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ROAD TO RECOVERY: RAMPING UP COVID-19

VACCINES, TESTING, AND MEDICAL SUPPLY CHAIN

WEDNESDAY, FEBRUARY 3, 2021

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 11:00 a.m., via Webex, Hon. Anna G. Eshoo [chairwoman of the subcommittee] presiding.

Present: Representatives Eshoo, Butterfield, Matsui, Castor, Sarbanes, Welch, Schrader, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Craig, Schrier, Trahan, Fletcher, Pallone (ex officio), Guthrie, Upton, Burgess, Griffith, Bilirakis, Bucshon, Mullin, Hudson, Carter, Dunn, Curtis, Joyce, and Rodgers (ex officio).

Also Present: Representatives Schakowsky and O'Halleran.

Staff Present: Jeff Carroll, Staff Director; Kimberly Espinosa, Professional Staff Member; Waverly Gordon, General Counsel; Tiffany Guarascio, Deputy Staff Director; Perry Hamilton, Deputy Chief Clerk; Stephen Holland, Health Counsel; Mackenzie Kuhl,

Digital Assistant; Aisling McDonough, Policy Coordinator; Meghan Mullon, Policy Analyst; Kaitlyn Peel, Digital Director; Tim Robinson, Chief Counsel; Chloe Rodriguez, Deputy Chief Clerk; Kimberlee Trzeciak, Chief Health Advisor; C.J. Young, Deputy Communications Director; Sarah Burke, Minority Deputy Staff Director; Theresa Gambo, Minority Financial and Office Administrator; Nate Hodson, Minority Staff Director; Peter Kielty, Minority General Counsel; Bijan Koohmaraie, Minority Chief Counsel; Clare Paoletta, Minority Policy Analyst, Health; Kristin Seum, Minority Counsel, Health; Kristen Shatynski, Minority Professional Staff Member, Health; Michael Taggart, Minority Policy Director; and Everett Winnick, Minority Director of Information Technology.

Ms. Eshoo. The Subcommittee on Health will now come to order.

Good morning, everyone. Due to COVID-19, today's hearing is being held remotely, obviously, so all members and witnesses will be participating via video conferencing. As part of our hearing, microphones will be set on mute to eliminate background noise. Members and witnesses, you will need to unmute your microphone each time you wish to speak. So keep that in mind.

Documents for the record will be sent to Meghan Mullon at the email address that we have provided to your staff, and all documents will be entered into the record at the conclusion of the hearing.

The chair now recognizes herself for 5 minutes for an opening statement.

I want to welcome everyone to our first Health Subcommittee hearing of the 117th Congress. It is entitled "Road to Recovery: Ramping up COVID-19 Vaccines, Testing, and Medical Supply Chain," all issues that the members are very familiar with.

A very warm welcome to all of our new members, both sides of the aisle. We look forward to the contributions that you are going to make. And a very special welcome to Congressman Brett Guthrie, who is the new ranking member of our subcommittee, and I look forward to working with him. We all look forward to working with you, Brett.

Over the past year, our country has undergone truly profound changes due to COVID-19. I think that the veil has really been torn off every system and laid bare, what I call our country's many preexisting conditions, including inequities of care, in communities of color, and the inability of too many Americans having a lack of access or can afford healthcare. This subcommittee, I think, needs to move quickly and purposefully to correct these wrongs and do the right thing.

We are in a race against death. We have lost nearly 450,000 of our fellow Americans due to the virus, and as deaths continue to climb, Native, Black and Latino Americans face the highest risk. According to the CDC, these communities are nearly three times more likely to die from COVID-19 than White Americans.

The previous administration lacked a national strategy to end the pandemic and administer vaccines to Americans efficiently, equitably, and effectively. And without effective Federal coordination for the vaccination campaign, we clearly are not going to make any progress. I think we are actually tripping at the starting block, and there are many manifestations of that in our States and our local communities.

With a new administration, and a new Congress, and a new commitment, we can optimize a new beginning. The President has put forth his American Rescue Plan, which recognizes that we are in a battle to save American lives. It responds to this crisis with an all-of-government approach, and an all-of-America wartime plan.

First, the American Rescue Plan provides $20 billion for national vaccination strategy to increase the supply and the vaccination sites to fully vaccinate 300 million Americans by the end of this summer. The plan also creates a public health core of 100,000 newly hired public health workers to conduct individual outreach in local communities to address the vaccine hesitancy and misinformation.

Secondly, it invests $50 billion to scale up testing by buying rapid tests, expanding lab capacity, and coordinating the genetic sequencing that is needed to detect the concerning new variants of the virus.

Third, it invests $3 billion in innovative COVID-19 treatments. While we have effective vaccines to prevent people from getting the virus, we don't yet have accessible medicines to treat patients who are sick with it. This plan funds the research and large-scale clinical trials needed to develop therapeutics, such as antivirals and

antibodies, to help people recover from the virus.

Fourth, it buys a strong supply of American-made personal protective equipment. I think that is music to all of our ears. The plan invests $10 billion to ensure we have sufficient protective gear by expanding domestic manufacturing.

So together, these public health efforts to crush the virus will cost $160 billion. The health benefits of this plan are abundantly clear, but the measures will also aid our economic recovery.

Last month, President Trump's White House Council of Economic Advisors estimated that every day our country speeds up vaccinations saves $10 billion in health and economic costs. Moody's Analytics found that the American Rescue Plan would create 7.5 million jobs and add 8 points to the GDP this year.

So I think we have the moral and economic duty to invest in this plan for the sake of our country, the people that we represent, and, obviously, our national economy. I hope our subcommittee is prepared -- I believe that we are -- prepared to hit the ground running to move these emergency actions through our deliberative process.

So I want to thank our very distinguished panel of witnesses today, including a former governor, a former top scientist of the FDA, a former director of the Strategic National Stockpile, and the former public health director of the third largest American city. Each of you are going to enlighten and guide our subcommittee on the urgent tasks before us.

So the chair now would like to recognize our new ranking member. We are very proud of you, Brett. Brett has been -- Brett, for new members, you need to know that Mr. Guthrie has been a high value member of our subcommittee. So I will now call on him in his new capacity as ranking member for 5 minutes for his opening statement.

Please remember to unmute.

Mr. Guthrie. I did, I think so.

Thank you, Chair, for those very kind words. I really appreciate it very much, and welcome to all the new members. On our side of the aisle, you are going to get to know John Curtis; Neal Dunn, who's a physician; Dan Crenshaw; and John Joyce, who is a physician as well. So I welcome them to the committee and all the new members, and all the members.

I want to thank you for holding this important hearing. My earplugs keeping popping out. Sorry.

Over 441,000 people have died from the COVID-19 pandemic in the United States, which is greater than the number of American servicemembers we lost in World War II. I know that all of us on this committee are committed to stopping this horrible virus. Specifically, I think we must fully evaluate our country's response efforts on what has worked and what lessons we have learned thus far during the COVID-19 pandemic. Our focus needs to be forward looking in order to make continuous improvements that will stop this virus. Each of us has a choice to make. We can stay in our camps and focus on ideological battles, or we can sit at the negotiating table and get work done that the American people expect us to do during these challenging times.

We need to examine ways to further expand testing, use of therapeutics, and increase vaccine confidence. We also need to prioritize quick and efficient distribution of vaccines.

Let me be clear: We are not starting from scratch. Without Operation Warp Speed, we would not have two vaccines that are currently being administered to Americans, nor potentially additional vaccines that may be authorized by the FDA in the near future. The Biden administration has taken credit for a pathway to 100 million vaccines in 100 days. However, 2 weeks into the Biden presidency, there have been

around 52 million vaccines distributed and more than 32 million vaccines administered, thanks to the previous administration's efforts.

As we move forward with vaccine distribution, we will find ways to improve, and we should explore those. Let us not forget this is the fastest we have with ever had a vaccine move through the development pipeline and come to market. We never cut any safety corners, despite the extraordinary speed, and that is success that should be celebrated.

Additionally, I have I have heard from Kentucky and many other States that the lack of additional Federal funding for States who distribute vaccine has been the biggest hiccup. We had two vaccines authorized, authorized prior to the latest funding package that was signed into law at the end of December. Let us not forget that this package was stalled for months. Valuable time was lost. When we did move forward, Speaker Pelosi said she moved forward because of a new President and a new vaccine. The money being sent to the States 2 weeks late, when it needed to be weeks if not months before, has cost us valuable time.

From my background in manufacturing, I know it takes time, hard work and detailed planning to get a manufacturing line up and going. Operation Warp Speed's tireless work on supply chains and simultaneous manufacturing during clinical trials meant safe and effective vaccines that were administered to our healthcare heroes, and vulnerable populations within a matter of days, rather than months, after receiving FDA authorization.

Each State and some large jurisdictions have been given the opportunity to run their vaccine distribution as they believe is best for their residents.

I am not sure if anyone here is familiar with Utica, Kentucky. It is a rural community in my district that I am proud to represent. I think Frankfurt, our State

capital, and Davis County, can do a better job of taking care of Utica than being run out of Washington, D.C., which is a person who has probably never stepped foot there. While some States may need to reevaluate their strategy, there are many States that are doing quite well with vaccine distribution.

In addition, I think it is key to remember the work the FDA has done to authorize 320 COVID-19 tests. According to the COVID-19 tracking project this Monday, we had more than 1.6 million new tests reported in a day. On March 3lst of last year, we had less than 116,000 new tests reported. Over the past year, we have seen the development and authorization of rapid point-of-care diagnostics to reduce instances of delayed results, tests using saliva samples to eliminate the need for swabs in short supply, and even a test that is sold over the counter.

While challenges remain, we have demonstrated that these type of private industry partnerships and the innovative products that are a result are essential to successfully responding to the pandemic.

Lastly, as the Republican leader of the Oversight and Investigations Subcommittee in the last Congress, I believe that oversight is a very important aspect of our response. We have passed around $4 trillion in COVID-19 aid alone. I have supported much-needed relief for American families, workers, and small businesses. We must ensure it is being used effectively and wisely.

And I agree, Madam Chair, that we have an esteemed panel of witnesses. I look forward to hearing their testimony, along with my colleagues, hoping my colleagues will join me in finding solutions and acknowledging how far we have come and work to get even farther as we go forward.

I yield back.

Ms. Eshoo. The gentleman yields back.

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

And, Frank, you need to unmute.

The Chairman. Thank you, Chairwoman Eshoo. And I want to, as you did, welcome everybody back for our first Health Subcommittee hearing of the 117th Congress.

There is no more pressing issue to begin with than the ongoing COVID-19 pandemic and our response so far and our need to increase vaccinations, testing, and mitigation of building a robust supply chain.

This pandemic has taken a devastating toll on communities all around the country. As Members of Congress, we have to do everything we can to ensure that this new administration has all of the tools and resources it needs to crush the virus.

With President Biden in the White House, I am confident that we can move forward with comprehensive actions to stem the tide on the virus. One of the first orders of business will be jump-starting and sustaining a robust vaccination program. After the scientific breakthrough of two safe and effective COVID-19 vaccines, and hopefully more on the way, we must do more to confront the challenge of getting the vaccine into people's arms.

Unfortunately, the Trump administration failed to prepare and provide reasons for a national vaccination campaign, and never developed a comprehensive national vaccine plan. Instead, the administration pushed all responsibility for distributing and administering vaccines to the States, and then they made that job nearly impossible when they opposed providing the States with additional resources to do so. And this failure of leadership led to only 3 million Americans being vaccinated by the end of the year, far short of the 20 million that the Trump administration had promised.

Yesterday, we heard at our O&I Subcommittee, we heard from States on the front lines about these vaccination challenges. While we were pleased to hear about how they have improved vaccination rates in recent weeks, they underscored the need for additional resources and clear, consistent communication as they work to get the vaccines in people's arms. And their insight is critical as we chart a better path forward.

In December, Congress stepped up and provided $8.75 billion for vaccine distribution activities, including $4.5 billion to States in the final omnibus and COVID relief package. And so, vaccination rates are increasing, but if we are to accelerate both production and vaccinations, more resources are needed, especially resources dedicated to the most vulnerable, hard-to-reach Americans.

And the same can be said for ongoing needs related to testing and contact tracing. From the early days of the pandemic, public health experts and House Democrats were calling for a comprehensive national testing strategy that would ensure testing supplies were allocated efficiently, and tests were available to all who needed them. But, unfortunately, just like with vaccines, the Trump administration never created a comprehensive national testing strategy, and turned over virtually all responsibilities to the States, with little support or guidance.

Now, I want to emphasize testing again. Testing reagents and supplies, like pipettes, have continued to face shortages, and as new outbreaks have occurred, new bottlenecks in testing have followed. And while we work to vaccinate all Americans, access to reliable, efficient, and speedy testing, contact tracing, and mitigation support, will continue to be critical if we are to reduce transmission and community spread.

And we also need a more robust and reliable medical supply chain. While States are administering more COVID-19 vaccines, they are running up against supply shortages of doses, but also the ancillary medical supplies, such as syringes that are used to extract

every available dose, and while some early therapeutics have been authorized by the FDA, their limited availability has also curbed their impact. And so, we also continue to face supply challenges for administering tests, like reagents and swabs, and supply challenges remain for critical personal protective equipment for medical personnel, including in nursing homes, vaccinators, and the public health workforce.

So I am pleased that President Biden has taken swift and decisive action to improve our response to the pandemic, as you mentioned, Madam Chair, but crushing the virus requires more action from Congress.

President Biden has proposed the American Rescue Plan, which includes $20 billion in funds for vaccine distribution administration, public awareness, and additional resources for improving our supply of vaccines. It invests $50 billion for testing and contact tracing, including expanding community-based and mobile testing sites, and it includes $10 billion to help support expansion of medical supply manufacturing capacity.

So, Congress needs to move President Biden's American Rescue Plan as quickly as possible. I know their process is beginning on the floor this afternoon, and I look forward to hearing from our witnesses about their thoughts on the Nation's response to the pandemic so far, and how we can improve going forward.

So thank you again, Madam Chair, for this important hearing of the Health Subcommittee.

I yield back.

Ms. Eshoo. The gentleman yields back. We thank him for his opening statement.

The chair now recognizes Representative Cathy McMorris Rodgers, our new ranking member of the full committee, for her 5 minutes for an opening statement.

Mrs. Rodgers. Good morning, everyone. Thank you, Madam Chair and

Republican Leader Guthrie, for holding this important hearing.

Exactly one year ago today news, outlets were reporting that the global death toll from the coronavirus was 362, with all but one of those deaths occurring in mainland China. A year later, this heartbreaking number has surpassed 2 million, with over 425,000 of these tragic deaths occurring in the United States. This pandemic has wreaked havoc on our way of life. The loss of life has been devastating.

Our previous booming economy has been decimated. Our mental health crisis has only worsened, and the long-term impact of our children being kept out of the classroom is incalculable.

Last Congress, we put our political differences aside to make extraordinary investments in the fight against COVID-19 through five separate bipartisan relief packages. These included providing over $30 billion for the States, Territories, and Tribes for testing, vaccine distribution, contact tracing, and public health infrastructure improvement; and over $23 billion to the Biomedical Advanced Research and Development Authority for the research, development, and manufacture of novel vaccines, tests, and treatments; and $178 billion for healthcare providers on the front lines of taking care of patients with COVID-19.

This investment and partnership with the private sector has led to unprecedented development of innovative vaccines and treatments coming to market faster than we ever thought possible. Operation Warp Speed is one of the most ambitious and successful undertakings in American history, with two lifesaving vaccines now authorized by FDA and a third hopefully soon to follow. There is light at the end of this dark tunnel.

However, our hard work is not yet complete. Vaccine distribution is ramping up, but we must ensure States have the resources and the flexibility they need to immunize successfully as many people who want it and meet the unique healthcare needs of their

individual population.

We heard yesterday in the Oversight and Investigations Subcommittee from West Virginia, which has relied on community pharmacists to get the vaccines to people. Unfortunately, other States, like my own Washington State, has not been as successful. Governor Inslee and others in Olympia have spent a great deal of time pointing fingers at Washington, D.C. for the State's slow distribution, instead of figuring out strategies to get people vaccinated.

Clearly, some States were better prepared and used the advice of the CDC career scientists to implement locally targeted strategies more successfully.

While vaccine distribution is critical to safety and responsibly reopening our economy and our schools, we also learned additional challenges during the response to COVID-19. We learned that our medical supply chain is incredibly vulnerable and that we rely too heavily on adversarial countries like China for critically important products, such as protective equipment.

We need to consider policies that will improve our domestic manufacturing without impacting cost and consumer access. Our Strategic National Stockpile and medical supply distribution logistics also need to be strengthened.

While we have met this unprecedented crisis with an equally unprecedented response, our resources are not unlimited. Congress has a responsibility to oversee the money we have spent, understand how it is being distributed and used, and learn what is working and what hasn't.

As Chairman Pallone said during our organizing committee just last week, this committee has a rich history of bipartisan cooperation and hard work, perhaps more than any other committee in Congress.

Between the pandemic, the economic crisis, the social and political unrest, last

year was one of the most difficult in our Nation's history. Despite these incredible hurdles, Congress was able to come together on five separate occasions to give the American people the relief they needed. This pandemic and our government's response is bigger than any single administration or political party.

As we discuss these important issues in our path forward with our distinguished witnesses today, I hope our focus will not be about pointing fingers on shortcomings, but the opportunity to learn what bipartisan steps we can take over the next several months to win the fight against COVID-19, restore our way of life, rebuild the greatest economy in our history, and prepare for future pandemics so that a public health emergency of this magnitude never happens again.

I thank the witnesses for joining us today, and I yield back the balance of my time.

Ms. Eshoo. The gentlelady yields back.

The chair would like to remind members that, pursuant to committee rules, all members' written opening statements are going to be made part of the record.

I now would like to introduce our witnesses, first Dr. Luciana Borio, vice president of In-Q-Tel, an organization that I am very familiar with, former Acting Chief Scientist, FDA, and former Director for Medical and Biodefense Preparedness of the National Security Council.

Dr. Julie Morita, Executive Vice President of the highly distinguished Robert Wood Johnson Foundation. Thank you to you for joining us today.

The Honorable Michael Leavitt, Founder and Chair of the Leavitt Partners, former Secretary of HHS and former Governor of Utah. That is really quite extraordinary.

Greg Burel, president and principal consultant of Hamilton Grace, and former Director of the United States Strategic National Stockpile. Welcome to you.

And, Dr. Luciana Borio, you are now recognized for 5 minutes. And you need to

unmute. So we look forward to your testimony and that of each one of the witnesses. I think we have really extraordinary witnesses today and you are all going to get some good, stiff questions from the brilliant members of this subcommittee.

So welcome. And you can begin.

STATEMENTS OF: LUCIANA BORIO, M.D., VICE PRESIDENT, IN-Q-TEL, FORMER ACTING CHIEF SCIENTIST, FDA, FORMER DIRECTOR FOR MEDICAL AND BIODEFENSE PREPAREDNESS, NATIONAL SECURITY COUNCIL; JULIE MORITA, M.D., EXECUTIVE VICE PRESIDENT, ROBERT WOOD JOHNSON FOUNDATION; HON. MICHAEL O. LEAVITT, FOUNDER AND CHAIR, LEAVITT PARTNERS, FORMER SECRETARY OF HEALTH AND HUMAN SERVICES, FORMER GOVERNOR OF UTAH; AND GREG BUREL, PRESIDENT AND PRINCIPAL CONSULTANT, HAMILTON GRACE, FORMER DIRECTOR, UNITED STATES STRATEGIC NATIONAL STOCKPILE.

STATEMENT OF LUCIANA BORIO, M.D.

Dr. Borio. Thank you. And good morning, Chairman Pallone, Ranking Member McMorris Rodgers, Chairman Eshoo, and Ranking Member Guthrie, as well as members of the subcommittee. It is my great pleasure to join you today.

As you know, I work at In-Q-Tel, a nonprofit technology investment term that serves U.S. national security. And before that, I served across four different administrations, and most recently, as a member of the Biden-Harris transition team in its COVID-19 Advisory Board. I am appearing before you in my personal capacity.

The situation is dire, and I fear that our worst days could be ahead, given the variants that emerged recently in the U.K., South Africa, and Brazil, and have spread

globally. The South African strain is exceptionally concerning since it invades at least partially the antibody-based therapies, and diminishes the protective effect of at least some vaccines.

In my testimony today, I would like to share a few thoughts about the past, present, and future.

I do not wish to dwell too much on the past, other than to say that the Nation learned the consequences of departing from the science-driven response, however imperfect, historically taken during public health emergencies. At the same time, we must recognize that many of the shortcomings of this response are due to factors that preceded the most recent administration, and repairing it will require reckoning with early missteps, a failure of imagination, and a significant complacency that has plagued us for years.

Here are seven priorities for the present: First, given the variants, CDC must immediately expand its genomic surveillance system in collaboration with public health, private, and academic labs. I am glad to see early steps in this direction.

Second, vaccines. We are quite fortunate. We have two safe and effective vaccines developed in record time with additional ones on the horizon. This incredible success would not have been possible without decades of investments in U.S. biomedical research, the people of Operation Warp Speed, and the FDA's Office of Vaccines under the leadership of Drs. Marion Gruber and Phil Krause. They guided the rapid development of these innovative vaccines without compromising the highest scientific standards, and ensuring transparency. This is what makes American scientific enterprise so powerful and so hard to replicate elsewhere. Sadly, the chaotic rollout of the vaccines has frustrated millions of Americans. The new administration has taken steps to fix the situation, and you should see more improvements soon.

Third, the virus variants. The threat will not be resolved with travel restrictions. We must take urgent measures to reduce the spread of this virus to lessen the opportunities for the virus to further mutate and become even more dangerous. The virus continues to burn through our country, while many people continue to gather indoors and in large groups and refuse to wear masks or social distance. Small businesses across our country that are lucky enough to have survived thus far, simply cannot afford another lockdown. If we care about our jobs, we must mask up and change our behavior urgently.

Fourth, the supply chain. I am encouraged to see vaccine manufacturers taking steps to develop new candidates that may be needed to effectively protect against new variants, but the supply chain for making and distributing vaccinations remains extremely fragile. The Federal Government is using the Defense Production Act to prioritize the allocation of limited critical materials. DPA helps, but it is not a final solution. HHS must urgently expand the industrial base for critical supplies to ensure the U.S. has sufficient supplies for this and future pandemics.

Fifth, we do need better therapies. The quest for cures has been hampered by the lack of a national capability for conducting simple and pragmatic randomized clinical trials. In departure from prior practice and under intense political pressure, the FDA issued a series of EUAs for products that had not been properly evaluated. Patient care needs to be driven not by hope, but by science.

Sixth, diagnostic tests. As the Federal Government worked to increase testing ability, it never developed a strategy to help guide clinical and public health practice. To maximize the impact of testing, I urge the CDC to develop guidance for testing in a variety of settings, travel, workplace, and educational settings, for example.

And, seventh, the U.S. still lacks an interoperable data infrastructure for public

health. This should be one of the principal areas of retention if we are to build a 2lst century public health system.

As for the future, biological threats are not going away. As we continue to battle this pandemic, we must also build a system that can meet future threats: one that integrates the private sector in cutting-edge technology, that values the critical role of public health in our collective well-being, health, and economic security; and realizes that good governance is necessary to bring capabilities to fruition.

A better day will soon come upon us if we let science and the American innovation lead the way.

Thank you.

[The prepared statement of Dr. Borio follows:]

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Ms. Eshoo. Thank you, Dr. Borio.

I now would like to recognize Dr. Julie Morita. You are recognized for your 5 minutes of testimony. And please remember to mute.

STATEMENT OF JULIE MORITA, M.D.

Dr. Morita. Chairman Pallone, Ranking Member McMorris Rodgers, Chairman Eshoo, Ranking Member Guthrie, and members of the subcommittee, thank you for this opportunity to testify. My name is Julie Morita, and I am the Executive Vice President of the Robert Wood Johnson Foundation, the Nation's largest health philanthropy, and I served on the COVID-19 transition Advisory Board in my personal capacity. Previously, I served as commissioner and chief medical officer of the Chicago Department of Public Health, an epidemic intelligence service officer at the Centers for Disease Control and Prevention, and a member of the CDC's Advisory Committee on Immunization Practices.

Our Foundation believes that everyone deserves a fair and just opportunity to live the healthiest life possible. The pandemic, with more than 26 million Americans infected and 440,000 lives lost, illustrates the critical nature of our mission.

Vaccines offer real hope to eventually end the pandemic, but we must improve distribution by adhering to three fundamental principles: equity, accessibility, and coordination.

We must begin with equity. People and communities of color are disproportionately impacted by COVID-19. These populations historically and currently face discrimination, marginalization, and neglect. As a result, they are more likely to be denied basic necessities, like a living wage, health insurance, and paid leave.

The CDC recommends that frontline and essential workers, predominantly people of color, be among those prioritized for vaccination due to high exposure risk. But today, the country is consumed with total allotments and weekly averages instead of whether shots are getting in the right arms.

We must course correct quickly. Our Foundation believes an equitable response to the pandemic starts with collecting and reporting all COVID-19-related data by race, ethnicity, and other socioeconomic factors. Yet most States do not publish vaccine data that includes race and ethnicity. Among States that do, the share of vaccinations among Black people lags behind the share of cases and deaths.

We can no longer accept the systematic racism that drives these disparities. Congress and the administration should encourage and enable all States to vaccinate priority populations first and to report vaccine by race, ethnicity, occupation, and neighborhood.

Second, we must increase accessibility. Vaccines are only as effective as people's ability to obtain them, and willingness to take them.

Across our Nation those with means and privilege are increasingly getting vaccinated before those with highest exposure risks. Necessities that some may take for granted, an internet connection to make an appointment online, a car to drive to a large-scale vaccination site, the time that it takes to navigate complex systems, are unaffordable for millions.

A fairer approach simplifies appointment systems and brings vaccines directly to priority populations. In Chicago, during the H1N1 pandemic, we partnered with pharmacies and federally qualified community health centers that provided care to the uninsured in neighborhoods with less access to healthcare providers. More than 700 locations in Chicago ultimately received more than 1 million H1N1 vaccines during a

critical 12-week stretch.

We also established meaningful connections with trusted community partners to address vaccine hesitancy, which remains an issue today. More than 1/4 Americans report they will not, or likely will not get a COVID vaccine. Notably, hesitancy rises to one in three among rural residents, Black adults, and essential workers.

Community groups, faith organizations, and other neighborhood pillars of trust play a pivotal role in helping people make appointments and understanding and addressing their concerns. Our Foundation is providing grant support to State, and territorial health officials, and community organizations to address vaccine hesitancy. As we await additional doses, funding and supporting critical and local efforts will help us move to vaccine confidence and equitable distribution.

Third, the incredible complexity and urgency of this vaccine rollout requires coordination and illustrates the unique role of the Federal Government.

I am proud of how Chicago handled H1N1, but we didn't do it alone. CDC's clear guidance, additional funding, and technical assistance were invaluable. Without that support, our vaccine rollout would not have been as successful.

I am encouraged that the current administration, particularly Dr. Rochelle Walensky, the new CDC director, is committed to improving coordination at the Federal level. Open lines of communication, increased transparency, such as more specific, accurate, and timely estimates of State allotments of vaccine, and ramping up our public health workforce, will all help State and local health officials perform their heroic work.

In conclusion, the Robert Wood Johnson Foundation is invested in creating a more equitable Nation during this pandemic and beyond. In the short term, America's ability to weather this crisis will require wearing masks, social distancing, washing hands, and additional support from Congress to help those hit hardest. Vaccines will eventually

lead us to this pandemic's end, but saving the greatest number of lives will require a recommitment from all of us to equity, accessibility, and coordination in vaccine distribution in all facets of our response.

Thank you. I look forward to your questions.

[The prepared statement of Dr. Morita follows:]

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

Ms. Eshoo. Thank you, Dr. Morita.

Next, I would like to recognize Governor Michael Leavitt. You are recognized for your 5 minutes, and we thank you for your willingness to be a witness today. Welcome to our subcommittee. And please unmute. We want to hear every word you have to say.

STATEMENT OF HON. MICHAEL LEAVITT

Mr. Leavitt. Well, thank you to all of the committee.

This hearing is about looking ahead. The summation of the submitted testimony that I provided can be expressed in a simple phrase, "scout the next valley." Explorers and others that navigated new territories always send scouts ahead to help them anticipate the problems. In a pandemic, surprises are just an inherent condition, but we should not be surprised by the fact that in every phase of this pandemic, there are new challenges.

So today, I would like to talk a bit not about the next pandemic, I think we need to focus now on what we should be doing next in this pandemic. What should we be prepared for 3 to 6 months from now? What problems will we likely face 6 to 9 months from now?

My submitted testimony lists 11 categories that we need to be planning today for predictable near-term problems. In the 5 minutes I am allocated today, I would like to focus on just one: the need to develop an open source vendor-agnostic digital vaccination and testing credential.

Here is the problem: Of course, we have vaccines and we celebrate that. We

are moving with increasing haste to distribute them, and it is happening at an increasing velocity. There is great anticipation this is going to bring down transmission rates and the disease prevalence will fall. But vaccines are, of course, voluntary. Many people are still reluctant. There are still risks even after vaccination.

Inevitably, to open up the economy, and to get back to what we consider to be normal, we are going to need to have many parts of our economy adopt a strategy of requiring some form of proof of vaccination as an entrance requirement. Now, dozens of efforts are underway right now by large companies and small enterprises that are building the killer app that would allow people to authenticate their status as a person who has been vaccinated. All of them assume that there is a trusted source of truth on which -- on who has been vaccinated, and who has not.

Today, my message is, that it does not exist. Let me repeat that. It does not exist. Unless action is taken very quickly, this is going to be a mess. This is a valley we need to scout now, or it is going to present substantial delay in the fulfillment of the need and the promise of vaccines.

Now, we have made this mistake before. While I was Secretary of Health, I was dealing with electronic medical records, the fact that there were 200 different standards, and we couldn't connect up and talk -- the computers could not talk to each other. We have seen it in banking. I remember the day when you would walk into an airport and there would be nine ATM machines, and you had to take your card and match up which one would fit into that system. We can't make that mistake again. Consumers need an easy means of voluntarily demonstrating their vaccination status.

Now, to be clear, I am not arguing here about mandatory vaccination. I am saying that consumers are going to need access to their own vaccination records. Yes, they have a card, and they will find that useful. But they are going to need access to

their records digitally and on paper. Let's be candid, paper records are simply not going to be adequate.

Every State has an immunization information system, and that is good, but every vaccination is not being reported and they need to be.

More importantly, every State should be participating in the CDC/APHL IZ Gateway. Let me explain. HHS developed a technology called the IZ Gateway, which allows State jurisdictions to share vaccination information. This enables individuals and provides access to vaccination information from any jurisdiction in the country. Here is the problem: Unfortunately, only about half the jurisdictions -- there are 64 in total, but about half of them are participating in the IZ Gateway. Without that data, such a system of being able to get our economy going based on the existence and validated, trusted records of who is vaccinated will not exist.

If the committee wants a way to scout the next valley, you should include in the next stimulus bill a requirement for States that give Federal vaccine, to participate in the IZ Gateway and to ensure that every vaccine that is administered gets reported to the States through their IIS system, and allows consumers the ability to access their own vaccination records.

In my remaining time, I will just list a couple of the other areas that have been -- that I will add emphasis to. Others have mentioned them, that is, the increased worry of supply chains on syringes and vials and drug ingredients, and so forth.

Madam Chairman, I think my time is up. I will stop. I look forward to the questions.

[The prepared statement of Mr. Leavitt follows:]

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

Ms. Eshoo. Thank you, Governor, very much. And we will follow up on the last point that you made with our questions.

Next, I would like to recognize Mr. Greg Burel for 5 minutes for his opening statement. And thank you again for being with us today.

STATEMENT OF GREG BUREL

Mr. Burel. Thank you.

Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo, and Ranking Member Guthrie, members of the committee, thank you for the opportunity to testify today.

It was my privilege to serve as director of the Strategic National Stockpile for almost 13 years until my retirement in January of 2020. I am now president of Hamilton Grace, and am an elected fellow of the National Academy of Public Administration.

COVID-19 has exposed the fragility of our Nation's medical supply chain. It brought to the fore the vital need to consistently and properly resource our preparedness for health security threats. The most glaring supply chain problem was the inability to provide PPE due to political and geographic vulnerabilities. We must channel what we have learned into better policies to prevent this from ever happening again. We must simultaneously address today's response by preparing to meet future health security needs.

To address the fragile supply chain, we must invest in sustained domestic critical healthcare manufacturing. Without regular investment post COVID-19, domestic manufacturing will wane again as the crisis abates and demand recedes while

competition from low-cost foreign sources undercut new domestic manufacturers. Continued domestic manufacturing is a national security imperative.

We find ourselves trying to successfully vaccinate our whole population. Rapid, mass delivery of medicine will always present challenges, but advanced preparedness investment, planning and use of operating distribution systems will better facilitate the process. A successful government-led response must engage the whole commercial healthcare supply chain.

We must pivot from our long history of inconsistent, inadequate preparedness funding to long-term mandatory sustainable preparedness. How we drive those policy changes today will define our success in the future. We have witnessed the devastating effects of a lack of preparedness on our Nation's health. To respond now and lay the groundwork for future needs, I offer the following recommendations:

First, we must rely on our healthcare system to bring an end to this crisis. We must engage all commercial healthcare distributors and manufacturers. Vaccines are not readily and easily available at expected dispensing sites. Part of this is due to the shortage, but another part is due to the lack of distribution partnering engagement. A sole distributor cannot reach the full breadth of dispensing capability. This is especially a problem for those unable to spend hours online searching for available vaccines and navigating failing websites to register. It is particularly vexing for those without technology resources or abilities. This affects the most vulnerable of our citizens.

Second, we must clearly assign responsibilities to the appropriate entities. The SNS has long been the lead to acquire, manage, and deliver countermeasures to secure the Nation's public health in emergency. But SNS appears somehow to have been sidelined somewhat during this response. Other Federal departments have been assigned responsibilities SNS can lead effectively. As a result, success in buying and

delivering the right products has been, at times, inconsistent. Engaging SNS expertise can make sure we get the right thing to the right place at the right time.

SNS needs significant increased appropriations if it is to be our bulwark against failing supplies of vital medical material in crises. Making such appropriations mandatory rather than discretionary would help achieve better preparedness.

Third, we know as a crisis abates, so does the urgency for sustaining their preparedness. We cannot continue to claim we are ready only to act shocked when we find ourselves unprepared because we couldn't invest to meet the need. We must invest in purchasing domestic capacity or otherwise providing incentives for manufacturers to sustain domestic production and create greater material stocks. We must support and resource regulatory structures friendly to domestic manufacturing while always respecting the science that assures safe and effective products. These actions, along with using the existing distribution infrastructure, will help create flexibility in an otherwise lean supply chain that can cushion surging needs.

As the current crisis subsides, we must incentivize those manufacturers who now boldly enter a domestic market to continue consistent production. They must be incentivized to improve capability, plants, and machinery to achieve better quality and higher output. Establishment of an aggressive government investment platform driven by clear needs for critical products will allow us to use and develop and maintain this domestic base.

Finally, we must improve planning at all levels. At one time, SNS supported State, local, Tribal, and territorial officials with dedicated consultants. A return to linking the medical logistics professionals in SNS directly with these public health officials will assure strong preparedness planning.

Our path forward must incorporate elements of all of these considerations. We

must unyieldingly fund health preparedness in the United States.

I look forward to your questions, and I always remain available to assist our Nation in these endeavors.

[The prepared statement of Mr. Burel follows:]

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

Ms. Eshoo. Thank you very much, Mr. Burel.

We now are going to move to members' questions, and I recognize myself for 5 minutes for questions.

First, to -- and, please, to the witnesses, know that each member only has 5 minutes to ask the questions, get the answers. So let's all try to be as -- you know, conserve time so that we can optimize it.

To Dr. Borio, the American Rescue Plan provides the resources needed to vaccinate the 300 million Americans by the end of this summer. How do the new mutant viruses affect the timeline, if they do, for this plan vaccine rollout? And what do we need to be doing today to be ready for that tomorrow and the days following?

Dr. Borio. So, you know, in that short time, nothing really changes. The response remains, which is to decrease transmission of the virus through public health measures, intervention and, importantly, vaccinations. So it is urgent that we get vaccine rolled out. Every dose that comes out of the manufacturing line should make it into somebody's arm as soon as possible.

Ms. Eshoo. Good.

Dr. Borio. In the midterm, we do need to begin to be prepared in case we do need to manufacture on large scale the new candidates if there is a significant erosion in protection and revaccinate the population. We do not know right now if that will be necessary. We hope that it may not be.

And also, I would just add that we do believe that these vaccines will need to be boosted periodically, whether it is the original vaccines, modified vaccines. So we do need to build the industrial base and capacity, just like we do for flu vaccines. That is the current thinking.

Ms. Eshoo. Thank you very much.

To Dr. Morita, thank you again for joining us today. In just the first few weeks of vaccinations, Black Americans are receiving them at dramatically lower rates than White Americans. How do the increased resources from the new administration's plan help bring the vaccine to underserved communities? You spoke to this, to the issue and the problem and the inequities relative to the rates, so can you be instructive to us in terms of what needs to change and how those increased resources are going to change the rates that -- the really shameful rates in our country?

Dr. Morita. So you are right. In addition to the disproportionate impact on our communities of color in terms of disease, who is dying, who is hospitalized, what we are seeing is that there is lower rates of vaccination administration in our communities of color as well.

Things that can be done to improve that situation would be to really make sure that the sites that are vaccinating are located in the communities themselves, that the appointment processes are simplified so that people can use the telephone. They aren't just internet dependent, that there are community workers that are going into communities and actually helping people to register, whether it is online or by phone.

So what we have seen are the processes are challenging for people to actually access the vaccine. I, myself, am trying to get my 91-year-old dad an appointment and struggling through use of the internet. These processes themselves have to be simplified, and additional resources will help; Hire staff to actually do the community work; Simplify the stand-up phone so that people can actually make phone calls instead of just going online --

Ms. Eshoo. I just want to get one more question in, so we can follow up with more questions with you, and all members can do that.

To Mr. Burel, on our Nation's national stockpile, it ran dry. And as someone that worked with former Congresswoman Susan Brooks on preparedness and the stockpile, it was absolutely maddening to all of us what we experienced. When you were selecting contracts for the stockpile, did you weigh the country of origin versus the cost?

See, I think we should have an American stockpile. This business of being dependent on other countries, some of them who don't wish us well, I think was a national embarrassment. So what can you share quickly with us about this?

Mr. Burel. Thank you for the question, Chairwoman Eshoo.

We followed all the appropriate procurement regulations in making our purchases.

Ms. Eshoo. What were they? Did we have buy American only? Or was it first come, first serve? Was it China? Others? I mean, it is --

Mr. Burel. Sure. I appreciate the question.

Ms. Eshoo. Both sides of the aisle care about this.

Mr. Burel. Yes, ma'am, I understand.

What we did is we procured products under Buy American, where that is appropriate, and that is most products. Where there were products that were not manufactured in the United States, we purchased those from a U.S. vendor.

Ms. Eshoo. What is not manufactured in the United States relative to PPE?

Mr. Burel. So much of the PPE we find is manufactured overseas, particularly N95 masks.

Ms. Eshoo. That is not true. We have a major American manufacturer for that.

I think I need to stop because I have gone over my time, but we are going to follow up with you with more questions.

Mr. Burel. Thank you.

Ms. Eshoo. Thank you, sir.

So the chair now recognizes our new ranking member, Mr. Guthrie, for his 5 minutes of questions.

Mr. Guthrie. Thank you very much. Thank you, Madam Chair, I appreciate it.

And this is to all the panelists. So my question is -- and I am not going to get back into why it was delayed -- but we had two vaccines approved mid-December. Then we had $4.5 billion approved December the 27th for States to distribute the vaccines. Some States have been successful; some States haven't.

So looking forward, we are looking at, perhaps, doing it different ways. Do you think now that the States have had the money for a month that they are going to improve, or do you think we really need to restructure how we are distributing these vaccines currently? So we have some States successful, some aren't. The money came late. They now have it. Are we seeing improvements enough, or do we need to overhaul how we are getting these vaccines distributed and in arms of people, which we all want?

So I can start with -- I can see Dr. Morita in my screen first, so I will just call on you if that is okay.

Dr. Morita. Thank you so much for your question. I really appreciate it.

So the challenges that we have experienced with the distribution are because of a lack of initial resources to support States and locals. As much money that went into Operation Warp Speed, which was an incredible process and incredible results with two vaccine being developed and manufactured so quickly, additional resources in equal amounts were needed to go to States and locals so that they could actually ramp up their systems. But they are playing catch-up at this point. What we heard consistently during the transition period was that they didn't have enough resources to hire staff, to

open up clinics, to actually do community work to improve understanding of the vaccine, to drive demand, enhance the electronic --

Ms. Eshoo. Excuse me. Dr. Morita, can you either maybe get closer to your microphone, speak a little louder? We don't want to miss a word you are saying.

Dr. Morita. Sure.

Ms. Eshoo. And whatever time I have taken to say that you won't lose.

Dr. Morita. Additional resources are necessary, so although things are improving, and I am thrilled to see how much the rate of administration is actually improving, additional resources are necessary so we can actually do this as quickly as possible.

What Dr. Borio mentioned, in terms of the variants, really gives us urgency in terms of the need to vaccinate as quickly as possible. And we can do it equitably if additional resources are made available so they can get in the community, help people sign up for the vaccines. Make sure those who need the vaccine the most are really able to access it as well.

Mr. Guthrie. Okay. Thanks.

And to get to all of my questions, I am probably just going to jump next, but it is sort of the same thing for Government Leavitt to touch on that, but also you, mentioned in your testimony about Medicaid and how the -- the competition with Medicaid and public health spending.

So as a former governor, I mean, the money has now moved forward. I know they need additional resources. But could you kind of address my question, please, for Medicaid and public health spending issues as well?

RPTR DEAN

EDTR ZAMORA

[12:00 p.m.]

Mr. Leavitt. Well, we have allowed public health to go to seed over the last 25 or 30 years in this country. There are probably a lot of things that have contributed to that, but one of course has been the tension that States are under to deal with both Medicaid and public health. We can pursue that.

Could I just comment briefly on --

Mr. Guthrie. Yes.

Mr. Leavitt. -- the previous question?

I had the privilege of serving as HHS Secretary when we rolled out Medicare part D to 45 million people. That is not a challenge of doing vaccines to 300 million, but I learned something, I think, important and that is we are going to get better at this. The first month, I am sure there are always going to be issues. The second month will be better. The third month will be better. If we were trying to give everyone in America a hamburger, we can get that done in 30 days because we have the infrastructure. Everyone knows how to do it, and people could go through the drive through and we would be finished. But the reality is we are standing up something entirely new, and we will get better at it. And it is a good thing, because we are going to likely be doing this for some time, well beyond this year.

Mr. Guthrie. Thank you.

And, Dr. Borio, just to kind of nuance that question, if you want to address that, you can. But I also have Kentucky BioProcessing in my district, and they are coming up with a new generation vaccine. They are telling me they are having trouble finding clinical trials because as more people get vaccinated, there are not going to be the test

populations, particularly placebo groups that they need. So could you talk about what HHS and BARDA must do to help development of the next generation vaccines?

Dr. Borio. That is a really great point, because once you have a product that is authorized broadly and broadly available, it makes it more challenging for new products to come in and evaluate them with the same type of standards that we would have accepted for the first trial. So we do the randomized control trials. You may have heard in the news, for example, that a company, Novavax, are now doing studies in the U.S. Some of the older patients in that study are dropping out of the study to be able to get the authorized vaccines. So that is not an issue that is, you know, just to this company.

I know the FDA is working really hard to then develop, you know, more of the pathway forward for these companies. How can we show scientifically and that these products are indeed safe and effective if they are -- you know, how to demonstrate that. And it may be that it will require a different type of trial than the original ones. And I know they are working hard at that.

It is possible that, you know, we be able to rely on immune markers to be able to establish the efficacy of these vaccines. I don't have the answers today, but hopefully soon.

Mr. Guthrie. Well, thank you very much. I see my time has expired. And sorry, Mr. Burel, but my time has expired.

I will yield back.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the chairman of the full committee, Mr. Pallone, for his 5 minutes of questions.

The Chairman. Thank you. Thank you, Chairwoman Eshoo.

I just wanted to comment, I heard when our Ranking Member Rodgers in her opening statement mentioned how we have too much reliance on China and other countries and we needed to do more domestically, including manufacturing. I just want to say I totally agree with you on that, and that is certainly something that we need to continue to look at; you know, too much reliance on other countries, particularly China, for supplies, ingredients and that. And also that we need to prepare for future epidemics or pandemics. One of the things that was always done in our committee every year, including under Greg Walden and Mr. Upton when they were chairs, was an annual flu hearing. So we would always, like, prepare for the future, and that continues to need to be done.

But I, of course -- with Mrs. Rodgers, I don't agree about her analysis of the Trump administration. I don't want to dwell on the past, but I think it is important to understand the message the Trump administration left behind. And one of the areas of concerns that we heard from States yesterday at the hearing was the lack of communications, lack of national preparations, guidance, and resources when it came time to roll out the vaccination program. And States were given a vaccine supply under Trump, but very few resources to carry out distribution.

Now, I know that, Dr. Morita, you talked about this, so I don't went to dwell on it, but give me a little more analysis, if you can quickly, about the lack of resources. And particularly, I don't know if you have seen or want to comment on Biden's American Rescue Plan, which we have put into legislation form, we are going to start the process today. How can we benefit from additional resources moving forward if we are going to meet President Biden's goal of vaccinating these 300 million people by summer or fall? I am only going to give you 30 seconds or a minute because I have to move on to testing.

Dr. Morita. Sure thing. Thank you so much for your question.

In my past experience, whether it was H1N1, Zika, or Ebola, the best responses were those that were really coordinated at the Federal level because the Federal agencies work so closely with State and local health officials. That kind of coordination is reflected in the American Rescue Plan, and we heard about it during the transition period as well as the planning was being developed. There is a strong commitment for there to be this coordination so that supplies are arriving appropriately, places that are doing well or recognized places that are struggling get the support and resources they actually need.

So this level of coordination that CDC and other Federal agencies can do is really, really critical. That and this clear and consistent communication regarding the science. So the science-based recommendations and guidance usually flow from CDC to State and locals were incredibly valuable. And that kind of issue, those guidances are already starting to flow, and the communication is much more consistent and regular. So we are really seeing signs that this can be a more coordinated and robust response moving forward. So those approaches are clear in the American Rescue Plan, but also in the strategy that was released the day after inauguration.

The Chairman. Well, thank you.

Now let met get to Dr. Borio. I want to emphasize the importance of our vigilance in testing and contact tracing in doing other mitigation activities. I don't think that vaccines alone are going to be enough to protect people as we continue to have outbreaks. So, Dr. Borio, as you noted in your testimony, the Federal Government never developed a comprehensive national testing strategy, despite the fact that we know one of the keys to controlling outbreaks relies on access to reliable diagnostic tests. And, of course, I was critical of the lack of a national strategy under President Trump.

So can you talk about the importance of national coordination in a testing strategy and the importance of providing resources to carry out mitigation such as contact

tracing? Do you think -- you know, tell us about additional national investments to increase testing. And if you want to comment on Biden's American Rescue Plan in that regard, I would appreciate it as well. You have only got 45 seconds.

Dr. Borio. So, yes, just like a clinician, you know, has usually a menu of options to care for patients and which tests to use, public health practitioners also need the menu of options to be able to optimize the use of these finite supplies of testing. It is not an infinite supply, and there are strategies that are more effective than others. And we need Federal guidance for that.

With respect to contact tracing, it is very critical. We cannot do it without technology, I will say that. And to be able to have, you know, people -- it is important, it is a critical aspect, but we are also going to have to need technology to be able to do it with a speed of which a pandemic requires. We need Federal coordination for that to develop the standard, the privacy standards, and to evaluate the effectiveness of these technologies that are just emerging. Other countries have deployed it; we need do it too.

The Chairman. Thank you so much.

And I yield back, Madam Chair. Thank you.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the ranking member of the full committee, Congresswoman Kathy McMorris Rodgers.

Mrs. Rodgers. Thank you, Madam Chair. It is great to be with you.

And, Mr. Pallone, chairman of the committee, I just want you to know that the Republicans stand ready to go to work, to identify the gaps, and to work together to continue to address the needs around the pandemic. And we really appreciate the chance to talk with our witnesses today. Thank you all for taking the time to be with us.

I wanted just to start by asking each one of you, at the start of this pandemic, did any of you anticipate that we would have a safe and effective COVID-19 vaccine to distribute and administer only 10 months later? And if you would just answer yes or no, maybe beginning with Dr. Borio.

Dr. Borio. Well, I'm an optimist, and I did. I did have deep hope. I wasn't 100 percent sure, but I have great confidence in, you know, the type of science that underpins the current technologies and also in our ability to be able to move fast, given the tools that we have today at our disposal. And thanks to the FDA for helping with that.

Mrs. Rodgers. Thank you.

Dr. Morita. So I too was not certain, was hopeful, and have been so appreciative of the work that Congress had for supporting Operation Warp Speed, because the amount of resource and attention that was provided guaranteed that this effort was actually going to be successful. So it is the amount of resource and attention that will be supported.

Mrs. Rodgers. Very good.

Mr. Leavitt. I will just say, based on past history and what I know about historic process, there was not a lot of reason to be optimistic. It was truly a remarkable feat.

Mrs. Rodgers. Thank you.

Mr. Burel. I was hopeful as well, but I was not convinced. I do think we have made a lot of progress in being able to do these sort of things in public health emergencies. We need to continue to invest to be able to do this in the future.

Mrs. Rodgers. Yes.

Has vaccine distribution of this magnitude and complexity ever been attempted in the United States before? And, again, I would just like to ask each one of you to answer yes or no.

Dr. Borio. Not even close.

Mrs. Rodgers. Okay. Thanks.

Dr. Morita. This is the largest I have seen in my lifetime.

Mrs. Rodgers. Great.

Mr. Leavitt. I think it is clear it is unparalleled.

Mr. Burel. No, we have never done anything at this level before.

Mrs. Rodgers. Great.

Governor Leavitt, given your experience serving in government and your tremendous service both at the State and the Federal level, I just wanted you to speak, and I know you did some in your opening testimony, but a little bit more about the appropriate role of the Federal Government when it comes to vaccines. If you would just talk a little bit more about that. And what flexibilities you believe need to be preserved to the State or local authorities to best respond to the unique needs facing their individual constituencies.

Mr. Leavitt. Well, I will start by saying there is a role for both, and both need to do their job and work together to make this work. The point that has not been made that needs to be, both of the vaccines that we have in the market today are based on new technologies that were actually developed under Federal procurement and/or other Federal investment beginning in 2006, 2007, and 2008, when we were dealing with the H5N1 and Congress responded by appropriating at nearly $8 billion.

The point here is if you want to have this kind of result, it doesn't just happen in 11 months. It requires perpetual investment and perpetual vigilance to be ready.

Mrs. Rodgers. Thank you. Good point.

To Dr. Borio, you mentioned in your testimony the complexities of the vaccine supply chain and how the disruption of any critical component will disrupt the availability

and the administration of the vaccines. I just wanted to ask you, are there any immediate additional actions that you believe that we need to be taking right now to ensure a stable supply chain for COVID vaccines?

Dr. Borio. Thank you. I really do believe that Operation Warp Speed has done everything to maximize the process, to optimize it, and to basically rely as much as they could have already on DPA, the Defense Production Act.

I think to be able to -- the next steps really is about expanding the industrial base, domestic base, to manufacture some of the critical supplies here. We are talking about filters and columns and syringes and needles and bags that are required for the biomanufacturing. We are talking about filling finish lines to be able to bottle the vaccines. Every little single component, no matter how small it seems, can really bring the whole process to a halt if we don't have access to it.

Mrs. Rodgers. Very good. Well, I ran out of time. Again, thanks all. I will save my questions for later.

Ms. Eshoo. We thank the ranking member.

And just to remind everyone that we leave the record open so that questions can be submitted to our witnesses. And I will do another reminder of that at the end of the hearing.

It is a pleasure now to recognize the gentleman from North Carolina, Mr. Butterfield, for his 5 minutes of questions.

Mr. Butterfield. Thank you, Madam Chair. Good morning, good afternoon to all of you. And thank you, Madam Chair, for you leadership, and thank you for the direction in which you are taking this subcommittee.

And let me just say in the outset to our new ranking member, Mr. Guthrie, I look forward, sir, to working with you as we worked together in previous Congresses. I look

forward to not only working with you, but also to all of you on the other side of the aisle.

Let me just take a moment to thank the witnesses. I have listened very carefully to your testimonies. Your testimony is very much appreciated today. And thank you for all the work that you do in the space in which you operate.

But I am going to concentrate my three questions, if I have enough time, on Dr. Morita.

Dr. Morita, thank you for your willingness to give the Nation the benefit of your expertise.

Since the very beginning, it has been clear that while COVID-19 affects us all, it does not affect us all equally. And I think some of the witnesses made reference to that in their testimonies. African American and Latino, Asian, Native Americans, all of these individuals are more likely than White Americans to be infected. That is a fact. More likely to be hospitalized. More likely to die from COVID. This reality is why health equity must be at the center of any plan for distributing the vaccines. Unfortunately, the trends from the first several weeks are headed in the wrong direction.

The previous administration failed our country in so many ways. And the chairman of the full committee is right, we are not going to dwell unnecessarily on the past, but the previous administration did fail, including not putting forth a clear plan for vaccine distribution. Because of this failure, we now have a lack of reporting and incomplete data.

According to the CDC, we only have race and ethnicity data for about half of those receiving the vaccines. And where do we have data? Only 5.4 percent of individuals getting the vaccines are African American, 11 percent are Latino, 6 percent are Asian, 2 percent Native American, despite the fact that these groups bear a higher share of the COVID burden and often serving on the front lines of our healthcare workforce. And we

have got to fix this now. I think we can all agree on that.

Dr. Morita, with such limited data, the situation might be worse than we know. How can we improve data collection and vaccine distribution?

Dr. Morita. Thank you for your question. The equity issue is critical. In order to respond appropriately, we need to really improve the data systems that are being used currently. And there need to be additional resources made to make the systems better but also to support the manpower necessary to enter the information. It takes time to enter additional fields like race, ethnicity, gender, geography, occupation. And so it is manpower and it is also data systems.

What can be done? While we already acknowledge that there are some discrepancies in terms of who is getting vaccines, improve the systems by making it more accessible to people. So making sure the sites are located in geographies where people can easily access them without cars if they don't have them. Make sure they can make appointments by telephone, to make sure that there are community workers going into the communities to actually help people register and make appointments. All these kinds of things are necessary to make sure that we are reaching the people who are most likely to die and be hospitalized because of COVID, and those things often require additional resources.

Mr. Butterfield. Let me share this with you, if I can. Ninety percent of Americans live within 5 miles of a community pharmacy. Retail pharmacies are accessible. They are convenient. They are based on recent modeling. They have the capacity to administer 100 million vaccine doses in 30 days.

From your experience as the chief medical officer in Chicago, what more can be done to utilize retail community pharmacies?

Dr. Morita. Retail community pharmacies played a major role in our response

during H1N1. They do have reach into communities. And so just yesterday, the Biden administration announced that they will be making more vaccine available through pharmacies throughout the Nation, particularly focusing on communities of color. They are one mechanism for getting vaccine to these communities.

Federally qualified health centers or community health centers and rural health centers are also places that are located in these communities and have trust within the communities to actually help address some of the concerns that people have about the safety or the efficacy of the vaccines. So a full-court press really needs to happen right now with healthcare providers, health centers, pharmacies, mass vaccination clinics, all those things need to be happening right now so we can get these vaccines out quickly and equitably.

Mr. Butterfield. Thank you very much, Dr. Morita.

And I yield back the 5 seconds that I have, Madam Chair.

Ms. Eshoo. We thank the gentleman. And thank you for your continuing focus on this issue. I don't really know whether our public health departments across the country are even equipped to gather the information that is needed in a very efficient and effective way, and I think that we need to do a little deeper dive on that.

The chair now recognizes the former chairman of the full committee, someone that is always -- he is really, I think, one of the most popular guys on the committee. Everyone loves Fred Upton.

So, Fred, you have 5 minutes for your questions.

Mr. Upton. Well, thank you for your generous words. I am delighted to participate in this most important hearing.

I just have to say we all have to work so hard together. I mean, we are just hearing all these frustrating stories, not only from our constituents, but you see the news

at night and the long lines of people in folding chairs in other places all around the country just waiting. The serious concerns about folks of color not having access. I mean, all these things just tear at our heartstrings, and we need to work together to do the very best that we can to improve the infrastructure.

Ms. Eshoo. Excuse me, can you speak up? I don't know if it is my computer or what.

Mr. Upton. Is that okay? Is that better?

Ms. Eshoo. A little bit.

Mr. Upton. All right.

The question that I have, I guess, for Greg Burel, what are your thoughts on the steps that we need to make sure that domestic manufacturing is, in fact, doing the right job being prepared as we look at the Defense Production Act? Where are we actually short in providing PPE for our communities that really need it? Is it masks, is it gowns, is it gloves, is it testing supplies? What products can you identify that we really need to step up, particularly as we have looked at the private sector, at least in my district, a whole number of different entities are producing that, which is a really good thing, but where do we need to go from here?

Mr. Burel. Thank you, sir. I think that we are short in almost every area of PPE, both in the medical field and for the public who might want access to those kind of, say, N95 masks.

I think what we have got to do is find a way to invest better in onshoring or nearshoring some of that work. Most of that is not manufactured in the United States anymore. And there are a lot of manufacturers that want to get into this business and stay in this business, not just to respond to a DPA. So I think that we need to continue to invest. We need to encourage those manufacturers after this event ends to increase

their capability, to make better quality products, to make products faster.

Mr. Upton. Thank you.

Governor Leavitt, as you well know, our committee and most of the members here, you will remember that we worked in such a bipartisan way to get 21st Century Cures done, which really lead to Operation Warp Speed so that we could actually get a vaccine approved within the 10 months. For me, it was obviously very personal, not only with the legislation that Diana DeGette and I worked on together, every member of the this committee, but even more so in my own district, Pfizer's largest production facility is in Portage, Michigan, and it was so exhilarating to see the trucks roll out on that December Sunday morning to distribute with UPS and with FedEx all around the country. But now we are hearing obviously troubling reports, at least in Michigan, a number of counties having to cancel or reschedule second doses of that Pfizer or Moderna vaccine because they are getting differing amounts than what were expected from the State.

FDA's data indicates that the second dose needs to be given about 21 days after the first one; in the case of Pfizer, about 28 days; in the case of those two companies in order to have the proper efficacy. So timing is critical. What steps do we need to take within the supply chain to ensure that the second doses are not foregone, especially in light of the recent decision not to reserve them, knowing that there is a line at virtually every entity of people ready to roll up their sleeve and get vaccinated?

Mr. Leavitt. Well, Mr. Upton, let's remember first of all supply, we have to have a steady supply. Second, could I say coordination and communication between every level of government. This is a coordination and collaboration exercise. And finally, may I say that we have to be persistent in improving continually our process. And that will include our data systems.

I recently had the privilege of getting my first vaccine. I was scheduled for an

appointment to go back for my second. I thought that was a very important step. I know when I am going, and assuming that the supply is there, I will get it. I think we will get better at this as we go and we need to. This needs to be an iteratively improved process with lots of communication between Federal, State, and local governments.

Mr. Upton. The last thing, and I wonder if you can -- knowing that my time is quickly expiring, can you provide us a list of the States that are complying with the IZ, the form that you talked about in your testimony? It is so easy -- you know, I have seen the little cards that people have. Obviously, it is so easy to counterfeit or whatever. I mean, we need a standard form. Whether getting on an airplane or going to a stadium, you would think that there ought to be some device that you can show on your iPhone or some program showing that you were vaccinated, to assure the folks around you and to your family members and others that, in fact, you have had that vaccination.

Mr. Leavitt. Thank you for highlighting that. Yes, we can. I will submit it to you and for the record.

Mr. Upton. Great.

And with that, my time has expired. Thank you, Madam Chair.

Ms. Eshoo. Thank you, Mr. Upton.

It is a pleasure to recognize the gentlewoman from California, my friend, everyone's friend, Ms. Matsui.

Are you unmuted?

Ms. Matsui. I am unmuted now.

Ms. Eshoo. There you are. Five minutes. Thank you.

Ms. Matsui. Thank you very much, Madam Chair, for really calling this important hearing.

And I want to thank all the witnesses. We are learning a lot with you and from

you, so it is very important. Yet the sad thing is we are about to hit 450,000 COVID-19 deaths in this country. And nearly 300,000 Americans over the age of 65 have died from the virus. And that we probably can estimate, by the time we look back on this pandemic, some 250,000 older adults will have died from COVID-19 while living in a nursing home, assisted-living facility, or a group home.

You know, these are people who have died and will continue to die until we improve our response to managing the pandemic for vulnerable older adults and the frontline staff who care for them. And that is really why as co-chair of the House Democratic Caucus Task Force on Aging and Families, along with Jan Schakowsky, I have called on the Biden administration to involve a geriatrician or expert in aging services on the COVID-19 response team. An aging expert, someone with a deep understanding of a long-term care system, will help ensure that moving forward we are really addressing the unique needs of older Americans as we take critical steps to get the virus under control and safely and equitably distribute vaccines, therapies, PPE, and tests.

Now, while the Trump administration left the delivery of most vaccines to the States, officials at Operation Warp Speed pursued a Federal public -- private partnership with chain pharmacies to supply and administer vaccines to long-term care residents and staff. Now, the former HHS Secretary Azar said in mid-December that we could have every nursing home patient vaccinated in the United States by Christmas. The only State that met this mark was West Virginia, which opted out of the Federal program and instead used local pharmacies to administer vaccines.

Now, like many aspects of the vaccine rollout, leveraging the existing network of chain pharmacies like CVS really has worked in some places but not in others.

While I am encouraged by the centralized leadership being taken at the Federal level, it seems like the one-size-fits-all approach to vaccinating long-term care residents

may cause further delays.

Now, Dr. Borio, in your view, what are some of the challenges with one-size-fits-all distribution and that leadership model? And what needs to be done to make the vaccination process more efficient?

Dr. Borio. You know, I think you really -- first of all, I would like to acknowledge that the pharmacy programs have done a tremendous job in preparing for one of the most challenging vaccination components of this challenging program. And, you know, this is not an easy task.

I think that nobody was prepared, for example, for the amount of hesitancy associated with vaccinating the workers in those facilities. The receptivity to the vaccine has been extraordinarily low, given the high-risk population that they serve. There was also issues with informed consent, and I think that they really wanted to make sure that patients, for example, were -- that the vaccinees or their families were comfortable. There is still an investigation of vaccine authorized by the FDA. Investigation is important to make sure that people are comfortable receiving those vaccines.

So these are things that -- I mean, you know, the other member said, you know, we are always going to have a lot of challenges when we launch a new program, and we have picked the most challenging component of this program as the step one of this.

But to answer your question directly, I think it is true, there needs to be a coordination and communication, as Secretary Leavitt says, because there is no such thing as one size fits all. You do need to be able to have Federal leadership and standards, but also tailor it to the needs of the community at the local level.

Ms. Matsui. Absolutely. When you brought up vaccine hesitancy, you know, there is no question that staff are a primary source of transmitting the virus in long-term care facilities. Now I am deeply concerned about the large percentage of long-term care

workers nationwide who are declining to take the COVID-19 vaccine.

Dr. Morita, what needs to be done to better support higher uptake of the vaccine by staff members of nursing homes and assisted living facilities and group homes? And I think I only gave you 25 seconds.

Dr. Morita. I will speak fast. Thank you so much for your question.

Vaccine hesitancy needs to be addressed across the board, and the way that we do that is really -- it is not easy work. It is hard work. It means talking with those who are actually hesitant, understanding what their concerns are, what information do they need, who do they want to hear from to have their questions addressed, because it is not one size fits all for that either. And so really getting into these communities and understanding what are their concerns, and that requires resources.

There are many States and locals who are actually doing that kind of work right now, but they need the dollars to pay the community workers, the trusted voices to engage with the people to address their concerns so that demand increases.

Ms. Matsui. Okay. We have run out of time, and I appreciate it.

And I yield back. And I have got further questions I will submit. Thank you.

Ms. Eshoo. The gentlewoman yields back.

The chair now recognizes the gentleman from Texas, Mr. Burgess, for his 5 minutes of questions.

Mr. Burgess. Thank you.

Secretary Leavitt, it is so good to see you in our committee again. You know, in this committee a year ago, we received a number of briefings from the top people in public health, and one of the things that, of course, people have brought up this morning, it still stands out in my mind, was Dr. Fauci telling us that under the best of circumstances, if absolutely nothing goes wrong, that it would take 18 months to deliver a

vaccine. And he also emphasized that it almost never goes perfectly. But here we are now a year later, not one but two highly effective vaccines, perhaps two more waiting in the wings to rapidly come forward, and really we should celebrate [inaudible] former Chairman Upton that [inaudible] watching my local news show about the trucks leaving. Fred, I thought it was from Kalamazoo. Maybe I was mistaken. But just the emotional response to seeing those trucks leaving the factory with the vaccines on board, I wasn't prepared to be as affected as I was, but the enormous sense of relief and joy at having those vaccines now on the road to get into the arms of people who would now be protected from this terrible virus. It really was a significant moment.

And, you know, I think some credit does goes to the previous administration. They made it a priority. The 18 months with perfectly reasonable in January, February of 2020. Now we know that that timeline can be significantly condensed.

And, Secretary Leavitt, I also -- your reference of your earlier work, and you are right, another thing short of stunning to get the rollout of part D done in the timeframe that you did. And I would remind members of the committee, that was on top of a public health emergency when Hurricane Katrina came ashore Labor Day weekend in 2005. And, in fact, I remember questioning you and Administrator McClellan at the time if it was even possible to go through the rollout of part D while this public health emergency was tearing across the country. And you assured me that it was, and I certainly became a big fan of your administrative capabilities at that time because, clearly, you were correct.

And one of the things I also remember from back then, 2005, I think the Defense Appropriations Bill where you got money for Sanofi to begin manufacturing vaccine in this country. Apparently, vaccines were no longer manufactured in this country, but in the advent of the bird flu, you thought it was important and got those dollars in that

appropriations bill to start that. And the reason that is significant, I mentioned yesterday in our hearing, Sanofi is one of those companies that was in development of its own vaccine. Things didn't go perhaps as they wanted, but they are now partnering with a rival, with Pfizer, to manufacture more vaccine, more of the Pfizer vaccine that has gotten through the FDA approval and shown to be so effective.

So that really brings up the point, one of things that is hindering our getting vaccine into people is the amount of vaccine that is available. So this type of partnering between private companies seems something that could be enormously effective. So I just wondered, Secretary Leavitt, if you had any thoughts on that.

Mr. Leavitt. You properly point out the fact that there has been investment in the vaccine infrastructure for some time now. And may I say that is a very important component. I would point to three other things that have added to this.

One is that we did enter into partnerships, as you have said, and that kind of collaboration is essential in this kind of emergency. The second thing I will mention is that we planted many seeds, knowing that not everything would turn out. And lastly, I will point out that the Federal Government did accept a lot of risk here. That kind of risk could not have been taken by the private sector or any State. Only the Federal Government could do that. And because there was a relentless concentration on delivering those four and many other ingredients, this has been a great success, one that we will have to perpetuate, because I have a feeling that over the course of not just this year, but probably 2 or 3 years, COVID is going to be with us. We are going to see variants. We are going to have to respond with different vaccines. And we have got to get better at this.

Mr. Burgess. Certainly, again, thank you for your long service to our country. And I have a number of other questions, I will submit those for the record.

And I will yield back my time.

Ms. Eshoo. It is a pleasure to recognize the gentlewoman from Florida, Ms. Castor, for your 5 minutes of questions. Unmute.

Ms. Castor. There we are. Thank you, Chairwoman Eshoo and Chairman Pallone, for calling this very important hearing. And congratulations to my good friend Brett Guthrie for serving as ranking member. I look forward to our continued work together. And thanks to the witnesses for your excellent testimony.

It is clear that we must act with urgency on vaccines, on the next generation of diagnostic tests and more, because we have got to get kids back into school safely and folks back to work. And Americans just want to live their lives again.

So my takeaway from the witnesses and your great testimony is you believe Congress must act with urgency and with greater specificity in support for our partners all across the country. I think that means that we must ramp up the equitable vaccine distribution. And thank goodness President Biden now has a robust plan in the American Rescue Plan. And then we have got to improve our public health infrastructure. It needs modernization, especially accurate and timely reporting of data. That transparent information allows our scientists and community leaders, everyone, to make the right decisions and ensure we are acting in an equitable way.

This has been a real problem. I mean, just in my home State of Florida, it has been very difficult at times to get transparent information simply on mortality rates, on what is happening in our skilled nursing centers, what is happening with testing.

So, Dr. Morita, you have a very unique perspective on this as the former chief medical officer in Chicago and your work at CDC. In your testimony, you say that an equitable response to the pandemic starts with collecting and reporting all COVID-19 related data by race, ethnicity, and socioeconomic factors. Yet most States don't do

this, and especially with vaccine data, they are not publishing and collecting the data that way. How can we improve our reporting and make sure that States are following through with what they need to do?

Dr. Morita. Thank you for the question. The Robert Wood Johnson Foundation issued some health equity principles early in the pandemic because we recognized that there were disproportionate impacts on communities of color. And the top recommendation that we have is really to have data [inaudible] by race, by age, by ethnicities, by socioeconomic factors, geography, all those things. That work, though, requires dedicated resources and higher education. And so the problem that we have had with past response is that the same people that were doing testing, contact tracing, arranging the -- investigating the outbreaks, were also asked to ramp up the vaccination systems. And some of the systems weren't equipped. They actually lacked this kind of information. So there is resources needed to support enhancement of our systems and also manpower to actually collect that information and then analyze the information, because it is not enough just to have the information. There have to be people to actually analyze the data, to generate reports, develop the systems to reporting consistently.

So all these things are critical. They need to be prioritized so that actually the work that is being done can be guided by what we find. When we see there are populations or communities that are underserved, we can actually get the resources to them, meet their needs, provide the services needed so they can actually have access to the vaccines just as much as everybody else.

Ms. Castor. And, Dr. Borio, you have made similar recommendations. And, Governor Leavitt, I heard you loud and clear as well on your specific recommendations.

I introduced the Ensuring Transparent Honest Information on COVID Act, or the

ETHIC Act, last Congress with Reps Underwood and Haaland. We are going to be updating that and introducing it soon to make sure that we are providing that specific direction to States in the next emergency aid package.

And, Dr. Borio, it is hard to believe that here we are a year later, and we do not have a true national testing strategy. I would have thought by now that our diagnostic testing capacity with public and private labs would be state of the art, but the prior administration just did not prioritize this. What else needs to happen in the next emergency aid package to ensure that we have the most robust diagnostic testing system?

Dr. Borio. So as I recommended in my written testimony, I would like to see the CDC working alongside sister agencies, the FDA, HHS and others, to be able to provide much more clear guidance for testing in the different types of settings.

What are the options, for example, for an employer? What are the options for workplace? What are the options for travelers? What are the options for higher education? Right now, there are so many different types of strategies being deployed in a very ad hoc manner. We don't have that much data about, you know, which strategy is the most efficient. And, again, the supply of testing is just not something that can grow infinitely. We have a finite supply, we need to be able to optimize what we have through a really public health oriented guidance.

Ms. Eshoo. The gentlewoman's time has expired.

The chair now recognizes the gentleman from Virginia, Mr. Griffith, for your 5 minutes of questions.

Mr. Griffith. Thank you very much, Madam Chair. And I am going to --

Ms. Eshoo. Good to see you. Speak up.

Mr. Griffith. Okay. I will try to speak up a little bit. I have this mask on.

There you go.

I am going to tag team with your questions earlier, Madam Chair, and, Mr. Burel, if you will help me out here. I agree with Ms. Eshoo that, you know, there were some suppliers in the country for PPE and that we need to have more domestic production. That being said, I need help and the committee needs help. We need to figure out, assuming that we can't bring all the production necessary for the United States back to the United States, what percentage -- and you may not have an answer today, but I want us to work on this going forward -- what percentage of our Nation's needs when it comes to, whether it be PPE or, as Dr. Borio mentioned, filters dealing with the manufacturing of vaccinations, et cetera, what percentage of that needs to be in the United States?

And then as a sidebar to that, we were having the discussion here that, you know, we had that problem when Puerto Rico got hit by the storms, and what percentage of that then needs to be split up so that we are not being hit by various storms? I mean, different parts of the country have different issues, but it would seem to me we need to make sure that we have a diversity of geographic locations. But I do think on these important matters we need to have production in the United States.

Knowing that we probably could have done better before, what can we do better going forward? And what percentage is necessary to be on our home territory, whether it be one of our territories, like Puerto Rico or Micronesia, or wherever it is, where we can get our hands on it when we need it?

Mr. Burel. Sir, I appreciate the question. I am going to have to come back to you with some thoughts on percentages or possibly other measures we might consider about what should be manufactured here. But I think it is absolutely vital. We have made efforts to invest in the vaccine infrastructure, as Governor Leavitt discussed. I think we have got to make investments at the Federal level in the PPE infrastructure,

because regardless of what pandemic event hits us again in the future, and I am sure there will be another, we have got to be better prepared. So we need to encourage people to enter the PPE market that are not currently in it. We need to encourage those that currently manufacture PPE to do that. And I agree with your discussion of, for example, the small saline bags that were manufactured only in Puerto Rico. We cannot limit ourselves to a single manufacturer or a single location geographically. We must have diversity.

Mr. Griffith. Well, I appreciate that.

And let me say that in relationship to the PPE infrastructure, earlier this year, we had a hearing where we had some of those people in. In fact, it must have been pretty early because I think we were live here in the room. And they said if the Federal Government would just issue contracts to purchase it, we don't necessarily need to buy the equipment. But if we said we were going to buy a certain amount of PPE, they felt like they could ramp up much easier. And in my district, several folks came forward. I know one is going to continue long term, I don't know if the others are, to make masks and to make other PPE, and they are ready to go. But if the market were to suddenly drop out, we would be back in the same boat we were in before. So I think that that is important.

Do you agree with that, Mr. Burel?

Mr. Burel. Sir, I do agree with that. I think that once we create more market, more manufacturing capability for these things in the United States, we have got to continue to support that market or the bottom will drop out again and we will have wasted investment. So my concern here is that we have a diversity of suppliers, we bring other people into the pipeline.

And one thing I would encourage your thoughts about are it is difficult to hold this

PPE because it is large. It occupies a lot of space. Maybe we need to hold bridge stocks and then have capability to turn directly, immediately to domestic manufacturers to bring in rapid surge directly to where the government would direct or directly to fill behind government needs.

Mr. Griffith. And, Dr. Borio, I want to get one more question to Mr. Burel, but if you could think about it and we might ask you to answer that question after this hearing because my time is almost up.

Mr. Burel, you specifically mentioned in your testimony the need to engage all commercial healthcare distributors and manufacturers. You reference the single vaccine distributor. Are you aware of other situations in which additional parties stand ready to partner with Federal, State and local governments?

Mr. Burel. Sir, I believe that most parties involved in the typical day-to-day healthcare supply chain are very much prepared to partner with the Federal Government. We have a system that operates every day. And if we make ourselves take advantage of all aspects of that everyday operating planning and distribution system, I think we will have a better, stronger result going forward. As we see vaccines increase --

Mr. Griffith. I have to cut you off, because I do want to say one last thing and my time is just out.

Dr. Borio, you always are so good to give us testimony in this committee and I always appreciate it. So I apologize I didn't get to you live today, but I would love to see some of your thoughts after this meeting is over. Thank you so much.

And, Madam Chair, I yield back.

Ms. Eshoo. I thank the gentleman. And I just want to say I look forward to working with you on the supply chain. In my book, it should be all American. This business of maybe we should do this and then be dependent on so-and-so, I just -- excuse

the expression, I just don't buy that.

Mr. Griffith. We certainly need to have a big percentage of it here.

Ms. Eshoo. Exactly, exactly. We guaranteed a market for the pharmaceutical companies to buy vaccines. So if we can do that, we can certainly promise a market for American manufacturers of American products to be used by the American people in their hour of need. So thank you very much.

I now recognize the gentleman from Vermont, Mr. Welch, for his 5 minutes of questions.

Mr. Welch. Thank you, Madam Chair. And I agree with all your comments. And, Mr. Guthrie, congratulations to you as well. I really look forward to working together to get some things done here.

You know, the last administration, I think, could be credited with doing a good job in public-private partnerships to create the vaccines. The challenge, however, is how do you get them injected into the arms of all Americans. And there really wasn't a plan.

Vermont is doing pretty well, but it is very rural and there are lots of folks who are homebound. And in the original package, the Federal Government passed legislation to work with our pharmacies. And we have got like 40,000 pharmacies that are well situated to provide help to rural Americans.

And the question I wanted to ask Mr. Burel and Dr. Morita is, how could we make that plan work better? The two things that our department of health director has said is there has to be predictability on the delivery of the vaccine. And, number two, there has to be better Federal and State coordination.

Mr. Burel, do you have any comments about that?

Mr. Burel. Thank you for the opportunity, sir. I believe that we can rely on our everyday outlets for healthcare delivery that our American citizens are accustomed to

seeing. But I think one of the important things is we must engage the entire supply chain, all distributors who are accustomed dealing with specific clientele across the country who are specifically ready to deliver to their normal clients. I think that we need to, as vaccine supplies increase, make sure that all the distribution capability we have in healthcare in the U.S. is engaged with assuring products are available at all of the outlets that people expect them to be.

Mr. Welch. Well, Dr. Borio, maybe you could follow up on that. And just, you know, this is operational now. We are not talking just general and abstract. This is like the really hard work of systems that are repetitive, reliable and sustainable.

Dr. Morita?

Dr. Morita. Thank you for your question. I completely agree with your health director in that having a predictable aware or knowledge of how much vaccine the health directors can actually anticipate on a regular basis really helps to do the kind of planning and operational work that you are talking about. That was part of the challenge with some of the cancellations that people were experiencing early on is because the health directors weren't actually hearing about the supply of vaccines, except for a couple of days before the vaccine actually arrived.

So what we are hearing now is the health directors are actually getting 3 weeks' notice. So they actually can predict and plan how to schedule their clinics, how to hire people, where to locate their clinics, how much vaccine can they give to their healthcare providers. So this predictability is really critical.

The other thing is this level of coordination, because as Mr. Burel mentioned, we have a strong infrastructure for delivering healthcare services, vaccines included. But there really does need to be a coordination to understand where does one system work and where does one system not work, because it is not a one size fits all. And so having

this Federal coordination which CDC is overseeing what is working, where is it working well, how do you share those best practices among various jurisdictions is really, really critical to having a successful ramped up system that optimizes all the different ways of delivery of vaccines.

Mr. Welch. Thank you very much.

Madam Chair, I yield back. I appreciate the time of the panel.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize a great Greek American from Florida, Mr. Bilirakis.

Mr. Bilirakis. Thank you very much.

Ms. Eshoo. How are you feeling, Gus?

Mr. Bilirakis. I am doing good. I appreciate it.

Ms. Eshoo. Do you feel better?

Mr. Bilirakis. I am feeling much better. Thank you.

Ms. Eshoo. Good.

Mr. Bilirakis. Thank you for the letter too. I appreciate it very much.

It is great to serve on this committee again in this term. It is a wonderful committee. And I want to congratulate my good friend Brett Guthrie as well for being the ranking member.

I have a couple of questions. The first is for Mr. Burel. I want to follow up on Mr. Griffith's question. Were States and localities properly set up to order and receive shipments from the Strategic National Stockpile? If not, how did that impact the effectiveness of the response for those particular States?

Mr. Burel. Sir, I think one of the things that we need to make sure of going forward is that the Strategic National Stockpile has direct communication with State public health officials. We used to have a strong connection to those so we all

understood what to expect from each other. That kind of got lost somewhere a few years back as priorities changed, money moved away from the Public Health Emergency Preparedness Cooperative Agreements.

We talked to them in the past around flu about allocations per capita, but some of those conversations I think have been broken and we need to reenter those between the SNS and those States so everybody really understands each other well.

Mr. Bilirakis. Absolutely.

Governor Leavitt, I have a question. Tell me a little bit about the availability of therapeutics. You know, I am all for the vaccines, don't get me wrong, but tell me the availability of therapeutics. Where are the challenges that we are facing in administering therapeutics?

Mr. Leavitt. Yes, we have failed to make the robust progress on therapeutics that we have on vaccines. And I think we can learn from that and realize that it requires perpetual investment, that we have got to enter into the same kind of partnerships, and we have got to plant a lot of seeds to make this happen. And as COVID elongates, and I think it is going to, we will I hope go back toward normal, but we are all going to be managing this for a long time, we need more tools. Even vaccines are not such that it guarantees our success. So those would be my suggestions.

Mr. Bilirakis. Thank you, Governor.

Mr. Burel, today's leading manufacturing supply chains often operate just in time instead of the just in case to reduce costs and maximize efficiency. However, this is a dual edge that can present challenges, obviously, in the midst of a pandemic response. As we saw with personal protective equipment, how can supply chains balance resiliency with value moving forward? Again, this is for Mr. Burel.

Mr. Burel. Sure. I like your words of just in case. And I think that what we

can do is, one, we can build stock in the Strategic National Stockpile. We can build stock at State and local levels with Federal assistance to do that. We can encourage manufacturers and distributors to hold some flexible stock for that really bad day that we just went through that we hoped we never would. I think that there are ways to incentivize that, and I would love to think about that and come back to you with further answers.

Mr. Bilirakis. Please do. I would appreciate that very much.

Again for Governor Leavitt, as policymakers consult the data to direct response efforts, where should the goal post be erected -- talking about the -- you know, we have the Super Bowl coming up. Go Bucs. In other words, where should the bulk of our attention and the resources be directed as States reopen? Is it about total confirmed cases, hospitalizations, or deaths? And, again, this is for Governor Leavitt.

Mr. Leavitt. Look, it is a combination of those things. Every one of them, everyone has their own metric they like to watch. But the reality is we have got to take a holistic view of this. But I would like to underscore the point that Julie Morita and others have made today, and that is the need data systems, because we won't get the data if we don't begin to invest in the system.

And might I add, this has been a challenge. And I might suggest also a priority for multiple administrations, and that part of the dilemma isn't that they have not been asking; it is that they haven't been funded. And so I think we need all of those metrics available in readily assessable ways in an integrated, open source fashion that give us the tools we need.

Mr. Bilirakis. Very good.

Thank you, Madam Chair, I appreciate it very much. Take care. And, again, go Bucs, everyone. Kathy agrees with me on that one.

Ms. Eshoo. Well, we are all relieved that you are feeling 100 percent better.

Mr. Bilirakis. Thank you.

Ms. Eshoo. And, Governor Leavitt, I couldn't agree with you more about funding of the public health agencies. They are not in good shape across the country. Some of them have systems. I mean, there are all kinds of levels, and I think the grades that we would attach to them, many of them are not where they should be in the second decade of the 21st century. So I think that is a point that members need to -- that we all need to take seriously, because we are not going to get beyond this lack of reporting of the kind of data that we need unless we have agencies that have the systems that are necessary to collect them. So thank you.

I now call on the gentleman from Oregon, a wonderful member of our subcommittee, Mr. Schrader, for your 5 minutes of questions. You need to unmute.

RPTR MARTIN

EDTR ROSEN

[1:00 p.m.]

Mr. Schrader. All right. It takes a while.

I agree with you on the public health piece, Madam Chair, 100 percent. It is time for us to start to incentivize public health at the State and local level, certain -- we should have some base funding that we put out there and then, frankly, use the database collection as an incentive to have local governments and States report good data on vaccines and other critical and public health pieces of information and they get more money. I mean, that is the way the system should work.

I will add my voice a little bit to the whole PPE situation. I am not sure I think it all has to be made in America to start with, but we have to have at least a base level made in America to make it worthwhile for American manufactures to be online and have that capacity.

And to Congressman Griffith's point, I think we need to put a panel together, a board, if you will, of manufacturers, public health officials, and other certified smart folks, to come up with what is a plan for ongoing manufacturing in this country. We have had testimony that it is mostly just a lack of having the ability to keep manufacturing going. So we should invest in that, I think.

And I am curious, Mr. Burel, you know, very specifically, what can we do to encourage, in this capitalist system of ours, the manufacturers to set up and continue to manufacture? I assume it has to do with churning over the stockpiles at a certain rate that it makes sense for manufacturers, making sure there is a percentage that providers of their gear, of their PPE gear that has to be coming from America. What specific

recommendations would you have for us going forward?

Mr. Burel. So I think there are several things. I would like to come back with you for a longer list, but a couple of things immediately come to mind.

The first is we know this are people who want to enter this market. There are people who have already taken risks to enter this market. We need to support them, whether that be through some sort of subsidy program, possibly investing in a joint venture of certain lines with them, guarantees of certain sales into the Federal Government, so that they can continue to manufacture, but not only manufacture, improve their ability to manufacture.

What we have found is the use of machinery made to do this are made offshore as well. So we need to invest in how to make our own machines.

I would like to come back with you with a more fulsome list, if that would be possible.

Mr. Schrader. That is great. That is very, very helpful and totally on point.

Dr. Borio --

Mr. Leavitt. Mr. Schrader, would you be open to me commenting on this?

Mr. Schrader. Please.

Mr. Leavitt. This points, I think, to a very important principle, and it is that there are certain expenditures that are just a cost of doing business for a country to be safe, and we make those expenditures in the area of defense every year. But we now find that there are enemies that are substantially more debilitating than anything we face as far as hostile opponents. And we need to invest not just in PPE and vaccines, but in readiness every year as a matter of national security.

Mr. Schrader. I would totally agree. And as the chair and the committee knows, active ingredients are largely manufactured in China and India for

pharmaceuticals, and we need to bring some of that back as another discussion.

Dr. Borio, what about treatment? I mean, there are a lot of different treatment options hawked out there, some more realistic and successful than others. I think a lot of folks are facing difficulties accessing treatment and knowing what treatments are peer-reviewed and actually going to be successful.

What can we do to make sure that folks are getting the right information regarding effective treatments?

Dr. Borio. Thank you for the question. It is indeed the wild west out there.

I have to say that in 2014, the U.S., the U.S. Government led the way in the conduct of very rigorous clinical trials that were very effective and very fast in West Africa during the outbreak, when the rest of the world did not think it was possible. We did the same thing in 2017 in the Democratic Republic of the Congo in the middle of conflict. We actually did clinical studies of vaccines and therapeutics. And here in the U.S., we had a proliferation of trials being conducted that did not meet standards, that did not have any hope for giving us really interpretable data that we need to be able to inform patient care.

We do need to establish a national infrastructure that can be used in peacetime for studying infectious diseases, but also that can rapidly be able to evaluate products quickly, but in a scientifically valid manner, similar to what the U.K. has done with recovery. And it is not too late to start. We need to do this today, because there is so many promising therapies out there, and we just do not want to waste more time in tiny little studies that are not going to help us get information we need to confidently use these products and ramp up supplies and really go the extra mile to make sure that that we can deliver them. We need data to make decisions in those investments.

Mr. Schrader. Very good. Thank you so much.

And I yield back, Madam Chair.

Ms. Eshoo. I thank the gentleman.

It is a pleasure to recognize the gentleman from Indiana, Dr. Bucshon, for his 5 minutes of questions.

Mr. Bucshon. Thank you, Madam Chairwoman.

And, Dr. Morita, I just want to touch on something. In your testimony, you talked about the equitable distribution of vaccines, and I represent a rural America area, which is 98 percent White. But we have a lot of the same challenges in my rural counties that we do in inner cities, which, in certain areas of the cities, are mostly African American.

It is a complicated process to register a vaccine, and what I want to talk about is, do you have data to back up the premise that currently there are people out there in our States that are purposely not distributing vaccines equitably to communities of color? Because if that is true, I was a physician with -- that is an appalling and unacceptable situation. Or is it because of the difficulty that I have in rural America, in actually accessing the vaccines that have been distributed? I know that is a distinction, but it is very important that we understand that.

Can you comment on that?

Dr. Morita. Thank you, Dr. Bucshon.

That is a critical distinction to make. I did not mean to suggest that there are people that are withholding actively the vaccine from communities of color. My concern is --

Mr. Bucshon. Yeah, I didn't think that you meant that, but I wanted to clarify that because, as a physician, it would just be an appalling and shocking thing if people were doing that.

Dr. Morita. What you described, though, in terms of the challenges of rural communities in terms of accessing the vaccine, are still the same in some of our inner cities, challenges they have in terms of making appointments, making it on time to the places as well. So it is really -- the challenges are very similar so the systems in both rural communities, as well as in urban areas, really need to be overcome.

Mr. Bucshon. Yeah, and we need to do better, no doubt about that. Thank you for that.

And, Dr. Borio, in your testimony, you speak at length on testing and warning that we are still not meeting the capacity and rapid response that we need in order to limit the spread of COVID-19 most effectively. I know some of this has been touched upon, but increasing our testing capacity is something I have been working on since the onset of the pandemic. When I heard from my constituents, they are unable to access the test, and even then -- even when they are symptomatic, and then once they were able to find a test, they had to wait 7 to 12 days. And let me tell you, in certain areas that has not changed.

And while our testing has come leaps and bounds since March, we still are not where we need to be. Turnaround times have improved for some, but in rural parts of the country, which I represent, I continue to hear from my constituents that the turnaround times are long. And, in fact, nearly 20 percent of U.S. counties lack a single testing site that administers for COVID-19.

And of last fall, nearly 40 percent of our public health labs still lacked access to a single high throughput testing platform.

If we can increase our capacity and have more rapid test results, it will continue -- if we can't do that, it will continue to make it difficult for us to limit the spread. That is why today, my colleague and I, Diana DeGette, will be reintroducing the

Access for Test Act, which would aid our public health labs in acquiring high throughput platforms and hospitals and doctors and pharmacists in also acquiring these tests. I think we have already touched on our lack of funding for public health.

Dr. Borio, could you speak more again to the need our country still has for greater testing capacity and more rapid results, and how arming our public health labs with more rapid high throughput testing platforms and supplying our doctors and hospitals with more point-of-care tests might achieve that goal, and better prepare us for the days ahead with variants now making their way across our borders?

Dr. Borio. Sure. So, you know, clearly, testing is critical for us to be able to know what are we dealing with and to provide the appropriate patient care and public health interventions.

But let me go and make a link that may not be so evident. You know, we have these monoclonal antibodies that have been authorized by the FDA based on very limited data. Initially they were designed, or hoped that they would be very effective in treating patients who were sick with COVID. It turns out they don't work very well then. We have to give them very early.

Now, if patients cannot access testing when they are sick, the delay in the results, they will miss the opportunity to be able to access the therapeutics that need to begin very early on. So you see how really difficult it is to break this into very discrete systems, because it is really about the patient, and the patient needs all of this to work --

Mr. Bucshon. Yes.

Dr. Borio. -- they can have some good outcomes.

Mr. Bucshon. Yeah. I mean, long turnaround times just are not acceptable. I mean, you need to be able to get a result the same day, especially, like you said, if you have early symptoms, and it takes you out of the window of getting these therapeutics,

these antibody therapeutics, if you can't get your test results for 4 or 5 days, and then you get really sick, and then you are out of the window where maybe you could have been helped and prevented hospitalization.

So thanks for that answer. And, Madam Chairwoman, my time has expired. I yield back.

Ms. Eshoo. Thank you, Doctor.

I would just add that there is $50 billion in this plan of the administration that will be coming before us, $50 billion, with a B, and $3 billion relative to the therapeutics that you were just asking about, which are really so important, because time has gone by, but we have not really developed what needs to be developed there. So I just wanted to add that to -- add that layer of money on the issues that we are talking about.

It is a pleasure to recognize a good friend, a wonderful member of our subcommittee, the gentleman from California, Mr. Cardenas, for his 5 minutes of questions.

Mr. Cardenas. Thank you very much, Madam Chair Eshoo. And also, I am looking forward to working with you, Mr. Ranking Member Guthrie, and all the members of the committee.

Four hundred thousand lives have been taken by COVID-19 in America. Tens of millions of Americans have been affected. I personally believe it didn't have to come to this. The numbers are too high. We are the greatest country on the planet, and when it comes to research, when it comes to development, when it comes to being able to step up when the country or the world is faced with, whether it be a pandemic or something that threatens the lives of human beings across the planet.

One of the things that I would like to report, put on the record, is President Biden met with some of us this morning, and this morning he, once again, reassured us that, as

the President, he is committed to provide every resource that our country can provide to save American lives and to reignite our economy.

And one of our presenters today, I quote, said a trusted source of truth, that is what people are looking for. And I believe in this current Biden administration, we are going to get that.

I also want to point out that vaccinations need to be recorded and reported as some of our witnesses have mentioned, and also when it comes to details as to who is getting the vaccination and some of the background information, because everybody knows, especially if you are a scientist, if you believe in science and you believe in progress, information is critical, and accurate information is important. And, again, I believe that we are going to have more of that going forward.

Also, I would like to point out that it is not enough, in my opinion, to just make sure that we got a vaccination to the market and available in record time. That is a feat, and it is phenomenal, and I am sure everybody applauds that. But I think about it when I grew up in a family where my mother and father had 11 children, and my mother used to serve 13 of us every single day. She didn't just put the food on the stove and leave it there and say, Come get it and find your own plate or find your own utensils and figure out how you are going to put it in your mouths.

No, no. She went the whole way. She went ahead and served it. She went ahead and provided everything that we needed to make sure that we got that nourishment every single day for decades.

And yet, at the same time, I personally am disappointed that the greatest Federal Government on the planet just decided to focus on a few things, and really allowed everybody to be to their own devices without the critical support that our Federal Government has proven that we are amazing at.

So with that, I would like to ask Dr. Morita, do you think there is a risk in the United States investing too little today in going forward, or should we invest as much as the science requires us to?

Dr. Morita. Thank you for sharing your story with us.

This is the biggest public health emergency we have experienced in our lifetimes. And the resources that are needed to respond to this public health emergency are large. And so, as much money that went into creating and supporting development and manufacturing a vaccine, also there needs to be a similar amount of resource and support given to assure the delivery of the vaccine into all Americans throughout the United States. And we recognize that some of the systems that are in place aren't meant --

[Audio malfunction.]

Mr. Cardenas. I am sorry, I think you cut off a bit.

I would also like to ask Dr. Borio the same question, but I would also like to insert that my father stayed married to my mother for 48 years. So that partnership, it wasn't just my mother. It was also somebody going to work every single day, 6 days a week, for decades to make sure that that partnership could provide that food on the table.

Dr. Borio, a similar question to you as far as -- let me get a little bit more specific. If we don't include good and robust appropriate funding for State and local governments and our local providers, would we be able to address this pandemic properly if we don't include that component in the next tranche of support legislation?

Dr. Borio. Clearly, funding it underpins a lot of the activities. So I can't say that we can respond adequately without the resources. As Governor Leavitt just mentioned, you know, there is a cost of doing business to be able to keep our citizens safe and -- but, I think I would go beyond that, which is there is a need at this point to provide more direct technical assistance as well because of the chronic underfunding that has existed

over the years.

So each locality has different needs. Some funding is all they need. Others will require a lot more of a hands-on approach to be able to get us to the other side of this crisis.

Mr. Cardenas. And when we don't do that, the people who suffer the most are the people who had lacked before the pandemic hit. So thank you very much. My time has expired, and I yield back.

Thank you, Madam Chair.

Ms. Eshoo. Thank you, Mr. Cardenas.

I would say God bless your mother. Imagine the work that woman did.

You didn't mention who cleaned up. Maybe -- hopefully most of the kids did after all the work she did.

Mr. Cardenas. Yes. Yes, we all had chores. Thank you very much, Madam Chairwoman.

Ms. Eshoo. God love her. God bless the mothers.

It is a pleasure to recognize the gentleman from North Carolina, Mr. Hudson, for your 5 minutes of questions.

Mr. Hudson. Thank you, Madam Chair. Thank you for holding this very important hearing. I also want to congratulate my colleague, Mr. Guthrie, on taking over as ranking member here in this first hearing. I look forward to working with both of you as we move forward.

It is no secret Washington is sharply divided, but this committee must focus on the areas where we can work together. Today, I have seen a lot of finger pointing, so I must remind my colleagues that finger pointing and assigning blame gets us nowhere. We need to focus on solution.

From what I hear back home, our immediate priorities must be increasing our manufacturing capacity for vaccines and creating better systems of coordination for vaccine distribution.

If we had held this hearing a year ago and an expert witness told us we would not have one but two vaccines and over 20 million Americans vaccinated at this time, they would have been laughed out of the room. Thanks to President Donald Trump's Operation Warp Speed, we have two vaccines approved, hundreds of millions of doses manufactured and more promising candidates in the pipeline.

In fact, despite all of the partisan sniping today, President Biden inherited from President Trump a million vaccines per day. President Biden came into office saying he had a better plan to end the COVID-19 pandemic, and promising better vaccine distributor. I am pleased this has been a priority for the President, but we are eagerly waiting to see what he will do differently than the Trump plan. I am eager to work with President Biden to get vaccines in the arms of my constituents.

And there is much room for improvement. We need every entity, from the Federal Government to the States, down to the individual facilities that are administering these tests talking to each other and coordinating vaccine supply. As an example, my governor told me he finds out how many vaccines he is going to get less than a week before. I learned this morning that a new system is being stood up to allow 3-week windows in the coming doses, which is good, but I fear may not be good enough.

Another example is a facility in my district declined to receive the vaccine they were offered this week, while another facility in the same large suburban county has a 7,000-person waiting list for the vaccine. This same county did not receive any doses of vaccine for the 2 weeks prior. There is simply not enough coordination to this effort yet, but I have faith we can get there.

Governor Leavitt, given your extraordinary experience as a governor and Secretary of Health & Human Services, how do you recommend increasing coordination among the many entities responsible for vaccine distribution, the facilities, the counties, the States, and the Federal Government?

Mr. Leavitt. Mr. Hudson, earlier I spoke of my experience rolling out Medicare part D, where we had a much lesser challenge, but it was 45 million people in a very short time. In the weeks prior to that, I spent a lot of time as Secretary going from community to community, drawing them together, Federal, State, local, civil society, and other aspects, churches, schools, and saying to them, We have to collaboratively work together to make this happen. And that is what it is going to take to make this happen, collaborative action among all levels. And if we do, we can do better, and over time we will get better.

Mr. Hudson. I am sorry I muted myself, but I think you are exactly right, Mr. Secretary.

And I would just say, Madam Chair, I think this committee could look at ways that we can promote better coordination in the communities like that. We, as individual Members of Congress, could play a role in this. In my State, I have got a Democratic governor, I am a Republican Member of Congress, but we have worked very closely together. You know, we have had issues, but we have tried to resolve them together, not in the media. You know, I think that is the model.

I think that is what we as a committee ought to be looking at is how we can help with this coordination problem, because there are people out there who desperately want this vaccine, and there is plenty -- I wouldn't say plenty, but there is a lot of vaccine out there. We need to make sure it is getting to the right places.

So I appreciate the testimony from you, Mr. Secretary. And, Madam Chair, I

hope this will be a good starting point for us to work together on this.

With that, I will yield back to you.

Ms. Eshoo. I very much appreciate the comments of the gentleman, and let's put our heads together about how best to do that. Sometimes -- my grandmother used to say the most uncommon of the senses is common sense. So I think that we can make some real headway together. And I sincerely appreciate what you said.

It is a pleasure now to recognize the doctor from California, Dr. Ruiz, for 5 minutes for your questions.

How are you feeling, number one?

Mr. Ruiz. I am feeling much better. Thank you for asking. I am --

Ms. Eshoo. But you are not all better yet? You still have a ways?

Mr. Ruiz. Not all better. I am still at home. I still have some of those long lingering symptoms, but I am much better.

Ms. Eshoo. Well, get all better fast. We need you.

Mr. Ruiz. Thank you, thank you. Thank you, Madam Chair.

Ms. Eshoo. Get your shots. Listen to your elder.

You are recognized.

Mr. Ruiz. Thank you, Madam Chair. Thank you for holding this very important hearing.

Large vaccination centers serve an important purpose, and they are good for getting large numbers of people vaccinated in a short period of time. And sites like that work for someone who has a computer to sign up for an appointment, a car to get there, and a job with flexibility that allows them to wait hours to receive the vaccine.

But those are not useful for everyone, like high-risk farm workers and other essential workers who are working for and also high risk of getting infected from COVID.

I know this from personal experience as a physician. Very early on in this pandemic, I have been coordinating and organizing testing outreach for the homeless, as well as farm workers, in trailer parks, churches, school areas, and so, I have had a really up close and personal interaction and have heard their stories, their concerns, their difficulties.

And many don't have internet to make an appointment. They don't have hours to spend on a phone trying to reserve their slot. They don't have transportation to get to the vaccination site, let alone spending hours waiting to receive the vaccine. And they don't have information in their own language to help them navigate the system.

So what we are doing now is just not working, and it is disproportionately harming underserved populations and communities of color.

A recent Kaiser Family Foundation analysis found that in Mississippi, Black people account for 15 percent of the vaccinations while accounting for 42 percent of the deaths. In Nebraska, 4 percent of vaccinations are to Hispanic individuals, even though they make up 23 percent of the cases. So this is not only a moral failure, this is prolonging the pandemic.

We need a science-based public health approach that serves the hard-to-reach communities, and we can't simply rely on our broken healthcare system that has produced the disparities in infections and deaths due to COVID to begin with to address equity. This means making better use of local physician offices and FQHCs. By and large, physician offices, outside of large group practices, have been left out of the effort to vaccinate patients that has heightened challenges, particularly in communities of color where vaccine hesitancy remains high. People trust their doctor, and they must play a critical role in addressing issues of access and hesitancy. According to a recent Harris Poll, the majority of Americans would prefer to get their shot in their family's doctor's

office and less than a quarter Americans want to be vaccinated at special sites built to administer the vaccine.

Activating primary care and vaccination efforts will open up thousands of access points providing broader reach and better accessibility. And FQHCs, the sites that are there to serve the very communities we are trying to reach, have been massively underutilized during this vaccination process. And they are ready. They just don't have the vaccines and resources to activate their plans.

We need to provide our FQHCs with vaccines and the resources to administer them both in their clinics and out in the community. We need to provide funding for mobile clinics. We need to provide funding for promotoras and the community health workers, or for providers to take vaccines directly to the people, like this past Monday where I joined a collaborative of growers, nonprofits, and public health officials to literally go into the fields to talk to the farm workers about the safety and efficacy of the vaccine, and then inoculate them on the spot. If we don't give them the resources to carry out a vaccination plan, it won't work, and we are seeing that play out now.

The Trump administration told States and counties to develop their own distribution plans, but left them no resources to do it. States, county, and travel budgets are already strapped from this pandemic. They need more resources if we expect them to do this right.

So I urge this committee as we move forward in this reconciliation process to make this a priority.

Dr. Morita, let's talk about FQHCs as a source of access point for vaccinating our hard-to-reach areas, rather -- and how could FQHCs play an important role? And do you foresee any barriers for them that we need to address?

Dr. Morita. Thank you so much, Congressman.

The federally qualified health centers played a major role in Chicago's H1N1 response because they are so well connected to our hard-to-reach communities. They are used to providing the social services, as well as they are the trusted messengers in sources of information for those communities. I think that can play a critical role as we are trying to develop a more equitable distribution system.

Mr. Ruiz. What were the barriers that you had to address with FQHCs so we can learn from those?

Dr. Morita. The barriers were really resources and adequate staffing, adequate vaccine, adequate -- just compensation for the work that was actually being done. So in order for those FQHCs to be able to provide the services, they really need the resources and support to get the work done. They are fully capable of doing it. They just need resources to ramp up the services they actually provide.

Mr. Ruiz. Thank you very much.

Ms. Eshoo. Does the gentleman yield back?

Mr. Ruiz. Yes.

Mr. Leavitt. Madam Chair, this is Mike Leavitt. Would you allow me 20 seconds to say and echo the community health center comment?

Ms. Eshoo. I would be glad to with the, I think, graciousness of the members. Go ahead, Governor.

Mr. Leavitt. As a former Secretary of Health, and, I might add, governor, I experienced directly and firsthand the importance of community health centers, and it is evident to me that they have to be a part of being able to solve the equity issues here. And I could break into song longer, but you have been gracious to allow what I have.

Thank you.

Ms. Eshoo. Governor, on that, there is full support -- first of all, full

understanding and full support from both sides of the aisle in community health centers, and Congress has increased funding for community health centers, I think really quite exponentially, so they are -- you are absolutely right, we agree with you. But we want you to know where we all are and that, as they say, it is preaching to the choir because, thank God, all of the members have a deep appreciation of them.

It is now a pleasure to recognize Mr. Dunn from Florida, and it is great to have you on our committee.

Mr. Dunn. Thank you very much, Chairwoman Eshoo. It is an honor to join you on this committee, and I certainly look forward to the many hard tasks that we have ahead of us.

I appreciate the opportunity today to discuss ideas relating to ramping up vaccine distribution testing and ensuring America as a robust medical response to this and to future pandemics.

As we pass one year from the date that the Trump administration declared a public health emergency, I would like to extend my sincere condolences to those who have lost loved ones to the virus. I also extend my thanks to all of the healthcare heroes who have risked everything to help us all through this emergency.

As COVID-19 began to spread in America last year, the Trump administration got to work implementing timely travel restrictions, launching the active partnership and Operation Warp Speed initiative to enhance agency coordination and, more importantly, to bring private industry ideas and capabilities to the Federal response. The pace at which Pfizer and Moderna, J&J and others, who have developed their vaccines, is truly unprecedented, and I commend the administration's actions for the fastest vaccine development in history.

As States ramp up their vaccine distribution capabilities, they must also continue

to employ robust diagnostics and, importantly, we have to continue to evaluate available therapeutics, that is to say, treatments for COVID-19. We also have to turn the lessons we have learned into action when it comes to supply chain challenges, all the way from production to distribution.

Dr. Borio, we are hearing about the different variants of COVID-19 and the challenges that they may present us with. Do you agree that the efforts to identify new and existing therapeutics are an important piece of our arsenal to combat COVID and epidemics in general?

Dr. Borio. I do. Dr. Dunn, I mentioned in my --

Mr. Dunn. You did.

Mr. Borio. Yeah, I think it is a very critical component. I mean, I think we know that vaccines -- in public health measures, vaccines are the most important tools to deal with pandemics, the contagious disease we are facing today, but we also need treatments to be able to take care of patients who are ill.

Mr. Dunn. So I like the vaccines for the specific, but I was thinking here more broad, about the broad-spectrum therapeutics, which should enjoy activity against many of the mutations as well as the original virus that we are combating. If you will forgive me, I am going to move on simply because the time is so short.

Governor Leavitt, in your testimony, you stress the importance of preparing what lies ahead, especially as it relates to ensuring the manufacture of vaccines and other epidemic-specific products can be sustained.

In December in a supplemental appropriations bill, Congress authorized $500 billion for domestic manufacturing capabilities. How briefly would you spend that money?

Mr. Leavitt. Briefly, that is a hard question to answer.

Mr. Dunn. $500 billion, just blow through it like that, right?

Mr. Leavitt. Well, I think we need to acknowledge what got us here in such a short time. We planted multiple seeds. We need to keep doing that.

The second is that we entered into partnerships. This was not just about the government. It was about the government and private sector, and we brought people in the private sector together. We need to continue to do it in this setting in the supply chain matters. And we invested in new technologies along the way, and I commented at various times through this hearing about the need for that to be an ongoing process, not simply when we are in the midst of a pandemic or another public health emergency.

Mr. Dunn. I could not agree with you more.

I had -- was party to doing that when I worked in the Army with USAMRIID, the Institute of Infectious Diseases, so I am on your side on that. You are going to get more -- or hear more from me about this after today.

And, Mr. Burel, you are, too. I am going to be reaching out to you on some ideas of what we should be spending that $500 billion on. I have my own ideas. I want to hear yours.

In the short time left, Governor Leavitt, you also recommended communication -- you know what, I am going to skip to my last question, because I care about that more. What advice do you offer the Federal Government to facilitate the use of future and currently available therapies for COVID-19? For example, monoclonal antibodies, you know, they are available. They are out there. They are approved. There are many providers who would have the -- do have the ability and willingness to set up outpatient infusion sites. What can we do to get this out to the people and other therapies?

Mr. Leavitt. Well, it happened with vaccines because we put the emphasis on it

because we put the dollars behind it, and because we operated in parallel -- we operated rather in parallel on certain parts of the process as opposed to requiring it at every case that it be sequential. That same formula will work in producing and enhancing our supply there.

Mr. Dunn. Our time has expired. I do think that we could use monoclonal antibodies more, in more cases effectively.

And thank you very much, Madam Chair. Certainly a pleasure to join your committee.

I yield back.

Ms. Eshoo. It is wonderful to have you with us, Mr. Dunn. I agree with you on the concern that you raised, and I think it is worth repeating again that in this recovery act, that there is -- as the Governor said, we put money behind the development of vaccines. There is $3 billion to develop exactly what you reference.

So thank you and welcome again to the committee.

Pleasure to recognize the gentlewoman from Michigan, Mrs. Dingell.

Mrs. Dingell. Thank you, Madam Chair, and to Ranking Member Guthrie, it is great to be here for the first hearing of this year to talk about a subject that means so much to all of us and our constituents.

And I think before I dig into what I really want to talk about, I want to associate myself with many of the comments of my colleagues. But what Dr. Ruiz was saying, I have spent the last -- last Thursday night I had a town hall that if anybody could believe, it was worse than the John Dingell one on affordable care, with people desperate that can't get answers. They feel like they are being deliberately discriminated against. They don't know where to call.

And, you know, we don't have -- we have a national strategy -- we are trying to get

one, to give it to the States. The States are giving it to State and local governments, and there is simply not enough vaccine right now. And there is not a central number to call, and people are -- if you call the hospital, the hospital says, Well, they are now giving it to the public health departments more, and the public health department is sending you someplace else. I was on phone calls with public health departments and hospitals not being on the same page yesterday.

And, quite frankly, members of the African-American community, communities of color, are feeling very isolated.

So I want to talk about that today. This -- you talked about today defining the public health challenges, that we ensure equitable vaccine access for disadvantaged communities addressing vaccine hesitancy and clearly communicating availability for all Americans. And I think we have got to be realistic about what that really means, because we can't get them all in everybody's arms right now.

Dr. Morita, in your testimony, you highlight the need for an equitable response to the COVID-19 pandemic as one of the fundamental principles required to improve distribution. I agree, couldn't agree more.

Yesterday, Dr. Khaldun, who is our chief medical executive in the State of Michigan and has been working this really hard, reiterated that my home State's commitment before -- she said it before the committee, is that no disparity exists in vaccination rates across racial and ethnic groups or by social vulnerability index. However, despite these extensive efforts, we continue to face challenges in Michigan, and across the country with meeting this commitment.

What additional steps should States be taking to address the racial disparities in vaccination rates? Michigan is partnering with local health departments and school-based health centers. Should we be looking at leveraging additional

nontraditional spaces? Is there other outreach that you are seeing that is effective here? We talk about community health centers, but they are not being given the vaccine to even be a place for it to be used. I would welcome your wisdom.

Dr. Morita. Thank you for your questions.

The accessibility of the vaccine is dependent on having the vaccine broadly available in multiple locations. When the vaccine supply is limited, it is really hard to do that, and so, there has to be a closer hold on the vaccine. As supply improves, more and more locations will actually be able to get it.

Currently, what needs to happen, since there is a limited supply, is that the locations need to be strategic, so they are equally accessible to all communities. And, in addition to that, there is effort that is being made to simplify the registration process for people who don't have access to internet, who don't have a car, who have to work during the day and have to access the vaccine later in the night or on weekends.

So, the systems have to be developed in a way that actually help people that are most difficult to reach or most likely to get sick to access the vaccines themselves.

Simultaneously, what needs to be happening as well is work needs to be done within communities to understand what their issues are in terms of concern or hesitancy, because there is an element of hesitancy that exists. And the way to overcome that is really to understand from the community what is happening? What are their questions? What are the concerns? Who do they want to hear from?

There are activities going on right now to support those efforts, but they are just ramping up. To use get out the count, get out the vote in rural-America type of approaches with community members going into their communities because they are trusted voices to really reassure the communities about how to access the vaccine and why they should get the vaccination.

So it is going to have to be a stepwise approach, because we don't have sufficient vaccine for everyone to be vaccinated. But while we have limited supplies, we also have to simultaneously make it available to the communities who are at greatest risk of getting seriously ill and dying.

Mrs. Dingell. And you said, it is a real challenge and there isn't one -- the problem is that no State, no local has one simple process of figuring out who to call. And I think it would be useful if we could figure that out nationwide.

I am out of time.

Dr. Borio. If I may add? I was going to add an observation that may be helpful to keep in mind. Because of the temperature control requirements of these vaccines, the early vaccines, as well as the presentation in multi-dose vials, it does present an additional hurdle to making them available at all of the sites that we would have liked, in addition to the supply constraints, of course. Hopefully this will get better with other vaccines being authorized that are less stringent.

Mrs. Dingell. You know, I think that is true, but in Michigan, we have had fire departments and community health centers actually buy the freezer wanting to be able to do it. They have got -- it is the supply right now. But then those that are able to access the system aren't necessarily some of those that need it the most. It is a real challenge.

Thank you.

Ms. Eshoo. The gentlewoman yields back.

Mrs. Dingell. I do yield back.

Ms. Eshoo. Thank you, Debbie.

It is a pleasure to welcome Mr. Curtis as a new member to our committee, and for his debut of asking his questions.

So welcome, and you are recognized.

Mr. Curtis. Thank you, Madam Chair, Ranking Member Guthrie.

Yes, this is my first Energy and Commerce meeting, and I want you all to know you pass what I call the elevator test, which is if I were to get stuck in an elevator, I would love to be with all of you. I am just really pleased to be on the committee.

I would like to jump in and discuss an issue. At lot of my colleagues, and rightly so -- and, Congresswoman Dingell, I think you did a really good job of emphasizing some of the inequities in our minority communities. Julie Morita talked about inequities in urban neighborhoods.

Governor Leavitt, hello. It is great to have one of my fellow members from Utah on the panel. As you well know, my district in Utah and many of the districts in the country represent vast areas of rural areas. And, if not careful, these areas too are underserved. They bear the burden of poor medical care in many cases, long distances, and, also, have the problem, I think, of being underserved in this.

What is the right way to think about distributing doses in rural areas? You brought up community health centers, and they are helpful, but they are still far and few between in rural places.

And, Julie Morita, if you would jump in after Governor Leavitt and maybe share your perspective on this as well.

Mr. Leavitt. Congressman, let me say, I resonate strongly with many of the things that have been said about the need for us to get vaccines to these areas that are hard to reach, and, like you, I have become very familiar with the dilemmas that happen in rural areas. And I think the first thing to remember is that the infrastructure in urban areas are not available in rural areas; and so, you have to deal with them in unique ways and customize the approach to each one. Without that, we will never be successful.

Dr. Morita. So thank you for your question. I would add into that as well.

The approach that -- I understand the challenges associated with rural communities as well, and mobile units can be used more regularly [audio malfunction] vaccines that are available that don't require the ultra-cold storage or freezer, freezer storage. So I think there is potential for increased access through mobile-unit type of approaches in the future.

I think it is really, again, as Governor Leavitt mentioned, really working with the communities to understand what are the challenges they are actually experiencing so they can inform the solution-making as well because, from an equity perspective, whether it is rural, whether it is urban communities, the communities know their needs best, and hearing from them and listening to them to understand what the solutions are will help to inform a more equitable response overall.

Mr. Curtis. Thank you.

I would love to give the State of Utah a little shout-out here. We are in the top 5 percent in the United States in our distribution, and my congratulations to our new Governor and so many that are doing a great job.

Governor Leavitt, you are unique in that you had experience on the State level and on the Federal level. There seems to be a little clash from time to time about who best handles certain parts of the responsibilities. Some have advocated the Federal Government should have taken over all distribution.

Can you kind of share, from your perspective, what the right marriage is here between Federal and State Government, and how can we maximize each of these two subsets?

Mr. Leavitt. As you pointed out, I served as the chief executive for the State, and I also served as the chief executive at HHS. And I can tell you from that experience, that

both have unique jobs and both have limitations. One limitation the Federal Government has is that it does not execute the capacity -- it doesn't have arms and legs to move around communities. It depends on the States, and it depends on the local communities. And so, to some, that somehow the Federal Government will execute on this at the local level simply is not acknowledging the reality.

On the other hand, there are many things that States could never do. States could, on their own, never have developed a vaccine. States need the resources that the Federal Government can apply at a point like this. States require the kind of international coordination that this kind of thing takes place. States cannot provide situational awareness. You have to have data from 50 States to be able to know what is happening and what can be done.

There is a role, a critical role, literally, a role that simply cannot be done without at both the State and the Federal level. This requires a collaborative attitude as much as it does any degree of statute or any degree of regulation. It requires us all to sort of put down -- lay down our swords, sit around the table, and solve a problem.

Mr. Curtis. Thank you, Governor. I regret that I am out of time.

I yield my time, Madam Chair.

Ms. Eshoo. I thank the gentleman for his questions.

And it is a pleasure to recognize the gentlewoman from New Hampshire, Ms. Kuster, better known as Annie.

Ms. Kuster. Great. Thank you very much, Chairwoman Eshoo.

And thank you, Governor. I think you said it exactly right, we need a coordinated approach between the Federal Government and the States. And I think the title of this hearing, "Road to Recovery," is exactly intended for that.

Last spring, after dozens of conversations with our public health officials and

business leaders in New Hampshire, my staff and I wrote a comprehensive outline of steps that Congress should take to mitigate this pandemic and support our economic recovery. And we titled that document "Road Map to Recovery," because there is so much work to do. And while many of these proposals were included in COVID legislation last year, we have more work ahead of us specifically related to the vaccine and improving our health data systems.

While some public health departments have access to the latest and greatest public health infrastructure, others are literally collecting case reports with pen and paper and can only transmit data via telephone and fax. In other cases, COVID vaccination appointments are made and canceled and remade and canceled again, while older Americans sit at home frustrated that they are locked out of the website that thinks they already received the immunization. So I am glad that Congress has put resources towards modernizing our public health infrastructure.

I want to ask you, Dr. Borio, you said in your testimony, "Improved data infrastructure needs to be one of our principal areas of attention." And I couldn't agree more. Can you give us a sense of what that data infrastructure will look like for a 2lst century health data system?

Dr. Borio. Sure, and I will be happy to elaborate in writing for you. But fundamentally, the way I see this is that, you know, a company like Uber did not disrupt transportation business by hiring the best drivers. They did so with technology, to provide a capability at the hands of every driver. And we need to do this -- think about public health data similarly. We need to have an integrated interoperable and, at the Federal level, tremendous analytic capability and link those to actual actions to information to the public.

And I just want to say that hearing Secretary Leavitt speak today, too, makes me

miss his leadership when I was young in my career at HHS. So thank you for that.

Ms. Kuster. Thank you, thank you. I appreciate that.

I just want to share with the entire committee, Congressman Bucshon and I have introduced bipartisan legislation to improve our data infrastructure by expanding the enrollment and training of vaccine providers, modernizing public health information technology, and communicating with patients and providers in real time.

Dr. Morita, can you tell us some of the current challenges that healthcare providers and public health departments are having on the ground due to inadequate immunization information systems? And how can we strengthen these systems?

Dr. Morita. So, as you pointed out, there are huge needs. What Dr. Borio mentioned was this critical need for interoperability, and I would say that is a major challenge for immunization information systems right now, because each of the 50 States have different systems that they are using. They have all been created separately and distinctly, and so they aren't necessarily interoperable.

But, in addition to not relating to each other, they don't necessarily relate to all of the vaccinators within the jurisdictions. So hospitals, pharmacies, healthcare providers, mass immunization clinics, there is not one system where all of the information comes together.

So as we look forward to the future, having an interoperable robust system for information to be shared within a State, and then also between States is really, really essential. What I would say we have seen play out this year has been a consistent lack of support. It is a boom or bust in terms of public health infrastructure, and the data infrastructure is where you see it play out most statistically.

In order for us to really be prepared for the next pandemic, or even do to better during peacetime, we really need sustained levels of support so we can actually maintain

these systems in a way that keeps up with the times.

Ms. Kuster. Well, I love your analogy to Uber.

What steps can be taken to give confidence to the American people that the information shared in these data systems will be protected, and only used to further public health response efforts? I know in my district, people are very concerned about privacy of their healthcare data. And can you mention the precautions and protections that would be in place?

Dr. Morita. So the public health data, when we access public health data at the health departments in the State or local levels, or at the Federal level as well, those data are protected by HIPAA. And so, the only way that we can use that information is to really guide or inform public health intervention.

So when we see there is a community that is not being reached, or we see a population that isn't getting vaccinated, we can actually target and direct our resources to them.

When information is shared, it is shared in aggregate, so that individuals can't be identified. And if there is too few people that have similar characteristics, that information is not shared out of respect for the privacy of these individuals. So because of HIPAA being in place --

Ms. Kuster. Thank you. I have to apologize. I have run over my time. I need to yield back, but that was very helpful. Thank you so much.

And I yield back.

Ms. Eshoo. The gentlewoman yields back.

I do have legislation on privacy relative to these systems, so we can talk more about that later.

It is a pleasure to welcome to the committee and recognize Mr. Joyce from the

great State of Pennsylvania. We are thrilled that you are part of the committee. And your debut, 5 minutes.

Mr. Joyce. Well, first of all, thank you, Chair Eshoo and Ranking Member Guthrie. I am truly honored to be part of the Health Committee on Energy and Commerce, and specifically, I want to thank the witnesses for appearing today at this incredibly important time.

President Trump's Operation Warp Speed has been successful at delivering multiple FDA authorized COVID-19 vaccines in less than a year. This truly is an unparalleled achievement. However, we are now facing new strains originating from the United Kingdom, Brazil, and South Africa. Now is not the time to let up on innovation in face of this additional health challenge.

Many experts believe the coronavirus might continue to be a public threat into the future. And while these first-generation vaccines are nothing short of incredible and significant achievements, I believe that it is imperative that we as a Nation begin thinking about the United States' approach to how we might this virus in the years to come.

It is also critical that we not lose sight of the development of new therapeutics to treat the virus, in addition to second generation vaccines that will speed the public's access to the latest therapies and the latest therapeutics.

My questions first are for Governor Leavitt. In your testimony, you said that the role of Federal policymakers in a pandemic's response is to scout the next valley, anticipating dangers, developing contingencies, and adopting strategies to mitigate potential threats.

Given the emergence of more COVID-19 variants that may be resistant to the limited treatments that we currently have, how can we, in Congress, do what you said, plant the multiple seeds? As the grandson of an Irish immigrant who planted beautiful

gardens, and I know the importance of planting multiple seeds, how can we best prepare to face these variants?

Mr. Leavitt. First, we acknowledge that this is likely to be a much longer process than just the time it takes to get people vaccinated one time throughout the country. It is very possible that over time, we will need to have booster shots, or we may have to have vaccinations, much like we do the annual flu, that this is going to be mutating, that we have to be prepared.

And there are supply chain issues, this is an ongoing issue. And there will be infrastructure issues that need to become more permanent, not just temporary.

That is what I think we have to be thinking about in terms of scouting the next valley. We have to anticipate that we need to get better.

I said earlier in the hearing that if we were talking about distributing 330 million hamburgers, we could do that in our sleep, because there is something on every corner that can disperse a hamburger and we all know how to get it.

We need to become good at distributing and receiving vaccines, and over time, our capacity to do this will improve.

Mr. Joyce. Governor Leavitt, what can we do now to equip agencies like BARDA to ensure that we have access to vaccines that can provide broad immunity so we aren't crippled by a new mutation in 2 or 4 or 10 years?

Mr. Leavitt. You start with funding them, make certain that they have the relationships that they need and the money that is needed to deploy it. You have to connect them with the regulatory agencies who are going to need to be partners. One thing I believe this committee could do that would move this, move our capacity forward, it has been referenced that we have learned a lot of lessons. We need to harvest those lessons and incorporate them in the normal process, not just the emergency process,

because this may be an ongoing need.

Mr. Joyce. My next question is for Dr. Borio. In your testimony, you mentioned vaccine manufacturers who are taking steps now to develop and test vaccine candidates that may be needed to protect against existing and emerging variants that we certainly will face in the future.

How do you recommend Federal officials lead large-scale vaccine manufacturing efforts and approach these challenges?

Dr. Borio. Sure. So at this point, as they develop the candidate, if they were to make a decision to go to full-scale production for the new candidate, they are taking away from what is already being produced for the strain that is also circulating. So, the most direct way to answer your question is that we do have to expand the industrial base for manufacturing these vaccines so that we can make more than we are making today, so that we have more flexibility and not make these very difficult choices.

Mr. Joyce. Thank you very much.

Madam Chair, my time has expired. It is great to be with you on this road to recovery.

Ms. Eshoo. Thank you, Congressman Joyce, and we are delighted that you are with us and part of the team. We love this subcommittee, and for good reason. It is so important, and members take the work very seriously and have been highly productive. So it is an honor for each one of us to be on the committee and to be together.

With that, the chair recognizes the gentlewoman from California, Ms. Barragan, for her 5 minutes of questions.

RPTR DEAN

EDTR ZAMORA

[1:59 p.m.]

Ms. Barragan. Thank you, Madam Chair. Thank you to our speakers, and for this hearing.

Let me start first by responding to one of my colleagues who asked, what is this administration doing differently than the last one? We will also remind people that we inherited over 400,000 deaths from this pandemic, partially for inaction that was taken.

The first thing that was done is the mask mandate. It is making sure that we are putting science first and making sure people understand the best thing we have against this virus right now is wearing a mask, social distancing, and doing those things that are necessary until people can get a vaccine.

This administration is calling for more dollars from Congress, which is why it is important that we invest, so that we can make sure we are getting money to local, State and local governments to be able to give more of this vaccine. The new administration has also ordered more vaccines when the prior administration wouldn't do so and turned it away. So there is a lot being done now. But our job in this committee is to say what can we do to help with what is going on right now. And I want to thank all the conversations we have had about the inequitable distribution of vaccines.

I represent a district that is almost 90 percent Latino, African American, low-income, poor. And we have seen firsthand the inequities that are happening. We are having some constituents having to take three buses just to get to a vaccination site. We just learned the other day that the pharmacies were no longer going to get vaccines. They were going to be pulled away and be given to mega PODs, which is harder for constituents like mine to get to. And so I appreciate [inaudible] about the creative

solutions.

And let me take a moment to say thank you to Governor Leavitt. For your testimony, you had an entire section about anticipating and addressing the barriers of the social determinants of health and equity in your testimony and spoke very specifically about not leaving those behind in low-income communities, rural communities, and minority communities. And you talked about the concerns that we have about transportation and people's situations.

The one common theme I am hearing today is long-term investment. And so making sure we are investing in things like social determinants of health and making sure we are addressing that long term, not just when the pandemic comes out. So it is something I hope that will also look into one of my bills on social determinants of health.

But I want to start the questioning with you, Dr. Morita. You have spoken about one of the things that needs to be done is to use federally qualified health centers and community clinics. When I was a kid, I relied upon them quite a bit. And so I have heard that, number one, many of them, the majority of them, are not getting the vaccine. There are shortages on gloves, shortages on the needles to be used.

Is there anything that you want to either elaborate again on or tell us as Congress on what we should be focusing on to making sure that the community health centers are getting what they need, whether it is staffing or supplies, to be able to reach target communities and those that are underserved?

Dr. Morita. I reviewed the Biden administration COVID strategy that was released the day after inauguration. Within that strategy is a commitment to providing additional resources to federally qualified health centers, recognizing the important role that they play in reaching some of our harder-to-reach communities who have been so devastated by this pandemic. And so I think that there is what is necessary. The

equities are committed. They want to do this work. What they need is the resources to actually ramp up and scale up their ability to deliver the vaccine and to deliver the healthcare that is necessary.

I appreciate also your point about the social determinants of health. What the pandemic has done has made a clear connection between the systemic barriers to people having good health. So it is access to insurance, access to good pay, a good paying job, access to paid leave. All of these factors contributed to why certain populations actually are at higher risk for having hospitalizations and dying. And so these underlying conditions really need to be addressed for the long term so that we are not in the same state with the next pandemic.

Ms. Barragan. Thank you.

I think this is a good opportunity to emphasize the need for us to invest in community health centers and clinics long term. Oftentimes we are not funding them long term. We are going year by year. And guess what? We are not giving them the increases that they need yearly to invest in our community health centers.

So I want to thank the panelists. There is a lot to cover, but I am out of time.

And with that, I yield back.

Ms. Eshoo. The gentlewoman yields back.

It is a pleasure to recognize the only pharmacist, I think, in the entire House of Representatives, Mr. Carter, for his for 5 minutes.

Mr. Carter. Thank you, Madam Chair. I have to correct you, though, we have another pharmacist now.

Ms. Eshoo. Oh, good.

Mr. Carter. We have two pharmacists in Congress now.

Ms. Eshoo. Well, that is great.

Mr. Carter. My colleagues are giving me --

Ms. Eshoo. [Inaudible] some of the distribution.

Mr. Carter. Yeah, yeah. But I am the oldest pharmacist in Congress, if it matters.

Ms. Eshoo. Okay.

Mr. Carter. So, nevertheless, I thank all of the panelists for being here and discussing this extremely important subject, obviously.

Governor Leavitt, I wanted to start with you and just talk about the distribution process. It is so vitally important. And one of the critical aspects is to pharmacies and to pharmacists, making sure that we are utilizing retail pharmacists. Whether it be independent or chain pharmacists, it is extremely important. As has been mentioned during this hearing, 95 percent of all Americans live within 5 miles of a pharmacy. Pharmacists are the most accessible healthcare professional in America. We need to utilize that. And I think we would all agree with that.

HHS has made some changes to authorize pharmacists to be able to administer the vaccine. In fact, early on, they, during this pandemic or during the administration distribution of the vaccine, the administration of the vaccine, they passed a rule where the people -- that pharmacists could give it to anybody 3 years or older, and that was very important. And just yesterday, they also passed a rule to say that the vaccines can be shipped directing to pharmacies, and that is very important during this pandemic as well.

I wanted to ask you Governor Leavitt, you have served at the State level, you have served at the Federal level, as have I. I have served at both levels as well. And is it your belief that all pharmacists should be able to administer the COVID-19 vaccine, if it is approved by the FDA, no matter what the State laws may be, no matter what varying State laws there may be?

Mr. Leavitt. I have referenced a couple of times in this hearing my experience with Medicare part D, which is another moment in time when millions of people all at one time were seeking some type of new Federal or new government service. The pharmacies were the main -- they were the heroes of that whole effort, because people went to the pharmacy, they knew they could get good advice, they knew they could find out the answers, and I became a great supporter of that. And I think they are a great support in the annual flu. Typically, that is [inaudible] I get my flu vaccine is at the [inaudible].

Now, I personally would not go so far as to say that the Federal Government has an interest in being able to override local decisions that are being made on what is best in every community. But I think many communities are and will realize even more how important the [inaudible] to your important statement is in being able to serve [inaudible] particularly the underserved communities.

Mr. Carter. And I would agree with that. And thank you, governor, for that point.

One thing that I wanted to point out, and I would be interested in knowing your opinion on this as well, is that during this pandemic, we have both relaxed some rules and implemented some new rules. And one thing that I hope that we do at the Federal level is to review this before we just go and put them all back into place. I mean, there are things that pharmacists can do that they need to be doing, not just during this pandemic, but they need to be doing the whole time in order to improve healthcare services here in the United States.

Governor, another thing that I wanted to ask you --

Mr. Leavitt. I concur with you having pharmacies operating at the top of their license being able to do all of [inaudible].

Mr. Carter. Absolutely.

I represent an area that has a high minority population as well. And it is very important and very concerning to me about vaccine hesitancy, particularly in the minority community. Just wondering what your experience is. What works? What doesn't work? Just some advice, if you would, on how we can improve that.

Mr. Leavitt. [Inaudible].

Dr. Morita. I think he is having difficulty. I am glad to jump in on this question.

Mr. Carter. Yeah, please, please do. Thank you very much.

Dr. Morita. Sure. So I think in addition to the challenges with people accessing the vaccine from our [inaudible] to our communities are color, there are also challenges of vaccine hesitancy because of distrust of the vaccine. Because of mistreatment in the past or discrimination in the past, people aren't trusting the vaccine itself. So it is really important for there to be community efforts where there are trusted messengers from within the community, engaging with the communities, to understand what their questions are, what their concerns are, who they want to hear from so we can actually address the concerns. So when a vaccine becomes more readily available, the communities that are at highest risk actually have more access to it and their concerns are addressed and they can demand the vaccine to do it.

Mr. Carter. That is so very important. Thank you, Doctor, for mentioning that. And I for one as a member of the Doctors Caucus and as a Congressman, I went through the clinical trials myself to try to set a good example. And I was fortunate enough to be able. Of course, it was a double blind study, but I did get the vaccine. So I want people to know that it is safe and effective.

Thank you very much, Madam Chair. And I yield back.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the gentlewoman from Delaware, Ms. Blunt Rochester, for 5 minutes of questioning. Great to see you.

Ms. Blunt Rochester. Good to see you too. And thank you so much, Madam Chairwoman. Congratulations, Ranking Member Guthrie. And thank you especially to all of the witnesses.

I want to start by associating myself with the comments of my colleague, Ms. Barragan, on illuminating the social determinants of health. It is an area that we have legislation on as well and it is vital, especially we have seen it illuminated during this pandemic.

And as our Nation marks the 1-year anniversary of declaring the coronavirus outbreak a public health emergency, it is clear that Congress must move swiftly and boldly with a pandemic response that protects the health and the economic well-being of our constituents and solves this public health crisis at last.

I am preparing to introduce or reintroduce my bill, the Coverage for COVID-19 Treatment Act, to guarantee access to COVID-19 treatment with no cost sharing, because no one should have to worry about how they can afford treatment if they contract COVID-19.

Like President Biden, however, I want to make sure that treatment isn't just affordable, but that it is widely accessible and effective. This is especially true for people dealing with long-term health impacts of COVID-19 or Long COVID Syndrome. And I would like to focus my first questions there.

Dr. Borio, in your testimony, you said that we desperately need better therapies for COVID-19. Why do you think we should continue to focus on investing in and support for the development of therapeutics and treatments for COVID-19?

Dr. Borio. The currently available treatments are very limited. They are limited

in benefit, they are limited in who they work, when they work. They are difficult to scale up. They are intravenous drugs. So we do need treatments that are more easily administered, more easily scalable to manufacture, more easily accessible. And also, this is not going the last biological pandemic. COVID is likely going to become endemic. We need better antivirals to treat COVID going forward.

Ms. Blunt Rochester. Thank you.

Dr. Borio. [Inaudible] research program -- it is already late. We have to start a research program that comprehensively tackles it as soon as possible.

Ms. Blunt Rochester. And following up on that, Governor Leavitt, thank you for your testimony. And you mentioned that Congress should be aware of the growing cohorts of patients with Long COVID Syndrome. What should Congress do to ensure there is better access to effective therapies to treat people with Long COVID Syndrome?

Mr. Leavitt. I will simply under -- I will first underscore the importance of this. This is a significant challenge. This is one we ought to be looking into the next valley, scouting the next valley and getting ahead of. And I would point to three things.

The first is data. We need more data about this. The second is the need for us to begin to isolate clinical pathways for those who have it, even to the point that we still can't -- we don't know how to diagnose it. We don't have a name for it. We don't have billing codes for it. We need to make progress in the context of clinical care. And lastly, payment. We have to begin to think about the impact this is going to have on payment systems.

Ms. Blunt Rochester. Thank you.

And, Dr. Morita, how can Congress help ensure equitable access to COVID-19 treatments for the growing number of people with long-term care COVID symptoms, many of whom are experiencing economic hardship right now?

Dr. Morita. I have to agree with Governor Leavitt. Having data and understanding who is actually getting treatment, how is the treatment working, making sure that those things are all in place so that it is that when treatments are available and they have been studied, that we actually can make sure that they are providing the right places.

In addition, though, as trials are being done with experimental medications, making sure that we have adequate representation in communities of color in the trials themselves so they can feel confident that the medications themselves have been tested in appropriate populations in those that look like themselves.

Ms. Blunt Rochester. Thank you.

And I am shifting gears. In the early months of the pandemic, I joined my colleagues, Congressman Pocan and Crist, to introduce legislation to harness the full power of the Defense Production Act. And I know invoking the DPA is a priority for President Biden.

Dr. Borio, how will using the Defense Production Act alleviate supply shortages in our country? And I think you also mentioned that we still remain vulnerable. Can you talk about vulnerabilities?

Dr. Borio. Sure. Thank you. Look, I am not an expert on DPA. It is quite a complex set of authorities we have. All I know is that Operation Warp Speed has leveraged it very heavily to be able to provide priority allocation to limited resources, to the vaccine manufacturers under a U.S. contract. It is not a final solution. You know, it is very important to recognize that sometimes allocating priorities for the filling finished lines for vaccine manufacturers is critical right now, has bumped products in those finished lines that were destined to other patients with some very critical diseases. So it is just not a final solution.

Ms. Blunt Rochester. I am out of time, but I do want to thank Mr. Burel as well, and I am looking forward to his recommendations on supply chain and DPA. We look forward to that.

Thank you so much. And I yield back.

Ms. Eshoo. The gentlewoman yields back.

It is a pleasure, a real pleasure to welcome a new member to our committee, the gentlewoman from Minnesota, Ms. Angie Craig. So it is just great to have you with us.

I might add, and I don't know how many members realize this, but all of our new members on the Democratic side are women. We have a whole new team. So watch out, gentlemen. Here we come. We are coming.

Ms. Craig. We are here. We are here.

Ms. Eshoo. We are here.

The gentlewoman is recognized.

Ms. Craig. Thank you so much, Chairwoman Eshoo. And thank you to our panelists for sharing your expertise with us here today.

It is really an honor to be here for my first Health Subcommittee hearing. I ran for Congress to tackle the very issues under this subcommittee's jurisdiction, particularly expanding healthcare access and affordability. And I look so forward to working with all of you.

I represent the State of Minnesota where, tragically, we have lost more than 6,200 lives to COVID-19. Like the rest of the country, people are struggling to survive both a global pandemic and widespread economic uncertainty.

With the new administration in office, we have an opportunity to provide the American people with the assistance that they desperately need. I am encouraged by the Biden administration's efforts to provide States with more transparency and increase

the vaccine supply, both of which will accelerate the number of shots in arms.

While our vaccine and testing capabilities continue to trend in the right direction, it is clear the Federal Government must do more, our lives and our economies are depending on it.

My first question is for Dr. Morita. As you noted in your testimony, an equitable vaccine allocation and distribution strategy relies on robust data. Last Congress, I introduced the Vaccine Fairness Act, which directed HHS to provide regular updates on their efforts to ensure the COVID-19 vaccine reaches the groups most at risk.

This week, the CDC released demographic data for the vaccines administered between December 14 and January 14, about half of the total vaccines administered to date. These data points support long-held concerns by public health experts about disproportionately low vaccination rates among Black and Hispanic Americans. These trends are reflected in Minnesota where we are seeing lower vaccination rates in the areas outside the Twin Cities and among long-term care staff.

I am encouraged by the Biden administration's commitment to provide real-time data, and I would further encourage the administration to include racial and ethnic demographics in on the CDC dashboard.

Dr. Morita, my question is, what impact does Federal data collection and reporting have on State and city efforts to implement an equitable vaccine administration program? In other words, why is it so important that we have centralized and transparent data?

Dr. Morita. So having disaggregated the data by race, by ethnicity, by geography, by occupation, is fundamental to the response being coordinated and an equitable response. In order for us to make sure that we are reaching the people that we actually need to reach who are at highest risk we really have to have the data

available.

What the Federal Government can do is really establish the expectation, require that these fields actually be included. So as the programs are rolling out, they actually are collecting -- the vaccinators are actually collecting this information. I talked with Walgreens at the beginning, prior to them actually rolling out their pharmacy vaccination effort in the long-term care facilities. And they said that they were required by Federal law to collect that information, race and ethnicity information, as they were vaccinating.

The challenge is that the systems within the States and local jurisdictions aren't necessarily equipped to handle that information or haven't been updated in time so that they can accept the information in a quick and efficient way. So what has to happen is the standard has to be established and an expectation for these collections of information, and then resources to support the systems so the information can be collected in an efficient way and then used and reported in a consistent way so there is transparency.

Ms. Craig. Thank you so much.

My next question quickly is for Mr. Burel. While the Department of Health and Human Services holds the primary responsibility for responding to and preparing for public health emergencies, a crisis as large as this requires assistance from FEMA. In your assessment, what have the contributions from FEMA had on the availability of medical supplies? And I only have about 30 seconds left.

Mr. Burel. I apologize, I wasn't prepared to answer that question. Let me give it some thought and come back to you. I do think it is important that when FEMA takes on those roles, it works with the people who are the subject matter experts in that space to make sure we get the right thing to the right place at the right time. And I think sometimes there is a disconnect there. Having worked both for HHS and FEMA, I know

it is something that we always have to work on to coordinate better.

Ms. Craig. I appreciate that very much.

And, Madam Chairwoman, I yield back.

Ms. Eshoo. The gentlewoman yields back. And, again, I am so thrilled that you are on the committee.

And speaking of being thrilled, it is a pleasure to recognize Dr. Schrier from Washington State, also a new member of the committee, and our fourth doctor, a pediatrician. So I know that she is going to bring a great deal to our deliberations. We will learn from you, and we are really thrilled to have you as part of our subcommittee. It is already enhanced. So you are recognized for your first 5 minutes of the subcommittee.

Ms. Schrier. Well, thank you for that welcome, Madam Chair. And thank you to our witnesses.

Like all of us, I am incredibly relieved that we have two highly effective vaccines, and more to come, in less than a year's time. And I cannot overstate how grateful I am to the scientists behind these achievements. With that said, as we all know, it will take months to immunize the country, and the more this virus spreads, the more mutations we will see.

To successfully reopen our communities and especially our schools safely, we just need more tools in our toolbox to contain the virus and prevent its spread. This is really hard when asymptomatic people spread the disease, and much of the Nation still does not mask or distance.

So surveillance testing helps pick up evolving outbreaks once a disease is under control. But right now, rapid at-home antigen tests done on a regular basis could dramatically slow the spread.

So for regular at-home testing to work, the test would have to be cheap enough for people to use every day or two to see if they are shedding the virus and then just take themselves out of circulation. Guess what? Homes tests like this already exist. So we are really close. But the ones that are currently available are way too expensive for daily use, at $25 to $50 per test. Some require a prescription and equipment.

But here is the thing, the components are really cheap. Produced at scale, they could cost less than $1 each. Did you know that the $15 pregnancy test in the store wholesales for 70 cents? And this is the same concept. So why aren't they already in our hands?

Well, there are lots of reasons, but one is that big companies are buying up those components, and their profit margin is higher to making 1,000 $30 tests as opposed to 30,000 $1 tests. So another is that the Trump administration didn't put it to weight behind this concept, and meanwhile a year later, 441,000 dead, more than 3,000 dying every day, and daily at-home testing would have been the curve. So I want to ask about that.

Dr. Borio, thank you for your service. In January of last year, you coauthored an excellent article called Act Now to Prevent an American Epidemic, and you encouraged government agencies to work with private partners to achieve robust testing. And so I want to ask you about antigen tests.

To your knowledge, Dr. Borio, has there been an effort to establish an independent comparative evaluation of different antigen tests, like a head-to-head comparison of test accuracy to find the best ones?

Dr. Borio. No, I am not aware of a head-to-head effort. I am encouraged that the new administration has established a pandemic testing board which will look comprehensively across all issues around testing.

Ms. Schrier. Great. And I understand there is this kind of test at the Frederick National Lab for serology or antibody test. And so it sounds like we could do the same thing for these lateral slow antigen tests.

Dr. Borio. There is no reason why not to do comparative assessments of the different tests.

Ms. Schrier. Great. And then if we did this comparing apples to apples and found the best test, could we procure the materials at scale to drive down the price for the American people?

Dr. Borio. That, I do not know.

Ms. Schrier. Okay. Because we would need millions every day.

And then, to your knowledge and from your prior experience, did the Trump administration dive in and take an active role in the testing, approval, procurement, and manufacturing of these sorts of tests?

Dr. Borio. So the prior administration did quite a bit to interfere with FDA's independence in regulating these tests in public health emergencies. There has been a lot of confusion as a result of this interference. I think FDA's now poised to be able to regain its mission to make sure that the American public has access to tests that work as intended. And they don't have to be the best test in the world, they just have to work as intended and do we understand their limitations.

Ms. Schrier. That is exactly right. We could have an imperfect test, but if you do it every day, if you don't catch it on Monday, you will catch it on Tuesday and you will stay home from work or school. Thank you for that answer, and that explains some of the holdup.

So thank you, Dr. Borio and all of our witnesses. This has really been a pleasure today. I can't wait to get these tests into every home in the country and open up our

economy and get our kids back to school safely and kind of layer these layers of Swiss cheese. You know, we can have masks and distancing and cleaning and rapid tests and vaccines, and we will get much farther much sooner.

Thank so much. I yield back.

Ms. Eshoo. Thank you, Dr. Schrier. Wonderful questions, wonderful points. I agree with you. I think in terms of testing, that so far we have missed the boat. Because these tests really should be 79 cents, $1 each. People should be able to buy a packet for a month or 2 weeks, especially essential workers. And I think the money in the recovery plan will go a long ways to making that happen.

We really have to put our pedal to the metal. This is the United States of America, for heaven's sakes. We can do this, and it is a source of embarrassment to me that we have these gaps. But, boy, with this committee pushing, we can close them and then some.

It is now a pleasure to welcome another new member to our subcommittee, the gentlewoman from Massachusetts, Mrs. Trahan. And I know that she has a great deal of biotechnology in her congressional district and that she will be a voice for issues coming out of that particular segment of the healthcare industry.

So welcome, and you are recognized.

Mrs. Trahan. Thank you. Thank you, Chairwoman Eshoo and Ranking Member Guthrie, as well as to all the witnesses.

I will start by just saying as Chairman Eshoo, Chairman Pallone, the Ranking Member Rodgers stated, I too want to emphasize that in order to build a system to address future threats and protect our national security, we must revitalize America's manufacturing industry. And I won't say much more about it, except that I welcome my colleagues to join the bipartisan Pandemic Preparedness Caucus that I started with

Congressman Balderson and Congresswoman Axne.

I will echo the concerns of my colleagues about ensuring equitable and accelerated access to COVID-19 testing, treatment, and vaccination. Now, I recently spoke with healthcare providers at Lawrence General Hospital in Lawrence, Massachusetts, a majority-minority gateway city in my district, and they shared that the mortality rate for Hispanic patients rose from below 2 percent pre-COVID to nearly 13 percent. A massive spike, and one we are seeing predominantly in our communities of color across the country. Conversely, the mortality for White Americans climbed just 1 single percent. So we can't allow inequities like this to persist. Rather, equity has to be our central concern.

And I too celebrate the miracle of having two highly effective vaccines. But we must be focused on dramatically accelerating the distribution, while also addressing the fact that we have fallen behind in testing innovation, as Congresswoman Schrier mentioned, and capacity building central to opening our schools and businesses. We have fallen behind on genomic research, specifically sequencing surveillance that identifies new variants. And we have fallen behind on developing treatments that mitigate the most severe symptoms.

So, today, I just want to zero in on one method to help reduce mortality for all Americans, and that is developing new therapies for COVID-19. The development effective therapeutic agents can greatly decrease the severity of the disease while we are vaccinating Americans and preventing hospitalizations, long-term effects, certainly death.

So, Dr. Borio, you have answered in your testimony and here today why it is important to continue to invest in developing COVID therapies, but also mentioned that the U.S. response was hindered by its lack of a clinical trial network that could be utilized quickly during a pandemic. Can you explain how a network like this can be established

and adapted to different novel diseases?

Dr. Borio. Thank you. Absolutely. So, you know, just taking a step back, we had to rely on existing clinical trial networks that existed for other diseases, for oncology, for et cetera, and we had to repurpose them. That took a long time.

NIH did some quicker studies. Actually they brought us remdesivir, for example. But they were limited to certain of number of sites across the U.S. And we really need to be able to leverage technology and leverage advances in how we conduct clinical studies, including around the oversight clinical studies, to really be able to capture patients where they are.

If you do the math and see how many cases we are seeing today across America, only a very, very tiny fraction of those patients are really able to enroll in clinical research. That allows us to have a learning system where we can learn as we go through this and be able to modify our practice according to new knowledge. So we need to be able to, you know, really use all of our healthcare systems, our networks, hospitals, medical centers, VA, et cetera, into a clinical research enterprise.

Mrs. Trahan. Great. Thank you for that.

You know, vaccine development for COVID-19 leveraged major biomedical research investments and it created these public-private industry partnerships to get a vaccine to market in record time. What lessons should we take from our early approaches to testing potential therapeutic agents as well as the success of vaccine development that would help catalyze better treatments for COVID-19 as well as other emerging infectious diseases?

Dr. Borio. I will say that just trust the importance of the adequately conducted studies, rigorous studies that give us definitive answers about whether a product works or doesn't, so we can go all in into making sure that we have sufficient supplies and ways to

administer them.

Vaccines are a great example where we did, you know, the gold standard in a most efficient way, very thoughtful approach, and we have definitive data about their safety and effectiveness. We do not have that same degree of information from most therapeutics, there are very few exceptions. So we can't cut corners in therapeutics if we want to really be able to provide cures that we can send support to our patients.

Mrs. Trahan. Understood. Well, thank you. I appreciate your answers.

And I will yield back. Thank you, Madam Chair.

Ms. Eshoo. The gentlewoman yields back.

And, boy, today is filled with a lot of pleasures relative to our subcommittee. Another great new member, the gentlewoman from Texas, Ms. Fletcher. Welcome to the subcommittee. We are thrilled that you are part of it. And it is your debut, your first 5 minutes of questions.

Mrs. Fletcher. Well, thank you so much, Chairwoman Eshoo. I am just delighted and honored to be here and to serve on this subcommittee. So I thank you and Ranking Member Guthrie for holding this vital hearing today. And I am so glad to be able to do the critical work to combat this public health crisis. And I thank our witnesses today for their time and their excellent insight.

My colleagues have touched on many of the critical issues before us. Focusing on vaccines and vaccination rates are vital issues in my district in Houston as well. But I want to pick up on the line of questioning that my colleague, Dr. Schrier, was asking about just now about testing. Because as we understand it now, that administering the vaccine will take time and that those vaccinated may still be carriers of the virus even if there -- you know, the impact of the disease that emerges from it with COVID-19. So that really brings us back to the need to having an effective testing strategy.

And, Dr. Borio, in your testimony, you talked about the need for CDC and FDA to develop still a national testing strategy. Part of any good strategy is ensuring that you have adequate supply to follow demand, and we know that if it is done right, there will be demand for a long time.

We saw last summer, particularly where we had outbreaks in the South, that there was driving demand, some labs had excess capacity and others were having long testing delays. So can you discuss a little bit how we can efficiently get testing supplies to labs where there is need and how we can do this on an ongoing basis?

Dr. Borio. So part of making sure that we have sufficient supply has to do with having the strategy so that we know where to focus, where to be able to put the dollars behind. And we don't have that today. So it is not sufficient to say let's, you know, increase the supply of every possible available test. We need to know which ones really need the most attention, which ones might be fine, and what is the balance of rapid tests and other high throughput tests. We don't have that information today because we don't have a strategy.

Mrs. Fletcher. Okay. Well, and I guess there is sort of a related strategic issue that I want to touch on with the time I have left for Dr. Morita and then anyone else who wants to weigh in, because I think another important aspect of understanding the supply issues is also ensuring that we have the adequate public health workforce to conduct the testing and the contact tracing while we are still vaccinating individuals. And I was glad to see that the American Rescue Plan includes resources for testing and a greater public health workforce. I also understand there was some testimony just yesterday in another hearing that State and local governments have diverted some of the resources for testing and contact tracing to vaccines.

And so what do you think, starting with Dr. Morita, what do you think can and

should be done to ensure that the proper resources and personnel are allocated to testing and tracing?

Dr. Morita. Your point is well taken. During the transition period of time, we spoke with a number of State and local health officials, and what they reported was they were really struggling in terms of manpower, because it was the same people that were being asked to do the testing, to do the contact tracing, to do the outbreak investigations, and to start planning for the vaccine. This is prior to the vaccine being available. And so there are just insufficient numbers of staff that are actually available.

What has to happen is really ramping up and shoring up that infrastructure with staff right now for the immediate response but in looking at how to sustain that for the long haul, because it is really difficult to hire a bunch of staff within State or local government and to get them mobilized and have them trained up to actually do the kind of work that is necessary, rather than having an existing solid network of workforce that could actually respond when the crisis actually occurs.

I think I agree with Dr. Borio in terms of there needs to be a testing strategy. And in order to have a strategy, there really -- it won't all be just public health workforce that is doing the testing. It can rely on healthcare providers that are in the community, in health centers and clinics and hospitals doing some testing as well, just because I don't think that the workforce necessarily has to do the testing on an ongoing basis. It can be a coordinated effort with other providers as well.

Mrs. Fletcher. Terrific. Thank you for that.

Would anyone else like to weigh in with their thoughts on that question?

Mr. Leavitt. I will simply remind us all that during the early part of this pandemic, we were in a big hurry to get tests, and a lot of tests went on to the market. And a lot of damage happens when tests are inaccurate on either side. And so there

needs to be a testing strategy. Part of that has to be accuracy and dependability. And a test is not a test that is not a test. They are not all the same.

Mrs. Fletcher. Thank you for that. And thank you all again for your insights today.

I am just out of time, so I will yield back. Thank you, Chairwoman Eshoo.

Ms. Eshoo. The gentlewoman yields back. Again, welcome to the committee.

And now I would like to recognize the gentlewoman from Illinois, Ms. Kelly, a really valued member of the committee.

Where are you, Robin? I don't see you. There you are. You are recognized.

Ms. Kelly. New glasses. Thank you, Chairwoman Eshoo. And thank you to all of our witnesses. Thank you for your patience. And, again, welcome to all of our new members.

As the chair of the Congressional Black Caucus Health Brain Trust, vaccine equity is very, very important to me and testing. I mean, there was a story on CNN about a vaccine that was supposed to go to a more Latino neighborhood but the appointments were taken by Whites coming into the neighborhood and them not getting their vaccines. And also stories around hospitals who are coding the way they give their vaccines out so doctors and nurses and folks like that come first and Black and Brown folks who are janitors are pushed to the background. So those stories are very, very concerning.

And the other thing that I am worried about, what happens with people with disabilities? Like, do you know anything about what is happening with people who are deaf or people that are blind? We don't seem to talk about that that much. And I was just curious, do any of you know anything about that population?

Dr. Morita. I can jump in on this question. Nice to see you, Congresswoman.

Ms. Kelly. Nice to see you.

Dr. Morita. In terms of just what is happening with communities of color and the challenges that are being experienced, the systems have to be developed. And whether it is communities of color or it is disabled communities themselves, the systems have to be developed in a way that everyone has easy access to them. So it can't just be a one-size-fits-all internet access appointment-making schedule, because that is just not going to work for everybody. And it can't just be vaccines offered in hospitals, large hospitals.

And so what really is happening right now is on the ground, and I have heard this from many jurisdictions, they are making the plans to broaden out how they actually make the vaccine available. They focused on hospitals and healthcare systems because that is who was supposed to get it first, but now as the groups are broadened, they will broadening out to the locations and places. But they also are working on developing systems to actually have community workers go out into the communities to help people register for the vaccines, making the vaccines available in the appropriate sites, working with federally qualified health centers that actually provide services to those communities themselves. And also that they should be building into the systems and are building for people with disabilities to actually access the systems as well. So it is a comprehensive type of approach.

And you mentioned it earlier and have been saying it pretty consistently, that in order to build the systems out and have the people to actually do this kind of critical work, more research is really needed to flow to the States and locals who are on the ground doing this critical work.

Ms. Kelly. I actually just got a phone call from one of my mayors. In our local supermarket, they are vaccinating 500 people today, and then they will be backs in 3 weeks to vaccinate 500 more. And this is in a suburban town outside of Chicago.

Just also out of curiosity, we can just go down the panel, how do you feel about school opening? It is a big issue in Chicago, as I am sure that you have heard about. And, you know, our Catholic schools have been open, but it is a big issue about public schools. I am just curious how each one of you see that.

Mr. Leavitt. Well, I will just say, as governor, I learned that those decisions are not well made at State capitals or Washington, D.C. They are best made by local school communities, because every school community is different and it changes from time to time and it needs to be managed in a very direct individualized way.

Ms. Kelly. Thank you.

Dr. Morita. There was a recently published article in JAMA by the CDC that described schools that have reopened safely and what assistance needed to be in place to allow them to open safely. So I think it is really important that these kind of publications are coming out. There is a lot of natural experiments that have been happening over the past year where school systems have been open, and understanding how to open them safely is really, really important. We all want our kids to be back in school, because we know learning is optimal in that school setting. And yet we have to make sure that the systems are in place, appropriate social distancing, requirements for mask wearing, or appropriate ventilation. Those kinds of assistance are critical for State schools to be open safely.

Ms. Kelly. Ms. Borio?

Dr. Borio. I think the data is really critical and I think we begin to see the data. I agree with Governor Leavitt as well that it is important to make decisions locally. But we do -- the Federal Government has a duty to be able to provide schools with information and with guidance and with assistance to be able to reopen safely.

Ms. Kelly. Thank you, Doctor.

Mr. Burel, my last few seconds.

Mr. Burel. Sure. I think that I agree with all of my colleagues. One of the things that I think we have talked about here is the need for availability of testing, the need for availability of personal protective equipment. I think all of these things would go a long way to creating a safer environment for schools and businesses to reopen faster.

Ms. Kelly. Thank you.

And thank you, Madam Chair. I yield back.

Ms. Eshoo. The gentlewoman yields back.

It is a pleasure to recognize the gentleman from Maryland, Mr. Sarbanes. And thank you for your patience.

Mr. Sarbanes. Thank you very much, Madam Chair. Can you hear me okay?

Ms. Eshoo. Yeah. Just speak up a little louder. I don't know if everyone's systems are as dim as mine, but everyone's voice seems awfully almost muted to me today. So do speak out.

Mr. Sarbanes. I will try to speak clearly for the benefit of you, Madam Chair, and other members in the panel.

I want to thank our witnesses today. This has been an exhaustive and long session, but I think you covered really important dimensions of the crisis that we are facing, particularly this vaccine distribution challenge.

Dr. Borio, I am very interested in your thoughts, and perhaps Governor Leavitt as well, when it comes to workforce challenges. We already had a public health infrastructure that lacked the kind of robust workforce component that you would need in normal times. The pressure that has been placed on our public health infrastructure and just broadly on our healthcare system by the pandemic has exposed these workforce

shortages and, of course, has aggravated them in many places, because the healthcare workers themselves have come down with the pandemic and they have been knocked out of work, many have lost their lives and so forth.

Could you speak, beginning with Dr. Borio, to what strategies you see for deploying in this moment additional healthcare workers, anyone, for that matter, who would be viewed as qualified to administer vaccines? Because as we tried to deliver the vaccine more creatively, whether that is having mass vaccination sites or mobile vaccination sites, reaching out to communities that have less access, et cetera, we are going to need the people. And that is often the bottleneck that we face. Along with protective equipment, along with the availability of the vaccine itself, along with the cold chain custody and all the rest of it, speak specifically to the workforce part of this crisis, and what we are doing in the moment to try to ramp up that capacity to handle all of these things, but in particular you could talk to the vaccine distribution.

Dr. Borio. So, briefly, I think that we always know about the four Ss: the supply, system, space, and staff. And we sometimes forget that staff is also a supply chain issue. There are efforts to now find a way to create more flexibilities with allowing practitioners to from State to State as well as rehire retired healthcare professionals to be able to participate in the program. Look at other types of health-related professions to be able to administer, whether it is EMS, dentists, and pharmacists. I think that there are ways to be able to do that in the short term. But in the long run, it is really about expanding public health workforce to be able to tackle the types of threats that we are going to face, continue to face in the future.

I don't want to over -- also take this moment to just share that, even in the manufacturing of this vaccine [inaudible] to staff it, because it is about staff. We think about the back, the filters, the columns, the space. But staffing with people that really

understand vaccine production has been a challenge as well. So it is all around the whole response program.

Mr. Sarbanes. Thank you.

Governor Leavitt?

Mr. Leavitt. Yes. I am of the view that in the long term, this has to be an all-hands-on-deck exercise. One of the things that I believe is limiting about a highly centralized distribution process is that it in many ways is not convenient for people and, hence, it will be less accessible. However, what militated against that in the early stages of distribution is that it takes infrastructure to do it. And I believe one of the things that will occur as time goes on, as this becomes an elongated process, that is to say it has to endure for a long time, there needs to be mobile units, employer-based units, all kinds of different mechanisms. But they not only need to know how to give a shot, they also need to be able to access the records so that, as we begin to deploy what I spoke of earlier, which is a vaccine credentialing process, that people can gain access to their own vaccination records and have them digitally presentable to people, they need to be part of that system.

Mr. Sarbanes. Thank you very much.

I yield back, Madam Chair.

Ms. Eshoo. The gentleman yields back. And we thank him for his always excellent questions.

So this concludes all members of the subcommittee that were with us today in having their time to question. We also extend a legislative courtesy to members of the full committee that wish to join us. And we have Mr. O'Halleran, the gentleman from Arizona, who is waiving on. And I would like to recognize him for his 5 minutes of questions.

So welcome back, Tom. It is always great to see you.

Mr. O'Halleran. Thank you, Madam Chair. Thank you for the panel. This has been an excellent presentation.

The first cases of COVID were detected in the United States a year ago. Early in the pandemic, Congress acted in four bipartisan bills, which is important for the unity that we need in America today.

Secretary Leavitt in testimony noted that we will get better at this. We are a year in, actually more than a year in, because we need to be working 24 hours a day. And so that year is really 3 years of work, hopefully.

Mr. Burel noted that we are short on everything. And Dr. Morita said that, today, we are going to need a full-court press. We needed a full-court press from the beginning.

Over the summer, in one of the hearings, I asked Dr. Fauci, would we be ready in the fall and early winter. He said, I hope so. Then I asked him again in another meeting, will we be ready in the fall or winter? In fact, he said that as we were getting into the fall. He said again, I hope so.

It is obvious from the testimony today that we are nowhere where we need to be in relationship to where we should be. From April until the end of December, Congress was unable to come together to provide additional support to build out a robust national testing contact tracing system. And, in fact, almost every other discussion we have had today.

Despite claims to the contrary, it became overly reliant, the prior administration, on States to implement their own testing strategies. That is clear. They are needed, but it has to be a coordinated process. Test kits, everything else, we are still in short supply.

I am going to try to cut some of this out because it has been talked about. But the national strategy has been talked about time and time and time again, and not just today but the need for it, and here we are sitting, talking about it still a year later. Time is of the most importance.

In my district, I have people in my district, similar to others, mostly rural areas, not being able to get tested. And when they get the first shot, they can't get to a second shot. The computer systems are in a situation where they are mostly, if you are dealing with somebody from the Hispanic community or some other Tribal communities, which I have a lot of, they have problems even having a computer, and it is required in many areas. And I am glad to see that the President has called for $50 billion to build out a national testing program, which we have talked about so many times over the course of this last year.

We have to ask so much from our frontline workers, and we are still where -- I can remember when this first started, they still don't have where we need to be.

Dr. Borio, I appreciate the honesty and self-reflection in your testimony. One of your recommendations called for the CDC to immediately expand its genomic surveillance system. Can you explain upon how, in conjunction with President Biden's plan to spend $50 billion in testing, this will help quickly identify new variants of infectious diseases like COVID-19, and how that will impact public health recommendations offered by scientists at the FDA or the CDC, and how it will help in the future?

Dr. Borio. Thank you. I will elaborate in writing for you afterwards. But, briefly, the fact is that early on, we knew this was an RNA virus, they mutate, they always mutate, and we didn't really have a system to be able to begin to sequence to receive viral samples from patients, to locals, to State labs, to the CDC, or under the sequencing labs, sequence them and then do a data analysis so we can really track the evolution of

the virus, detect the emergence of variants, and understand where they were spreading. So we took, you know, the alerts in the U.K. and South Africa to get us then to begin to scale up our systems, but it still is very inadequate for what the need is.

Mr. O'Halleran. Doctor, I have to interrupt you because my time is almost up. And I would like to ask you, how long has this system been needed and how long have the professionals been asking for it?

Dr. Borio. The need precedes this pandemic.

Mr. O'Halleran. Thank you very much.

And I yield. Thank you, Madam Chair.

Ms. Eshoo. The gentleman yields back. And always know how welcome you are at the subcommittee, Mr. O'Halleran.

Well, that concludes all of the questions for today. I want to thank our witnesses, Dr. Julie Morita, Dr. Luciana Borio, Governor Leavitt. It was really wonderful to have you join us. I think members -- well, members have learned from each one of you, and, of course, to Greg Burel as well.

I need to request unanimous consent to enter the following into the record, which includes documents submitted by both Democratic and Republican members. It is a rather long list; I am going to speed read. And if any of my colleagues want to interrupt and ask for unanimous consent, before I finish reading it, otherwise bear with me.

A January 31, 2021, Politico article entitled, 'It's a mess': Biden's first 10 days dominated by vaccine mysteries; a statement from the Association of American Medical Colleges; a letter from AARP; a statement from the National Immigration Law Center; a statement from the Asian & Pacific Islander American Health Forum; a letter from the American Academy of Family Physicians; testimony from Dr. Arthur C. Evans, CEO and executive vice president of the American Psychological Association; a statement from the

American Society for Microbiology; a statement from Steven C. --

Mrs. Fletcher. Madam Chairwoman?

Ms. Eshoo. Yes.

Mrs. Fletcher. Madam Chairwoman, I rise to request unanimous consent that all of the items be included in the record.

Ms. Eshoo. Is there a second to the motion?

Ms. Schrier. I second. I second.

Ms. Eshoo. Wonderful. Thank you, Dr. Kim.

Mr. Guthrie. Madam Chair? Can we just make sure the list -- can we read -- I don't want you to have to read. That is fine. Is there a procedure that we can verify that if we had something that was left off for some reason that we submitted, gets admitted?

Ms. Eshoo. Absolutely.

Mr. Guthrie. Just make the motion that if something we agreed to as admitted can be included in the record? That is all. I am fine with you not reading them. I just want to make sure we double-check.

Ms. Eshoo. Absolutely. And as I said, this includes documents submitted by Democratic and Republican members.

Mr. Guthrie. Okay. All right. Thank you.

Ms. Eshoo. So if there are any members that have something, please submit it and we will gladly add it to the list.

I hear no objections to the motion. So ordered.

And, let's see, it is 3 o'clock, so 4 hours on the dot. And this has been quite an extensive hearing, but I think every moment, every comment, every question, and all of the information gleaned from our witnesses are absolutely essential to this national effort

to crush COVID. So thank you, everyone.

Again, it is really a joy to welcome the new members from both sides of the aisle.

And I don't think we have any other business before us. So the Health Subcommittee hearing of today has now ended. Thank you. Thank you, everyone.

[Whereupon, at 3:01 p.m., the subcommittee was adjourned.]