HOUSE OF REPRESENTATIVES
COMMONWEALTH OF PENNSYLVANIA

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Zoom hearing to Discuss Treatment Options in Pennsylvania For COVID-19

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House Health Committee

Irvis Office Building
Room G-50
Harrisburg, Pennsylvania

Tuesday, October 20, 2020 - 9:31 a.m.

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COMMITTEE MEMBERS PRESENT:

Honorable Kathy L. Rapp, Majority Chairwoman
Honorable Valerie S. Gaydos (virtual)
Honorable Jerry Knowles (virtual)
Honorable Brad Roae
Honorable Paul Schemel
Honorable David H. Zimmerman
Honorable Dan Frankel, Minority Chairman
Honorable Mary Jo Daley (virtual)
Honorable Pamela A. DeLissio
Honorable Elizabeth Fiedler
Honorable Sara Innamorato (virtual)
Honorable Stephen Kinsey

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MAJORITY CHAIRWOMAN RAPP: Good morning, ladies and gentlemen, members of the public, members, thank you for being here.

For the physicians who are with us today, we truly appreciate you taking your time to presenting your testimony. We have had a change in our schedules, both the Republican caucus and the Democrat caucus. So, at the end of the testimony, I think the last presenter is Mr.--Pardon me if I mispronounce your name. Jim, I know you just spoke earlier--Pettinato. After your testimony, we will not have any comments or questions because of the change in our schedules.

But, members certainly, if you have questions, you can hand them to Whitney; get them to Whitney or Erica. We'll make sure you get any questions. And if you wouldn't mind responding that way, we would truly appreciate it. It's just the -- the way things happen here, we never know when our schedule is going to change.

So, at this point in time, we truly are thankful that you are here today giving us information regarding the treatments of COVID. We all know that this is a pandemic. It is real. But we are at the point where a lot of our constituents

are saying, what's the treatment, what's the treatment, what do I do? So, we are very pleased to have you here today.

We had a presentation two weeks ago which was absolutely excellent. It was nice to know that we have a physician in Pennsylvania involved in Operation Warp Speed. And so, we're really looking forward to what the presenters today can add to what we learned the last time we were here.

So, Professor Weiss, if you would like to go ahead. Doctor Susan Weiss is a professor and Vice Chair of the Department of Microbiology, Co-Director of Penn Center for Research on Coronavirus and other Emerging Pathogens at the Perelman School of Medicine at the University of Pennsylvania.

Welcome, professor, and you may proceed.

A VOICE: Would you unmute your microphone, please?

PROFESSOR WEISS: Thanks. Sorry.

I'm going to give you a short history of coronaviruses, which has actually been around for quite a long time. This pandemic is not newly -- a new virus, and then I'm gonna talk about what we

know about these viruses and how they can inform us in terms of thinking about vaccine development and drug strategies, and also, how we can prepare us for future emerging viruses, which coronaviruses are very likely to re-emerge in the future as well. So, just let me show you a little bit about what these viruses are.

So this is a picture of a coronavirus. It has this crown-like morphology. This is a picture from an electron microscope. Maybe this is familiar now to most of you. But the coronavirus is a family when they're very larger -- a large virus family called Nidoviruses.

Here's a diagram of a coronavirus. It has a very long RNA genome, and that's complex with a protein called a nucleocapsid. And this -- Sorry. This is going -- hard to manage.

This is a helical nucleocapsid inside of the virus particle. Around the virus is a membrane that's actually derived from the host membrane. And in that there are three proteins in the viral membrane, the spike protein. People probably heard about that. That's the protein that vaccines are directed against. And it's a really important protein because it mediates entry of the virus into

the cell.

It's important to determine what cell types are infected, what the immune response is, and how virulent, or how pathogenic the virus is.

Other proteins in the membrane are called M and E. They also have important roles in replication, but they're not usually used as vaccine targets, and some coronaviruses in COVID, hemagglutinin-esterase protein as well.

I want to give you a brief timeline of coronavirus research release. Way back in the '60s and '70s, we can find reports of two human coronaviruses that caused the common cold, OC43 and 229E, caused the common cold, but OC43 can sometimes cause a more lower respiratory track disease and more pathogenic infection.

There's a lot of research done on these viruses in the '80s and the '90s shown here by a small group of researchers. This was always a field that was kind of hard to get funding for because nobody thought it was very important at the time.

There's also a lot of animal coronaviruses that were studied during this period. Those are important pathogens of chickens, of cows,

of dogs and cats as well.

So, in 2002 when SARS, the first SARS emerged in southern China, it was quite a shock to the world and to the coronavirus community who only knew about these common cold viruses as human coronaviruses. This epidemic, I'll talk about it in a minute a little bit more, it only lasted for about eight months, and in the wake of that we realized that that -- that's were actually a large reservoir for many coronaviruses.

We also, at the same time, people started looking for more human coronaviruses and identified HKU1 and NL63 as causing pneumonia and bronchiolitis.

So then, things were pretty quiet in the world of coronaviruses until 2012 when MERS-Coronavirus emerged in the Middle East causing an epidemic that still leads to and infects new people, but -- but it didn't really spread beyond the Middle East.

Then in 2019, as we all know, SARS-Coronavirus-2 emerged in Wuhan, China, causing the epidemic that we're living with today, that causes -- All of these flu viruses in red cause severe acute respiratory syndromes, and so COV-2, the

disease, has been named COVID-19. So this has sort of been an analogy to HIV and AIDS. So COV-2 is the virus, and COVID-19 is the disease that it causes, just to be clear about that.

I just want to talk a little bit about the three epidemics. So SARS, the first SARS emerged in China in 2002. It has a reservoir in a Horseshoe bat. It treads -- was transmitted from a bat to a civet and then to humans. And then once in humans, it's spread by human close -- human-to-human close contact and spread mostly in Asia. It did get to Toronto and some other parts of the world. But it pretty much stayed in Asia. And in eight months, there were about 8,000 infections with about a 10 percent mortality.

Did this happen again? We don't really know. Was this a one-time transmittance to a civet to a human, or did it happen again? We still don't know that.

This coronavirus is a little bit different. It also has its reservoir in bats; was transmitted to camels where it has a major reservoir. So many camels in the Middle East and Africa has MERS virus in them, and it transmits from camel to camel, camel to human. And then once

in humans, it does spread among humans, but in a much more limited way than SARS. It's mostly in the Arabian peninsula. There was an outbreak in Korea from a person who traveled from the Middle East. Camels are reservoirs, as I said, and there's still people being infected by MERS-Coronavirus.

There's similar cases in 2020, but only been about 2,500, but this is the most lethal of the three lethal coronaviruses, 35 percent mortality. In 2019, again, the SARS-CoV-2 we believe it has a reservoir in the bat. It was transmitted, perhaps, through an intermediate species, but I think some data suggest that it might have gone directly from bats to humans.

Then once in humans, as we all know, it spreads really, really rapidly mostly because of its asymptomatic or presymptomatic spread, which wasn't true for either SARS or MERS, and you spread all over the world as we can see here. This is, as of yesterday, there were 30 million infections in the world, over a million deaths, and in the U.S. over 8 million infections and over 200,000 deaths as well.

So, each one of these epidemics

originated in a bat, transmitted to humans, but the actual way it was transmitted is slightly different or somewhat different in the way it transmitted among humans.

So, I just want to make this statement in response to some of the conspiracy theory that's been floating around. How do we know that SARS was not engineered by humans? We know that because very similar viruses are found in bats. It doesn't resemble any known or common virus, and it's not easy to make a new virus, and it's really not possible for anyone to know how to design a virus with the properties of SARS-CoV-2. It's not obvious from its genetics or from its genome why it would behave this way.

I just want to give you a little science here of what was done, a couple more slides. For the scientists among you, if there are any, coronaviruses are divided into different lineages. I just want to show you that all of these viruses, these human viruses are divided among these lineages as well.

229E and NL63 are called alpha-coronaviruses. The rest of them are betacoronavirus, OC43 and HKU1 and lineage A, SARS

in lineage B, and MERS-Coronavirus in lineage C. They all have very similar genomes, and this is important in terms of thinking about therapies. They have very similar 16 proteins encoded in this part of the genome, similar in all of these viruses. The spike protein that is encoded here in all of these viruses, and then the other structured proteins here.

So, when SARS-2 emerged in China and it ended in 2019, it was quickly sequenced and it was shown to belong into this category, and that's why it's SARS-CoV-2 because it's closely related to SARS.

I just want to make the point here that the spike protein, which is generally the target of vaccines, is generally very -- it's similar structure of these viruses, but it's different enough so that a vaccine made against MERS, for example, would unlikely protect against SARS and vice versa, and even within the SARS category, they're unlikely to cross-protect. That's why it's really important to think about the remedies and why it's important to think about these proteins here, which are really similar and are -- and can be really -- really are thought of as potential

targets for antiviral drugs.

And just really quickly to show here, in these replicase proteins we have two proteases and an RNA dependent, RNA primase. These have been shown to be really good drug targets for other viruses such as HIV or hepatitis C virus.

The coronavirus has also encode, and this is the target that Remdesivir is directed against. But coronaviruses encode all of these other enzymes that are potentially serving as drug targets and should be explored for that.

So, just in my summary slide, I just want a pitch to prepare for future emerging viruses, and there will very likely be other viruses, coronaviruses and other viruses emerging from that. We need to continue vaccine development and monoclonal antibody treatment. And even though an antibody or vaccine developed against SARS-2 may not work against the future virus, the platforms that are developed will be there and will allow quicker development of vaccines.

We need to develop pan-coronavirus antivirals directed against all those proteins I just described, which would be really important for quick response to future outbreaks. We need to

continue to identify and characterize coronaviruses and other viruses from bats and other species so we know what's out there and what to prepare for.

It's really important also to support basic biology research because it's only when we understand these viruses that we can really figure out how to combat them.

And just -- I want to acknowledge the people I work with in my lab, as well as all these other people in this country working in very difficult virus safety three conditions to understand these viruses better, and that we are funded by the National Institutes of Health.

I will stop here. Okay.

MAJORITY CHAIRWOMAN RAPP: Thank you, Professor Weiss. We appreciate your testimony.

I was remiss in trying to get the meeting off -- I'm state Representative Kathy Rapp. I chair the Health Committee. There are members here. I'm going to have them just introduce themselves quickly.

Chairman Frankel, did you have anything you wanted to open the meeting with, sir, before we have --

MINORITY CHAIRMAN FRANKEL: Thank you,

Madam Chair. And thank you to our presenters, Doctor Weiss. That was a quick but very thorough presentation. I really appreciate the opportunity to hear from you. I wish we had more time today, but, obviously, the schedule was out of our hands. I don't want to take anymore time. We should continue with the presentations.

MAJORITY CHAIRWOMAN RAPP: Thank you, Chairman. Representative Roae.

REPRESENTATIVE ROAE: Good morning. Brad Roae. I represent parts of Crawford County and parts of Erie County.

REPRESENTATIVE ZIMMERMAN: Representative Zimmerman. I represent northeast Lancaster County.

REPRESENTATIVE DeLISSIO: Pam DeLissio, parts of Philadelphia and Montgomery County.

REPRESENTATIVE SCHEMEL: Paul Schemel, portions of Franklin County.

MAJORITY CHAIRWOMAN RAPP: Thank you, members. We also have members who are --

A VOICE: I'm representing --

MAJORITY CHAIRWOMAN RAPP: -- joining us virtually as well.

So, at this time we will move on to our

next presenter, Director Amy Walker, who is a director for Infectious Diseases Policy, Biotechnology Innovation Organization. Director Walker.

DIRECTOR WALKER: Thank you very much. Good morning. Thank you for the invitation to speak with the committee today.

I'm here representing the Biotechnology Innovation Organization or BIO, and will be discussing the status of research and development of COVID-19 vaccines and therapeutics. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States in more than 30 countries.

BIO members are involved in the research and development of innovative health care, agricultural, industrial, and environmental biotechnology products. Our membership includes developers and manufacturer of vaccines, therapeutics, diagnostics, and medical countermeasures against emerging infectious diseases, pandemic pathogens, and other health security threats.

The public-private partnership between the biotech industry and the U.S. government is leading the global race to develop vaccines and cures to protect individuals from the novel coronavirus. Specifically, our industry is devoting our expertise, resources, and capabilities to identify science-based solutions and medical treatments to combat this threat. These efforts have encompassed unparalleled collaboration and cooperation between industry, academia, non-governmental organizations, and governments around the world.

Pennsylvania is playing a vital role in the research, testing, and manufacturing of these products. A number of the biotechnology companies answering the call on COVID-19 have research and manufacturing facilities in the state. Pennsylvania's academic institutions have laid the foundation for this later-stage work in partnership with biotechnology companies.

As of Monday, October 19, there were announcements of 759 programs for COVID-19 vaccines and therapeutics that have been launched over the past 9 months. Of note, of the more than 750 products, 25 percent are vaccines to prevent

infection, 27 percent are antivirals or antibodies targeting the SARS-CoV-2 virus itself, and 48 percent are treatments for secondary effects of infections, such as acute respiratory distress syndrome, inflammation, and cardiovascular issues. More that 90 percent of products are being developed by biotechnology companies. More than 70 percent of products in the pipeline have been discovered by small companies, and more than 50 percent have been discovered by companies based in the U.S.

Approximately 40 percent of all products are at clinical stage development, and more than 60 percent of the pipeline are biologics and vaccines, while around a third of the products are traditional small molecules. The products in clinical stage show a variety of modalities and technologies, ensuring that we have many shots on goal for success.

Companies are compressing timelines through parallel rather than sequential R&D and manufacturing work. Streamline protocols and trial recruitment, enrolling data submissions to the Food and Drug Administration.

In addition, Operation Warp Speed has

partnered with eight companies to de-risk the R&D process by providing funding for development, manufacturing and procurement of vaccines and therapeutics.

Efforts are being made to ensure that this acceleration does not come at the expense of safety and efficacy. The clinical trials for the vaccines are enrolling a high number of patients to help ensure the data on safety and efficacy are robust. These Phase 3 studies are being conducted using clinical trial designs that represent the gold standard in vaccines R&D, randomized, placebo-controlled, event-based trials.

FDA recently provided guidance on the use of emergency use authorizations, or EUAs, which shows that high scientific standards are being upheld. In September, industry leaders issued a pledge that affirmed that companies would follow the science and not seek FDA review until Phase 3 data is collected.

While all this progress we have seen is promising, there are a few challenges to getting these products to the American public.

The pandemic has highlighted existing disparities in health care, infection risk, and

confidence in our medical system. Companies have been proactive in recruiting to clinical trials diverse populations from communities especially hard hit by COVID-19 to ensure that the products are safe and effective for the people who need them most. Even so, recruitment of communities of color lags behind where we would like it to be.

In addition to manufacturing on an unprecedented scale for COVID-19 products themselves, scale-up is needed for ancillary products, like needles, syringes, and adjuvants to ensure that there are no bottlenecks with fill-finish capacity. This all must be done to increase capacity and not pull manufacturing capacity or supplies from existing routine vaccinations or therapeutics. We do not want shortages of drugs or outbreaks of other diseases on top of COVID-19.

Now that trials and manufacturing of vaccines are underway, attention is turning to how we will get those vaccines to people once they are authorized or approved by the FDA. The supply of vaccines will be constrained initially. We won't have 300 million doses, much less 600 million doses available on the day of a FDA authorization or

approval.

The CDC's Advisory Committee on Immunizations Practices, which makes recommendations for all vaccines in the U.S., held monthly public meetings since June to transparently discuss COVID-19 vaccine development and prioritization. As inputs into their process, ACIP is using other frameworks developed by respected groups, such as the National Academies of Science, Engineering and Medicine; Johns Hopkins University, and the World Health Organization.

The current focus is on a risk-based approach, or getting vaccine first to those most at risk of exposure to COVID-19, with preliminary groups including health care workers, older adults, and adults with numerous chronic conditions and essential workers. Final decisions on prioritization will be made once we know what vaccines are ultimately authorized or approved.

Operation Warp Speed issued their distribution plan and guidance to states in September. States' initial distribution plans were due to CDC on Friday, and refinement and adjustments to the plans will continue throughout a vaccination campaign. Vaccines will largely be

distributed using existing infrastructure, with improvements as need.

While we do not know when a vaccine will be authorized and what vaccines will be authorized and special considerations like cold-chain requirements will be, we are pleased to see that planning for these complexities is happening in advance. We hope that Pennsylvania will be a leader in ensuring the phase immunization infrastructure as prepared for a vaccination campaign on a scale not previously seen.

Finally, public confidence in the safety and efficacy of any potential COVID-19 vaccines and treatments are also a concern. Polling numbers related to the number of people who are willing to get a COVID-19 vaccine are lower than expected, with many people citing concerns around the acceleration of testing.

The promise of COVID-19 vaccines can only be fully realized when people are willing to get the vaccine. We must work together to communicate the importance of this vaccine, provide fact-based information about the development process and what acceleration actually means, and the rigorous and continuous testing that these

products will undergo.

With COVID-19, we must learn from the mistakes of previous outbreaks and bring products across the finish line. If not for this outbreak, then for the next. If resources had been available to advance research on SARS and MERS products over the past decade, as Doctor Weiss previously said, we might have been even further along on COVID-19 products today.

The biotechnology industry is committed to bringing safe and effective vaccines, therapeutics, and diagnostics across the finish line for the people in Pennsylvania, the United States, and around the world. As this important work continues, remember to wash hands frequently, wear a mask and social distance, cover your coughs and sneezes, and get the flu shot.

Thank you again for this opportunity, and I look forward to your questions following the hearing today.

MAJORITY CHAIRWOMAN RAPP: Thank you, Director Walker.

Director Walker, you might not have heard me say, but our schedules have been changed here in the House so that, we actually have a

meeting at 10, but we're going to continue with our last two presenters. But if our members have questions, we will make sure that those questions are given to you for a response. So thank you very much.

Our next presenter is Sharon Lamberton. Again, I apologize if I mispronounce anybody's name. She's is with the Pharmaceutical Research and Manufacturers of America.

Sharon, you may begin your presentation.

MS. LAMBERTON: Thank you, Chairwoman Rapp.

Ralph, can you see my slides?

A VOICE: No, I see a U. I do not see your slides.

MS. LAMBERTON: I'm sorry. Okay. Do you see it now, Ralph?

A VOICE: Yes.

MS. LAMBERTON: Thank you. If I may kindly ask the other participants to mute the microphones. I'm getting a lot of feedback when I heard Amy. I just wanted to see if you all could mute so we can reduce background noise.

Thank you so much, Chairwoman Rapp, and members of the committee, for allowing PhRMA to

present PhRMA's -- a trade association of over 34-member companies representing an industry full of companies that are working tirelessly right now to beat this pandemic. Typically, we're competing against each other trying to bring brand-named medicines to market for patients all over the world, but right now we're fighting the pandemic, and that's our number 1 priority.

So I'm very happy to bring you some slides you should have in your packet. But I want to tell you a little bit about what our industry is doing.

This slide talks a bit about, in Pennsylvania, we have over 285,000 jobs that our industry has brought to the state and about $4.6 billion worth in revenue for jobs. We are working tirelessly trying to look at what's on the shelf; what are currently the medicines that are the shelves that we could use to bring (indiscernible) that might help treat or serve in the vaccine development.

We're also putting all hands on deck. Those that are currently running clinical trials are continuing. However, we're shifting scientists and resources to really work to fight COVID, and

that's across the board.

We're also sharing in realtime some of the clinical trial learnings, and that's with governments, foreign governments like the Chinese Medicine Association, the European Medical Association, people that we typically not worked hand in hand, but we know that's essential if we're gonna have a vaccine and treatment to share our information and work together.

We're also manufacturing a scaling before a medicine is even approved. That means some of our companies are manufacturing millions of doses of medicines before FDA approves it. You might think that's crazy because it's not approved. There are millions of doses that then get trashed. However, that's just even more close that we can get that medicine to those that need it, and in the hands of our providers that will be disseminating it in Pennsylvania and throughout the world.

We're also working to make sure that it's affordable. You might have seen several of our CEOs recently make a pledge in addition to making sure that science is first and we're not going to be cutting corners. We want to make sure that it's affordable to all. So that's another

commitment that we've made.

The next slide talks a little bit more about what we're doing. You might have heard an incredible start with Doctor Weiss explaining the coronavirus. When we look at other viruses like SARS that took us more than 20 months to sequence that virus, I'm happy to say, because of the strong foundation that we have and the research and development infrastructure and our industries, we were able to sequence that virus within four months. Scientists are so far advanced right now, and we are so happy that was the case because we were all that much further in getting a vaccine hopefully within 14 months as compared to what, typically, is a seven-year timeline for a vaccine to come to market.

And we're also looking at a number of other things besides the up-scaling of manufacturing. We're looking at what existing medicines can we use, antibiotics, antivirals for treatment of those that already have the virus so we can reduce the symptoms and lessen the severity.

The next slide is one of my favorites because it gives us promise and hope, showing that there are over 1,649 clinical trials throughout the

world on coronavirus treatments and vaccines. And of those, 115 are on vaccine. And I can give you a drill-down on Pennsylvania or any other state to show you in your backyard where those clinical trials are occurring.

For example, here in Pennsylvania, there are 29 sites throughout the state that are conducting clinical trials. This ranges from areas in Allentown, Doylestown, Danville, Hershey, Lancaster, Philadelphia, Pittsburgh, Scranton, West Reading and Wilkes-Barre. And again, happy to provide Chairman Rapp and the committee members with specifics.

We look at vaccines, and we know that this is difficult to come up with a vaccine. On average, a medicine takes 8 to 10 years to come to market, and about $2.6 billion, and only 12 percent succeed. Unfortunately, with vaccines, it's even worse. We have a 15 percent fast rate; sometimes 5 percent. So that means we need as many shots unfold and many attempts as possible so that we can make sure that we have a vaccine ready to go.

And we know that vaccines over the course of the history have really eliminated terrible diseases that have taken so many lives.

Sixteen vaccinations represent a wonderful history of how we've been able to almost eradicate some of these other terrible diseases, and we look forward to doing that with coronavirus. It's also saved over $1.6 billion in direct medical costs when people are not going into the hospital, the emergency room, missing work and so forth.

We (indiscernible; video difficulty) that are associated with coming up with vaccines. You all know that. The (indiscernible) are tremendous. We are using biologics. We're looking at how we can use our immune system to leverage it, to fight the virus. There are seven different ways that vaccines could be manufactured, so we don't have a one size fits all, which is good news, but also challenging.

Of course, clinical trials are challenging, too. We want to make sure that we have sufficient, diverse populations for those clinical-trial volunteers. As a nurse, I worked in NIH, and I saw the importance of making sure that the end-treatment population, folks that are going to benefit from that medicine, are really well represented in that clinical trial.

So, for coronavirus, we know that the

communities of color are disproportionally impacted. We know those with comorbidities, like diabetes, has tremendous complications. Sometimes three to four times than those that don't, the healthier folks that get coronavirus. Why is that? We need to make sure we're studying that in our clinical trials.

Of course, the manufacturing distribution challenges are great. Just thinking about refrigeration, we have to make sure that some of these vaccines are stored at negative 70 degree, um, temperature. Some are negative 20. The transportation, the delivery, and ensuring that the vaccination is appropriately stored in the correct temperatures are going to be a challenge for all states, but not just states. Thinking about the other folks throughout the world where many of them don't have refrigeration. It's going to be a challenge.

But, we are up to it. We are making incredible progress. I referenced SARS and how far we've come from then. In using novel approaches like RNA, that we can maybe make sure that this virus is actually eradicated by using our own genetic sequencing so that it can attack the virus.

Adjuvants are another thing that we are seeing many of our companies partner with others which can boost our immune system. It's almost like a V-8, if you will, the medical compliment, our natural immune reactions.

There are seven different approaches that I referenced that help ice this virus. And we look at inactivated virus like you typically seen for our flu virus, and all the way down to six o'clock, if you will, on this circular map would show the RNA virus.

Never have we had a vaccine yet approved using RNA technology, but this is exciting because it could potentially provide longer immunities so that we don't need to get continual boosters like you might for tetanus where, every 10 years when you cut yourself with something or potentially encounter something rusty, we don't want to react negatively and die from those spores, so we have to get every 10 years a tetanus shot. So how wonderful it would be if we had a one-time immunity to COVID using RNA.

It is a wonderful smattering of all the different companies that are doing great work, but this is the slide where it shows the front runners

of the Phase 3 clinical trials; meaning, that there are four different companies that are bringing the clinical trials in the human phase, Phase 3, to bear. So this, they're coming to conclusion. We should have data as early as November, and this is really exciting.

You might ask, Sharon, how in the world does a vaccine timeline be shortened? You just referenced seven years to bring a vaccine to market, 12 for a normal medicine. How are you all doing this in 14 months, and how are you doing it safely?

I had mentioned we built on our previous knowledge. Our incredible scientists throughout the world and our technology that we've had allowed us to sequence it quickly. We are investing billions in technology that helped us decode it more quickly. We're up-scaling before FDA approval. We are doing a lot of things that are helping us bring that to market much quickly. Operation Warp Speed, a new entrance that we've seen, is helping. Part of the federal government that's not just providing funding, but they are identifying the most promising candidates so that we can expedite that through clinical trials.

And safety is of upmost important. We are not cutting corners. FDA has one of the best gold standards, safety records in the world. We want to make sure that whatever is approved will be safe for us, for our family members, and there are a lot of things already in place that will monitor for the safety profile of the medicine approved, not just before that's approved by the FDA, but as well after. This references some things like the vaccine adverse event reporting system, and some of the other entities that are continually working with health care providers in our communities to identify any issue whatsoever so that we can rectify it.

And then, finally, this is just showing you a few of the different processes that we -- that Amy and Doctor Weiss had referenced. There's a lot of cooks in the kitchen once there's an approval. There's a lot of folks that will be advising on the guideline on how this vaccine will be used, with whom it should be used first, which are the minority populations for Pennsylvania, and, of course, how is it going to be covered and paid. And what's the implementation going to be like in the state to get such a massive vaccination done so

quickly?

So this shows you some of those entities that are hard at work right now, and some meeting just this Thursday, actually, where there's FDA committees meeting this Thursday.

And then, of course, I mentioned we have a price that several of our member companies said, we, no matter what you might hear or political drama going on in this news, we want to reassure that -- we could uphold to reassure the residents of Pennsylvania and everyone throughout the world that we are working to make sure that this vaccine is safe, and that we have an efficient range of options so that one size doesn't fit all.

There's one vaccine that might be a one time only. Another one that might need to go again. After 28 days you might need a booster. So if we have as many choices as possible for our population, that's even better.

And then, finally, looking at when we do have that approval, probably make sure that the medicine supply change is equipped to quickly handle it. How do we make sure that we have that robust inventory? How do we make sure we have the health care providers on hand to administer it?

What locations are they going to be in Pennsylvania? Are they going to be mobile units? Are they gonna use existing qualified health care centers and hospitals and clinics?

These are all things that Pennsylvania -- And I do say that your state is far ahead in planning and very well equipped with figuring out how we are going to disseminate it in a clear way to make sure that it's safely administered using the distant guidelines that we need to maintain for quite some time.

Finally, these are just last resources that are important for you as your federal legislators working to bring to your constituents. We have heard about the many, many Americans who have lost their jobs who need help. But first, those that want to know, how do you get in a clinical trial even if you're a healthy volunteer? These are some great resources to tell your constituents, should they want to get into a clinical trial.

But, more importantly, if you're having trouble affording your medicines, it might be diabetes insulin. It could be asthma medication. Whatever it might be because of a loss of a job or

a change in economic circumstances, we have a program called Medication Assistance Tool, M-A-T dot org that compiles 950 different programs and gives you free or nearly-free medicines through this programs.

You do not have to be uninsured. You can have insurance but just not enough. You could have other public programs and it's assisted. So please know that this is a swath of wide programs that are equipped to get patients to medicines that they need.

And then, finally, you probably heard of Healthcare Ready, who is a third-party entity that was erected after Hurricane Katrina, where patients didn't have a hard copy prescription to go say, hey, I swear I'm a diabetic. I need my insulin, but I don't have a prescription at hand. My mom-and-pop pharmacy has been shut down because of a natural event, a disaster.

Now it's not a natural disaster, but it's a pandemic and mom-and- pop shops are closing, and patients don't have access to their medicines as quickly as they do. So Healthcare Ready is a great partner in just working with your Governor, and with many of you all to get supplies and

medicines to those that need it.

And then, I stand ready, as Amy and Doctor Weiss said, Chairwoman Rapp, and your members of the committee, please feel free to give PhRMA (indiscernible) any of us with questions, and we will be very responsive and get that information back to you.

Thank you for this time. We appreciate it.

MAJORITY CHAIRWOMAN RAPP: Thank you, Sharon. That was very informative.

Our last presenter today is Jim. Jim, again, I apologize if I'm mispronouncing your name, Pettinato, Chief Nursing Officer and Director of Patient Care at Wayne Memorial Hospital.

Jim, you may proceed as soon as you're ready.

MR. PETTINATO: Thank you very much. I appreciate the invitation. Very well on the name, so no problem there.

It's really a pleasure to be able to give an overview of what our hospital has done here. Am I getting feedback coming through?

A VOICE: No. You sound fine in the room here.

MR. PETTINATO: Okay. All right.

At the start of this response, we really got a lot of support from our Department of Health and our local office. I can't say how important that was to us as we began to respond by developing a containment unit in our hospital.

Being a small community hospital, resources were definitely tapped, but we were able to isolate a 21-bed unit and create a safe environment; creating a lot of negative pressure rooms and areas for our staff to work in. And our local Department of Health was very helpful in helping us establish that unit, as well as our staff here in the hospital in helping to pull it together.

We started our incident command structure back in the first week of March, seeing the wave coming and as the direction of the local officials. And our incident command involved not only our local government, it involved, obviously, our health system, our affiliate, our federally-qualified health care center, and included in our system where our nursing homes in the area, and most recently as there has been a return to schools, our schools have joined our incident

command system as well.

We hold bi-weekly meetings at this point. They were more frequent during the height of our initial hit. But we hold bi-weekly meetings to kind of give updates and just get a pulse for what's happening in the community and what's going on and try to share information.

Our physician leadership here at the hospital has also provided clinical expertise to nursing homes and the schools as they're developing policies and procedures in response to COVID-19, and that has been widely accepted and appreciated. We have a community physician, Doctor Cruz, and Doctor MacVeigh, who's our hospitalist critical care medicine trained physician who offered their services, essentially, around the clock to be able for questions and clinical concerns.

Most of our patients were seen in the initial hit back in March and April. We had a total of 42 patients since that time be hospitalized at our institution in our containment unit. I'm proud to say that, however, our death rate was lower than the national average based on the number of infections in the area, and I attribute that mainly to our physicians and staff.

We were never at a situation where we were either out of ventilators or out of staff to care for patients.

When I tell you as a 95-bed hospital, with running about an average capacity of 50 patients a day, it really put a strain on us when our containment unit even became at a 50 percent occupancy. So at 11 and 12 patients, it was very intense, and the community response, be it supplying us at the time, PPE was a huge concern, homemade gowns, homemade masks, cleaning supplies, and 95 masks from people's basements and local businesses really stepped up and were dropping off supplies. It might have been a box with five masks, or someone who just had an N95 mask in their basement and dropped it off at our front desk. The community response initially was fabulous.

It was large, in part, to all that helped that we were able to do a good job containing it. To date, we've had no cross-contaminations in the hospital of COVID-19 to patients or staff as it related to the care, as we did contact tracing from the very beginning and did that in combination with the Department of Health. That entire response really was a success because

it was a community response.

Treatments, we offer the full gamut here that was available. The hydroxychloroquine, the steroids, the antibiotics were appropriate. Initially, there was, obviously, not the convalescent plasma when we were in the height of our hit, and we did do some blood transfusions which did prove to be somewhat effective in buying some time sometimes for patients to get them over a hump, and that really went quite well again for buying time. I don't know that there was a huge change in patient outcome as it related to that.

The biggest change I think we saw was the initial clinical data coming out was to ventilate patients, ventilate them early before they really got into trouble. It may be somewhat coincidental, but I can tell you that it was during that time we saw our string of fatalities in that process. And then quickly, those were reversed and the modalities of using more aerosolizing treatments, which were kind of initially viewed as very dangerous and harmful, potentially, to the staff. In the right environment, could be done safely. Patients actually began to do better, and avoiding getting them ventilated in an early

fashion was really seemed to be the key.

I know, at least for us, the ability to provide one-on-one nursing, physician coverage to the degree that was, truthfully, probably not seen in a small community hospital like ours, with critical care folks rounding and physicians and surgeons and medicine all joining together to be sure that the containment unit was covered 24 hours a day with either boots on the ground or immediate access to having boots on the ground, really, is probably what contributed to the good outcomes that our patients did receive.

We continue to offer whatever services we now have for Remdesivir available. However, to date, we have not had any patients critically enough to require that. So, in my opinion, that's a good thing. But again, it is available to us. And we have really tried to stay up on all of the current treatment recommendations, and what would bring the best care to our patients here at the hospital and, you know, continue to work also locally with our other hospitals.

We actually formed a somewhat unofficial network. There's obviously all the pre-planned hospital engagement contracts and the task force

throughout the state. But as a group of local hospitals in the Wayne and Lackawanna County area, we kind of got together early on, probably the end of March, beginning of April, and decided that with the nationwide struggle that was going on, even if we needed help with the best of intentions of everyone wanting to help, we probably weren't going to receive it.

So, we set up an unofficial, kind of network, where, in 15 minutes through a group page, all clinical leaders, nursing directors or critical care directors would get on a phone. If one or more hospitals were suffering some shortage of something, be it staff, supplies, something that needs an absolute immediate response, that we would get on the phone in 15 minutes and we would respond to one another's request to the degree that we could.

I think it was a good networking situation, and there were probably a total of about six hospitals that agreed to participate. We kind of just chatted weekly for about 10 or 15 minutes just to keep in touch with each other until such a time that we all felt as though the initial threat of having that immediate need was over.

Again, it wasn't done to circumvent any of the regular systems that were in place. But just as a very quick process to just, listen, we're short a ventilator. Who has a ventilator they can give us? Or, we are short-staffed. Is there somebody that can send one or two nurses? Those were kind of the agreements that we came up with on the fly.

I do have to say, it was nice knowing we had that help and support, because any requests just for things like supplies or staff that go through the normal mutual-aid chain, obviously, would take time to respond. We all committed to one another that for the things we can handle amongst ourselves, we were going to work together on.

So, again, that was kind of our response, you know -- Statistically, again, I'm really proud to say we did not see the same death rate. But, hopefully, it continues that way as we're now beginning to see numbers tick up again. Our containment unit since the initial hit has only ever had one or two patients on it at a time. And many weeks it has been closed with no patients, so that's a good thing also.

I'd be happy to answer any questions that the committee might have. Those are my comments. Hopefully, I covered what the committee was looking for.

MAJORITY CHAIRWOMAN RAPP: Thank you, Jim, and yes, you did.

As I stated at the beginning of the meeting, unfortunately, the caucuses have been called to a meeting. Actually, we were called in at 10, but we decided to go ahead and allow the presenters to present today because we think it's important. So, I want to thank each and every one of you for your time today. It was very informative and we truly appreciate your time.

Obviously, we are all looking for a vaccine, or, you know, treatments, or just that this pandemic would go away. I don't think that's going to happen. But we certainly very much appreciate your input, and you taking your time out of our busy schedule to present to us today.

And again, to the members, please feel free to, if you do have questions, Erica and Whitney can take your questions, and we can forward them on to our presenters today.

Thank you, members. Thank you, too,

members of the public who joined us today. Thank you.

(At 10:22 a.m., the Zoom hearing concluded).

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C E R T I F I C A T E

I, Karen J. Meister, Reporter, Notary Public, duly commissioned and qualified in and for the County of York, Commonwealth of Pennsylvania, hereby certify that the foregoing is a true and accurate transcript, to the best of my ability, of a public hearing taken from a Zoom/videotape recording and reduced to computer printout under my supervision.

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Reporter, Notary Public