, funding is available.

Question. Dr. Disbrow, How are you making sure that both large and small businesses have the opportunity to participate in Operation Warpspeed?

Answer. BARDA's review criteria are independent of company size. The review criteria are based on the science and the company's ability to have an immediate impact on the pandemic. Any business that can meet the technical criteria are eligible for funding. Proposals that can meet the immediate needs of the nation are prioritized over those that require more time to achieve key milestones such as Emergency Use Authorization or FDA approval/licensure/clearance.

Question. Dr. Disbrow, where is BARDA putting its emphasis on COVID diagnostics? Has BARDA considered the need for specific antibodies for diagnostic use?

Answer. BARDA's initial focus has been on the development of molecular tests that could be used on existing FDA-cleared platforms commonly used in commercial and clinical laboratories. BARDA is currently supporting the development of multiple types of diagnostics, including molecular assays that detect the virus in respiratory samples, antigen tests that detect viral proteins in respiratory samples, and tests that detect antibodies to SARS–CoV–2 in blood. Current investments include tests that can be used in small and large laboratories, and in point-of-care settings. Twelve diagnostic assays developed with BARDA support have received Emergency Use Authorization and, as of July 20, 2020, contributed over 22 million tests to the response.

Tests that detect antigens (viral proteins) require specific antibodies that will detect SARS–CoV–2 antigens and not cross-react other coronaviruses. BARDA supports diagnostic companies in developing, manufacturing, or acquiring the antibodies needed for their proprietary assay. BARDA is coordinating with FDA, NIH (NIAID and RADx) and DoD to ensure efficient and effective development of COVID–19 diagnostics.

Question. Dr. Disbrow, I understand that there is currently a backlog in manufacturing capacity for vaccines and antibodies. What is BARDA doing to fund alternative manufacturing routes?

Answer. BARDA is working with each of the vaccine developers and multiple vaccine manufacturing companies (contract manufacturing organizations (CMO)) to ensure sufficient capacity exists to support all vaccine production. DoD and HHS are collaborating to monitor each asset in the production process to minimize or eliminate conflicting production needs and maximize throughput. Where required, HHS is funding capacity expansion and/or reserving capacity for vaccine and antibody production. Additionally, OWS is working to implement manufacturing partnerships among domestic antibody manufacturers, to make significantly more capacity available to developers of COVID–19 therapeutics.

Question. Dr. Disbrow, it is my understanding that there are multiple groups pursuing manufacturing and clinical trials for antibody therapeutics against COVID–19. This requires significant manufacturing capacity through relatively standard, established methods in bioreactors; however, there is not nearly enough capacity for any one of these companies to produce enough of their medicine to meet national demand, yet this is necessary for the best-in-class therapeutic to emerge and treat patients. What plans are there to handle the problem of scale in manufacturing for antibody therapeutics, looking at short-term crisis management? In the long term, the same concern applies for vaccines. What plans exist on that front? Are there novel or unusual manufacturing techniques that can be used to address these concerns? How does BARDA consider the manufacturing techniques required when choosing which products to invest in?

Answer. In support of OWS project goals, DoD and HHS personnel are working with industry partners to ensure all of their available in-house capacity is immediately deployed to manufacture COVID–19 therapeutics. This effort will make available hundreds of thousands of treatment courses by the end of the year should the candidate therapeutics demonstrate efficacy in clinical trials. Additionally, OWS is helping to implement manufacturing partnerships amongst domestic antibodies manufacturers, to make significantly more capacity available to developers of COVID–19 therapeutics. These combined efforts are expected to make available hundreds of thousands of treatment courses per month during the second quarter of 2021. OWS continues to analyze and engage domestic pharmaceutical manufacturing and fill/finish capacity across the vaccines and therapeutics landscape. OWS is also identifying suppliers of secondary items for administration of any successful vaccines, and providers of pharmaceutical distribution to ensure sufficient capacity exists once FDA approved products are available. HHS is investing in procuring secondary items (syringes, needles and other ancillary supplies) and domestic manufacturing capacity while product approval is pending in order to maximize domestic

supply chains and ensure Americans are poised to receive safe and effective vaccine(s) and therapeutics as soon as possible.

Question. Dr. Disbrow, what are you doing to bolster those smaller companies such as CentiVax, CytoDyn, Serronto, and S-Cell Biosciences to advance treatments, antibody therapies and potential cures of COVID–19?

Answer. BARDA's review criteria are independent of company size. The review criteria are based on the science and the company's ability to have an immediate impact on the pandemic. Any business that can meet the technical criteria are eligible for funding. Proposals that can meet the immediate needs of the nation are prioritized over those that require more time to achieve key milestones such as Emergency Use Authorization or FDA approval/licensure/clearance.

QUESTIONS SUBMITTED BY SENATOR MARCO RUBIO

Question. In the CARES Act, money was provided for the development of COVID countermeasures, prioritizing platform based technologies, such as continuous manufacturing, using domestic manufacturing. What is BARDA doing to partner with platform companies with domestic manufacturing capability to respond to COVID?

Answer. The global pandemic has highlighted the vulnerabilities of the global supply chain for many products. It is critical that steps be taken to invest in expansion of domestic manufacturing capacity. BARDA has made an investment in PHLOW, a consortium of organizations that will expand domestic manufacturing of raw materials and active pharmaceutical ingredients for drugs. This effort includes support for continuous manufacturing. The efforts will target drugs on the FDA drug shortage list that have become even more critical during the COVID–19 response. BARDA is working with the FDA to identify which products to manufacture. Vaccine manufacturers are relying on proven technology platforms and other methods to provide for the large volume of vaccine doses being required in a short period of time.

Question. What steps are being taken to ensure the United States has the manufacturing capacity—from the drug to the glass vials and syringes—needed to produce hundreds of millions of vaccines by early 2021?

Answer. HHS funded contracts with negotiated delivery dates and quantities sufficient to meet the Nation's needs for administering any FDA approved vaccine(s) as it becomes available. While HHS has endeavored to contract with domestic sources, in some case we have been required to work with off shore companies. In cases where we have awarded such contracts to non-domestic companies, HHS is funding additional contracts to ensure supplies are readily available to administer vaccine. HHS is working with DoD's JPEO–CBRND office to expand domestic capacity for needles and syringes and vials that will be required for sterile injectable products.

Question. This pandemic has exposed multiple problems in our medical supply chains. What have been some of the more alarming issues you've seen and what can Congress do to help correct those problems?

Answer. In the early days of the COVID–19 pandemic, personal protective equipment (PPE) shortages caused by a rapid increase in demand were exacerbated when manufacturing was shut down in China. China manufactures not only much of the world's PPE but also a large percentage of the active ingredients that manufacturers use to make drugs. While HHS broadly understands that a large percentage of the world's API is made in China and India, the FDA has had limited insight into the extent to which the U.S. drug supply chain is reliant on API from specific countries, regions, or manufacturers. Although the CARES Act expanded the scope of information FDA is able to collect about API manufacturing, it did not expressly provide FDA the authority to collect information about API at the level of detail that would help us understand the extent to which the U.S. drug supply chain is reliant on API from specific countries, regions, or manufacturers. Congress could consider granting FDA authority to collect additional data about the drug supply chain, including the sources of API that finished dosage form manufacturers are actually relying upon and how reliant they are on each such supplier (e.g., how many dosage units were manufactured from each supplier of API during a given period).

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

MANUFACTURING OF ANCILLARY SUPPLIES

Question. Manufacturing over 300 million doses of vaccine will require significant planning and national-level coordination by the Federal Government to effectively execute. In addition to producing the necessary volume of vaccines to inoculate more

than 300 million people, manufacturing must also scale up for necessary ancillary supplies like vials, rubber stoppers, and syringes, that will likely be necessary for a COVID–19 vaccine, the seasonal flu, and other routine vaccines or drugs over the next year or two.

In addition to the $110 million ASPR has spent on two orders for needles and syringes, what other funding has been allocated for ancillary supplies for COVID–19 vaccines and therapeutics?

Answer. Supporting and securing an adequate supply of ancillary products is a collaborative, interagency effort.

Specific to securing needles and syringes, to date, BARDA has awarded four large task orders for such products. Going forward, BARDA will support additional solicitations, in coordination with the Strategic National Stockpile (SNS) to maximize the availability of needles and syringes toward the end of 2020. BARDA and the DoD Joint Program Executive Office for Chemical, and Biological, Radiological, and Nuclear Defense (JPEO–CBRND) have awarded three agreements to increase needle and syringe capacity in the U.S. for the future, some of which will be available in time to support the COVID–19 vaccination in early 2021. Lastly, BARDA and the JPEO–CBRND have awarded agreements with two domestic manufacturers of vials to increase capacity of vials to support multiple vaccine candidates.

QUESTIONS SUBMITTED BY SENATOR JACK REED

DEFENSE PRODUCTION ACT

Question. This Administration failed in ensuring sufficient supplies of personal protective equipment (PPE) and testing supplies are available, in part because of a reluctance to invoke the Defense Production Act (DPA) to speed manufacturing and distribution of these supplies. This question is for all the witnesses, will you commit to fully use available HHS DPA or other authorities to fund industrial expansion authorities if needed for a vaccine or other equipment and supplies? Do you have sufficient funding to meet industrial expansion needs and to maintain a domestic supply of needed equipment and supplies? We cannot afford to repeat the same mistakes.

Answer. NIH defers to BARDA regarding manufacturing and distribution of supplies.

Under the SNS 2.0 initiative, SNS is working with DoD to expand domestic manufacturing capacity. Using CARES Act funding SNS has funded a number of projects including:

—Melt blown fiber (MBF)—to date SNS has obligated $16.25M to expand the domestic manufacturing capacity to produce MBF, critical component in N95 and surgical mask production.

—Increased domestic production capacity for surgical masks—to date SNS has obligated $17.85M to allow manufacturers to stand up additional production lines and production centers to produce surgical masks.

—Increased domestic production capacity for nitrile gloves—to date SNS has obligated $22.5M to increase annual domestic production capacity of nitrile gloves by 450M.

—Increased domestic production capacity for testing swabs—to date SNS has obligated $51.15M to increase domestic production capacity for swabs. Under a cost-sharing agreement with the manufacturer, the USG has agreed to fund the cost of machinery, equipment, and facility retrofit costs to increase capacity in this area.

Prior to the COVID–19, response SNS did not have experience with expanding domestic manufacturing capacity. The partnership between DoD and HHS, which allowed SNS to tap into DoD's contracting resources and experience with industrial based expansion projects, was critical for the success of USG's efforts to expand domestic production capacity of medical supplies during the COVID–19 pandemic.

Importantly, it will continue to be difficult for FDA to prevent and mitigate shortages of medical devices including PPE, ventilators, and testing supplies that are critical for U.S. patients and our healthcare workers on the front lines because Agency does not have sufficient authorities for medical device shortages. The linchpin for tracking potential supply chain issues to avoid medical product shortages, is to be able to obtain information on potential shortages and other supply chain disruptions well in advance of an actual shortage occurring. In the absence of the broader authorities FDA has asked for so that the device program has comparable authorities to the drug program, there will not be sufficient intel to deal with supply chain issues during outbreak, as a result. By the time the PHE is de-

clared, there is already a problem. COVID exemplifies this. For instance—consider some of the supply-chain issues we saw during this pandemic. Even if the outbreak had not reached the U.S., there would have been supply chain issues for PPE and other supplies within the U.S. because other nations had outbreaks and were going to need supplies, rapidly and in greater quantities than anticipated. Absent the broad authority FDA has asked for, the Agency would not be able to get the intelligence necessary to anticipate impacts on the U.S. supply chain or the global supply chain generally, including which essential devices could be in short supply and the production volume of impacted manufacturers to better understand the extent of the impact.

By the time the U.S. formally declared the public health emergency for COVID–19, there were problems and shortages for weeks. With such additional authorities, the U.S. could have been planning well before. Lack of broad shortage authorities and the requirement for manufacturers of essential/critical medical devices to routinely monitor their supply chains and take mitigating actions when appropriate undermines the U.S. ability to act and this was evident for the ongoing COVID pandemic.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

Question. Factors for selecting vaccine candidates for BARDA investment and to move to Phase 3 trials.

Is the primary reason for BARDA's focus on a gene-based vaccine that it can be developed faster?

Answer. Under OWS, all vaccine approaches have been considered to support the quick, efficient, and safe development of a vaccine to protect again COVID–19. OWS selected vaccine candidates on the basis of four criteria. We required candidates to have robust preclinical data or early stage clinical trial data supporting their potential for clinical safety and efficacy. Candidates had to have the potential, with our acceleration support, to enter large phase 3 field efficacy trials this summer or fall (July to November 2020) and, assuming continued active transmission of the virus, to deliver efficacy outcomes by the end of 2020 or the first half of 2021. Candidates had to be based on vaccine-platform technologies permitting fast and effective manufacturing, and their developers had to demonstrate the industrial process scalability, yields, and consistency necessary to reliably produce more than 100 million doses by mid-2021. Finally, candidates had to use one of four vaccine-platform technologies that we believe are the most likely to yield a safe and effective vaccine against Covid–19.

Question. Are traditional vaccine approaches also being prioritized?

Answer. Under OWS, all vaccine approaches are being considered to support the quick, efficient, and safe development of a vaccine to protect against COVID–19. Selection of the approaches was based on the overall assessment of delivering a safe and effective vaccine.

Question. Does the evidence indicate that a gene-based vaccine will produce a durable immune response?

Answer. The durability of gene based vaccines is supported by observations in animal models and tumor suppression in individuals with recurrent or refractory melanoma. However, the duration of protection afforded by gene-based COVID–19 vaccines remains to be established. This is true for any vaccine technology used to develop a vaccine. Duration of immunity can only be determine through clinical trials for each vaccine candidate.

Question. How is Operation Warp Speed ensuring adequate representation of racial and ethnic groups, as well as of age groups, in vaccine trials, and would a trial without adequate representation be disqualified from moving into a Phase 3 trial?

Answer. The goal of OWS is to develop a safe and effective vaccine. In support of OWS project goals, HHS intends to carefully evaluate the safety of any identified vaccine and will deliver a vaccine that is safe and effective for the American people. Vaccine development companies are responsible for planning and executing clinical trials for their candidate vaccine. The companies do this in coordination with NIH, and under the regulatory oversight of FDA.

The FDA remains an independent body to protect and promote the public health. The FDA accomplishes their mission by rigorously reviewing new medical products against the agency's time-honored standards of safety and effectiveness. Like for all other medical products, the FDA will independently review both the safety and effectiveness of vaccines developed through HHS funding in support of OWS project goals. HHS will follow standard practices and procedures to ensure that the development conforms to the requirements and best practices of medical product develop-

ment for the intended populations for these vaccines. Additionally, HHS is ensuring that the development conforms to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, codified in titles 21 and 42, respectively, of the U.S. Code, and to FDA's implementing regulations in title 21 of the Code of Federal Regulations.

Criteria for representation of racial and ethnic groups, as well as of age groups, in clinical trials are outlined in FDA guidance document titled Development and Licensure of Vaccines to Prevent COVID–19—Guidance for Industry, published in June 30, 2020 and can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19.

Question. Supply chain and manufacturing issues in mass producing a COVID–19 vaccine.

What are the most pressing issues with the supply chain and mass manufacturing of a coronavirus vaccine? What are each of the key components necessary to administer a vaccine, and what is the current availability of each component?

Answer. Successful development and manufacturing of a vaccine for COVID–19 requires a holistic view of the vaccine supply chain (vaccine, vials, syringes, etc.) to ensure there are ample quantities to meet demand. HHS is funding needle and syringe manufacturers to ensure sufficient supply remains available throughout the duration of the vaccine administration campaign. BARDA and JPEO–CBRND have collaborated to support domestic expansion of manufacturing lines for needles, syringes and vials. Finally, within OWS, working groups supporting vaccine development and supply chain issues are working closely with CDC in the distribution and administration of vaccines without disrupting existing vaccine programs.

Question. How will Operation Warp Speed avoid the supply chain issues that have led to States and countries competing against each other for test kits and PPE?

Answer. HHS funded contracts include negotiated delivery dates and quantities sufficient to meet the nation's needs for administering any FDA approved vaccine(s) as it becomes available. While HHS has endeavored to contract with domestic sources, in some case we have been required to work with off shore companies. In cases where contracts were awarded to non-domestic companies, HHS is funding additional contracts to ensure supplies are readily available to administer vaccine. In addition, HHS is working with DoD's JPEO–CBRND office to expand domestic capacity for needles and syringes and vials that will be required for sterile injectable products.

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

Question. Nanovaccines represent a new type of vaccine delivery technology that can enhance our future preparedness because they offer faster global impact, higher effectiveness, lower cost, and higher safety for medical staff. This approach has already been used to design effective vaccines against respiratory infections such as influenza, pneumonia, and respiratory syncytial virus and tested in multiple preclinical and clinical models, and is particularly suited for pandemic scenarios.

What efforts are underway through Operation Warp Speed to ensure new delivery technologies such as nanovaccines are in the pipeline to be readily adapted to develop a new COVID–19 vaccine?

Answer. Nanovaccines encompass a broad range of vaccine types. Generally, nanovaccines use particles made of lipid and detergents as carriers or as adjuvant for a protein or nucleic acid. Recombinant vaccines combined with adjuvants and mRNA vaccines associated with lipid nanoparticles are nanovaccines. The OWS portfolio currently includes such vaccines, recombinant proteins combined with nanoparticle adjuvants and mRNA vaccines carried by lipid nanoparticles.

Reports indicate that BARDA has stopped funding potential treatments for severe lung disease caused by COVID–19, and has suspended requests for proposal for prophylactic countermeasures for COVID–19.

Question. Why was the decision made to suspend funding or requests for proposal for these countermeasures? What funding efforts are underway by BARDA and OWS to invest in treatment and prevention countermeasures in addition to a future vaccine?

Answer. BARDA and OWS have focused on antivirals as products with potential to safely and effectively treat SARS–CoV–2 infections. While immune modulators and therapeutics targeting lung repair are interesting candidates for the treatment of COVID–19, clinical trials evaluating each potential therapy individually is not efficient. Under the ACTIV Public Private partnership, clinical trial networks and clinical trials are being established to evaluate multiple antivirals,

immunomodulators, anticoagulants and other products to address secondary pathologies associated with SARS–CoV–2 infection. Companies can submit their data to the ACTIV portal and the information will be reviewed and prioritized for inclusion in the clinical trials. This is a more efficient way to evaluate multiple candidates.

The pathology of severe COVID–19 is still unknown, and there are many plausible hypotheses on how to use immune modulators or therapeutics targeting tissue repair. Instead of using a one-drug-one-clinical-study paradigm, BARDA and OWS are using platform clinical trials to investigate many candidate therapeutics at once. The ACTIV clinical trials will be investigating coagulopathy and immune modulators in addition to antivirals with possibilities to expand to new candidate therapeutics as each candidate completes its enrollment. Platform clinical trials allow for increased efficiency because there can be shared placebo arms, potential patients that are ineligible to receive one of the therapeutics being tested can possibly be enrolled into other arms of the study that they are eligible for and allows for the removal of candidates that are toxic or not performing as expected.

Vaccines are the main focus for prevention because vaccines are the only technology that can manufacture enough doses in the timeframe needed. Therapeutics can be used to prevent disease, such as using oseltamivir to prevent an influenza infection when someone in your household gets infected. However, by using the drug to prevent disease in someone who may never have been infected, it is taking away a treatment from someone with COVID–19. The balance between treatment and prevention must be weighed carefully.

One area under investigation by OWS and BARDA is prevention of disease in the nursing home population. Outbreaks of SARS–CoV–2 in nursing homes has devastating consequences, and the U.S. Government is investigating candidate prophylaxis drugs that could be used in this population as well as investigating how to test efficacy.

Released documents indicate that HHS and BARDA have waived certain Federal march-in rights in its contracts with treatment and vaccine manufacturers. These rights were conceived as an important tool to ensure the provision of drugs on reasonable terms, including with respect to price, and the removal of these contract provisions erases an important oversight tool at the government's disposal.

Question. Please detail why a decision was made to waive Bayh-Dole "reasonable terms" provisions from manufacturer contracts. Particularly considering the Federal investment in these drugs, how will the Administration ensure that these countermeasures are priced in a fair and equitable manner and accessible to all patients?

Answer. The Bayh-Dole Act pertains to intellectual property arising from Federal Government-funded research. Specifically, Bayh-Dole includes "march-in rights" under 35 U.S.C. § 203, which give the Government the ability to obtain a license, in four limited circumstances, to "subject inventions" that are first conceived or reduced to practice in the performance of a Government contract, grant, or cooperative agreement. Importantly, march-in rights do not apply to IP that is created or reduced to practice before the Federal funding agreement is awarded. Neither do they apply to activities undertaken outside the scope of the Federal funding agreement.

BARDA is funding several agreements under Operation Warp Speed (OWS)319L(c)(4)(B)(iv) of the PHS Act (42 U.S.C. 247d–7e(c)(4)(B)(iv)), which gives BARDA other transaction authority (OTA). By design, OTA allows for flexible intellectual property (IP) and data rights. The Bayh- Dole Act and associated patent and data rights regulations do not apply to Other Transactions. OWS generally leverages OTA flexibility to negotiate more favorable IP and data rights terms than the Government would have under Bayh-Dole.

In the case of OWS, the Government has used OTA flexibility to negotiate corresponding rights that put the Government in a better position than would be the case under the Bayh-Dole regime.

Some OTA agreements may incorporate provisions that permit the Government to obtain a non-exclusive license to background IP (i.e., IP generated before or outside the scope of the Government agreement). For example, some OWS OTA agreements give the Government the ability to license background IP if the original party to the OTA is unwilling to continue pursuit of the vaccine, which could permit the Government to find alternative ways to manufacture the vaccine. These licensing provisions, permitted under OTA authority, place the Government in a significantly better position than would be the case if Bayh-Dole rights were in place.

Finally, BARDA's goal in contracting with treatment and vaccine manufactures is to negotiate for a specific price per dose and not rely on undefinitized "reasonable terms."

SUBCOMMITTEE RECESS

Senator BLUNT. The subcommittee will stand in recess.

[Whereupon, at 2:45 p.m., Thursday, July 2, the subcommittee was recessed, to reconvene subject to the call of the Chair.]