Podcast Transcript

"Vaccine Development for COVID-19"

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Moderator: Laura Blake, Outreach and Development Manager, Women In Government

Panelist: Julia Worcester, Director of State Policy at PhRMA, Mid-Atlantic Region

Voiceover: Welcome to the Women In Government Podcast. Whether discussing important issues or policies of the day, this is the place where lawmakers and decision-makers unite to get the conversation started.

Laura Blake: The past eight months have transformed our daily lives. We've seen masks, social distancing, and washing our hands for 20 seconds or more become part of regular routines, all while we wait for a treatment or vaccine for COVID-19. As we head into the cooler months and the infection rates increase around the country, the biopharmaceutical industry is working around the clock to find solutions.

Hi, I'm Laura Blake, Outreach and Development Manager for Women In Government. Thank you for listening to the latest Women In Government podcast.

On this episode, we're talking about one of the most important topics affecting lives around the world: the outbreak of COVID-19, a disease caused by a novel strain of coronavirus, and where we stand in terms of a vaccine.

Joining the conversation with us today is Julia Worcester, Director of State Policy at Pharmaceutical Research and Manufacturers of America, better known as PhRMA, for the Mid-Atlantic region.

Julia Worcester: Thanks, Laura for having me today. It's a real pleasure to be here with you.

Laura Blake: Now, before we get started, I'd like to thank everyone for listening. Don't forget to subscribe to, like, or share our podcast. You can also email us by visiting womeningovernment.org.

It's been the leading story for most of 2020: the COVID-19 pandemic. According to data from Johns Hopkins University, at least 31 states across the country reported at least one record-high day of new cases in the past month. Medical experts say the worst is yet to come.

Now there is good news and hope on the horizon. America's biopharmaceutical companies are working hard to develop ways to diagnose, prevent, and treat those with coronavirus. The companies are also donating medical supplies, personal protective equipment, existing treatments and medicines, and are providing monetary support to frontline response teams.

Julia, I understand there are a few ways your industry is combating COVID-19. The first is by developing potential new treatments and vaccines. Recent news looks very promising, maybe a vaccine by the end of the year. What has the pharmaceutical industry done so far regarding a treatment or a COVID-19 vaccine?

Julia Worchester: Thanks for asking that question. I know it's at the very top of our minds, and I feel like all of our friends and family are asking these questions every day, especially with the holidays approaching. You know, the good news is across the country, our researchers are working around-the-clock in hopes of finding something that helps states get back to their sense of normalcy, and all of this progress is incredibly promising.

My association, PhRMA, represents the innovative biopharmaceutical industry, and our members have been focused in four areas in terms of our response to COVID-19. The first was on diagnostics - how we determine whether or not someone has COVID. While some may think that our companies are just medicine, several of our member companies stepped up into the diagnostic space. Eli Lilly, for example, based out of Indiana, took one of its own labs to be able to perform testing for locals, first line healthcare responders, and then expanded to the public. Another one of our companies, Genentech, also has a diagnostics division with a successful test to help. So, while that's not the primary focus of our industry, it is something I think that's very interesting when our industry has been so innovative right from the start.

The second area that we were looking into is the vast libraries that companies have of medicines that they've already done the research for, but for whatever reason didn't get approved or that didn't show success in treating what they were originally intended to do. Some of them may be drugs that were already on the market and treating other diseases called existing therapies and over the past several months have shown promise in treating COVID patients that are hospitalized and requiring ventilation or oxygen. Of course, the very first treatment of this type was Remdesivir. This was discovered by Gilead in a previous study for Ebola. So, companies are using this kind of search of their libraries of what might be successful, and again, we're seeing pretty great progress there.

The next area where we've been researching is antibodies, and looking at patients who have successfully overcome COVID, and those antibodies in the body that demonstrate that you have in fact had the virus and successfully fought it. Can we use these antibodies to create a medicine to treat COVID patients while they're sick? The best antibodies are the strongest ones that genetically reproduce, and those that are currently in development, which is exciting because it shows a lot of promise in terms of preventing people from getting COVID in the first place, but also in terms of treating people who have it in the future.

And now our main event, the fourth area that we are working on is vaccine development. Currently, we have 1,706 clinical trials going around the world for this vaccine and treatments for COVID-19. 132 of them are for investigational vaccines, and 1,574 are for investigational therapies. Of those clinical trials for vaccines, there are 40 in phase I and phase II clinical testing, and 11 are in phase III human clinical trials with over 30,000 participants in each trial - spanning a wide range of ages, cultural backgrounds, races, and medical history, in our largest effort in history to get the most diverse population in vaccine trials ever. It's incredibly exciting, and this level of collaboration and engagement across the industry has never been greater.

Laura Blake: Wow, Julia, that is really impressive - especially when you consider that up until the outbreak began, COVID-19 did not exist. The rapid pace at which researchers have been able to understand this strain and get medicines into human clinical trials is a testament to lessons learned from past public health emergencies. Can you provide a little bit more detail as to why the industry was in a good position to take on this challenge and really expedite the search for a treatment or a vaccine?

Julia Worchester: Sure, it's a great question. It's important to note that the industry wasn't caught flat-footed when the pandemic hit, and here are a few reasons why we were uniquely positioned.

The first is the scientific knowledge that is accumulated over literally decades of experience that our companies have had with other viruses, ones you've heard of before: SARS, MERS, influenza, HIV, Hepatitis C. All of that knowledge has been gleaned over a very long time and has helped us improve our likelihood of success in developing a potential vaccine to help address this.

The second reason is the billions of dollars in technologies that the industry has developed and used over time. So, it's shrunk the amount of time it takes now to decode a virus once we know it exists, and then develop a potential vaccine. It's all really new and exciting. And when you think back to SARS, Dr. Fauci has mentioned previously that it was over 20 months from the time scientists recognized the virus of SARS, to when we could actually test it in people. Well, in the case of COVID-19, it was a few weeks to sequence the gene, and then less than four months to decode it, due to technology that's so advanced, so that we can work faster towards a potential vaccine and human testing.

The other area our companies are looking into is how they can partner with others to manufacture and broadly disseminate vaccines and treatments as they come through the pipeline of approval. We know that demand worldwide will be incredibly high, so companies are ramping up production facilities and infrastructure capacity before anything is approved so that there aren't additional delays getting it to people. Right now, companies have also established relationships and contracts with other manufacturers to start producing a medicine that they don't even know will be approved - but if and when it does, they want to be ready when it happens.

So, this is unique that companies would do this - take on such a risk, spending millions on this kind of manufacturing ability, even if their vaccine candidate isn't approved. You know, the story of drug development is that unfortunately, we fail 80-90% of the time. Medicines for a multitude of treatments and diseases are studied, researched, and never even make it to approval or to market, so, it's a huge level of risk. But we have a high level of confidence knowing the seriousness that companies are taking in this process, and they're anxious in rising to that challenge.

Laura Blake: In addition to manufacturing, we're seeing individual companies are developing and deploying their own clinical trials as quickly as possible to test promising, investigational antiviral agents. According to Forbes, most are focusing on the traditional vaccine, which introduces small or inactive forms of the virus to stimulate the immune system, whereas Pfizer, along with BionTech and separately,

Moderna, are testing out novel technology for clinical trials in the manufacturing process. There's a lot of talk about these things right now. Help us to understand some of the timing involved and the process for developing a vaccine or treatment.

Julia Worchester: Sure, this is one of the most talked about issues, and thanks for asking me about it. It's been all over the news, and at times may also seem all over the map. But to take it back a step, most estimates that we've seen is that it takes the FDA 18-24 months for a potential approval of a vaccine, the COVID vaccine, and it's important to put those numbers into context, especially since our state governments will be tasked with dissemination post-approval manufacturing.

There are currently 385 clinical trials investigating therapeutics in 47 states and Washington, DC. 148 of the 385 clinical trials are being conducted in more than one state. Our member companies are laser focused on safety and efficacy of these trials. In the trials, companies are testing multiple sets and types of vaccines concurrently, and that in other times would normally happen consecutively. This pandemic has pushed us to expand the capacity of testing multiple components at the same time, thus shrinking some - not all - but some of the time it takes for development.

We've talked about how much faster we've been able to sequence the COVID-19 virus, with SARS having taken 20 months and COVID-19 taking a few weeks. This helps to ramp up the timing and allows companies to begin to scale up to that clinical trial phase. The tricky part is that we can't always predict how the immune system will react, as it's incredibly complex, which is why we're running these very large scale and longer trials to show that it's not only safe but actually effective in the patients in what it's supposed to do.

As I mentioned before, there's a high rate of failure per vaccine. Typically, only 5-10% of vaccines in development actually succeed, which is why we need as many shots on goal and why we're confident that we will have one. As our CEO Steve Ubl said in his letter to Stat News just before Thanksgiving, our researchers are closely monitoring this data, including any reports of adverse events throughout the clinical trial process, to understand the safety profile of each and every vaccine candidate. For each vaccine candidate to be found safe and effective that receive either approval or emergency use authorization from the FDA, the biopharmaceutical companies that develop them will continue to take steps to ensure product safety, including manufacturing controls that help ensure quality and ongoing oversight, and assessment of adverse events during the clinical trial phase and beyond once it's out in the public.

Because our industry has been working at a furious pace to provide as much timely, accurate, and transparent data as possible, companies have taken unprecedented steps to share clinical trial protocols and trial recruiting updates in as close to real-time as possible. They're sharing data with each other as well as with the public institutions and academia. Information on clinical trials being conducted across the U.S. is also readily available to the public at clinicaltrials.gov.

Laura Blake: So, in the news, we've heard a lot about vaccines being in different phases. Can you describe the four phases of a clinical trial and where we stand right now with a potential treatment or COVID-19 vaccine?

Julia Worchester: Yes, absolutely. As we talked about, there are epidemiological studies and research that's done in advance of any trial, and this is the part that usually takes several years. Like we said, a lot of the virus vaccine background has already been done, but on this novel virus, we had to combine all that.

So, with a trial, once you're in a first trial, the first phase is done on a very small group of people, usually 20-50 people, to evaluate safety, dosage, and to identify side effects. The second phase is when the experimental drug or treatment is given to a larger group, usually around 300 people, to see if it's effective, and further evaluate safety. The third phase is much larger, with a group to confirm its effectiveness - typically around 3,000 people, but in the case of the COVID vaccine trials, this phase has been 10,000 to 30,000 people per trial. This period of time monitors known side effects, compares it to commonly used treatments, and collects information that will allow that experimental drug or treatment to be used safely.

And then there's the fourth phase which is post-marketing studies, which are conducted after a treatment is FDA approved, manufactured, and administered to patients. These post-trial studies will provide additional and long-term information about the treatment, including drug risks, benefits, and best uses.

And you mentioned the Pfizer and Moderna vaccines are showing at 90% effective - this is huge. It goes beyond the minimal standards for the FDA approval. So, this really is incredibly great research that has been happening.

Laura Blake: So, I'd like to ask you a follow up question. You've mentioned safety. What critical steps are being taken to ensure ongoing vaccine safety and effectiveness?

Julia Worchester: Yes, this is the most important topic and something we want to talk about openly, given the pressing need along with the volume of information that remains unknown about the disease. A wide range of approaches are being tested to greatly improve the odds that one or more vaccine candidate will be successful.

No matter the approach, the biopharmaceutical research companies are going to comply with a number of regulations throughout the development process to help ensure vaccine safety. Evaluation of vaccine safety begins in the earliest phases of research, with preclinical trials involving animal and human cells or tissue systems. In that phase, scientists examine whether vaccine candidates produce the outcome they expect as well as look for any signs of negative reactions. If the candidate is successful in preclinical trials, researchers then conduct early clinical trials with the small number of human participants which we spoke about.

If everything goes expected, the vaccine candidate can advance to the longer studies, which are designed to study the safety and efficacy in larger and much more diverse groups of people. Additional clinical trials examined the vaccine in hundreds to even a few thousand people, and as we said in large scale 30,000 participants or more phase three trials.

Vaccines represent some of the most impactful advances in public health, helping prevent the spread of so many infectious diseases and in many parts of the world, eliminating some of the most devastating conditions. In the United States, 16 diseases are now preventable as a result of childhood vaccines, resulting in an estimated $1.4 trillion in societal costs saved and countless lives that have been saved.

Over the years, the biopharmaceutical companies have advanced new technologies that further address safety, including better methods of analyzing the interactions of vaccines and the immune system, as well as improved manufacturing capabilities. This means that biopharmaceutical researchers have specialized skills and experience to navigate this development successfully as they understand the pressing need for a safe and effective vaccine to help combat COVID-19.

Laura Blake: Safety at every phase is crucial when it comes to a COVID-19 treatment or vaccine. This includes after vaccines are licensed. Right now, there are many questions regarding an official rollout.

We've heard what some of the larger states plan to do. At the start, Texas and California will make the vaccine available to first responders and people in high risk categories. New York is planning to set up mass vaccination sites. Governor Cuomo said hospitals, urgent care centers, and pharmacies are among the sites being considered for vaccine distribution.

Julia, based on your experience, how do you see a successful rollout? And when do you think the general public will have access to a vaccine?

Julia Worchester: News released on November 30 shows Pfizer has applied for emergency use authorization, and their hope is to potentially get their very first vaccine candidate out to the public potentially by the end of the year or the first of the year. This is very huge.

The National Academies of Science, Engineering and Medicine (NSEM), or the National Academy, is the collective scientific agency of the U.S. for these types of studies and reports in mathematical, physical and biological studies since the 1800s. At the request of the NIH and the CDC, the Academy has formed a committee that's going to assist policymakers in the states and those large-scale states with their vaccine implementation plans, as well as global health communities and planning for an equitable allocation of vaccines against COVID-19 after the manufacturing phase.

As part of this new study, the committee is going to consider what criteria should be used to set the priorities for equitable distribution among groups of potential recipients, taking into account factors such as population health disparities, individuals at higher risks because of health status, occupation, living conditions, and geographic distribution of the active virus spread like hot spots and hot zones.

In addition, that committee is going to consider how communities of color can be assured access of COVID vaccines in the U.S. and recommend strategies to mitigate the hesitancy among the American public.

Based on the timeline to manufacture and for state governments to partner with local stakeholders, such as local health departments, each state is going to need to budget and develop logistics for dissemination, storage and transportation of large amounts of the vaccine. The good news is that the companies ramped up infrastructure over the last several months so that the deployment to the first line workers - the health care professionals - may start the end of this calendar year if all goes well.

Laura Blake: Sounds like an unprecedented effort and levels of partnership. Responding effectively to a public health emergency requires close collaboration between public and private organizations around the world, not only to share insights, but also to accelerate treatment and prevention strategies. So, I'm curious, how has the pharmaceutical industry worked with the public sector toward a shared common goal?

Julia Worchester: Well, I think as you know, COVID has been a challenge that demands attention from all of us working collaboratively as much as we can if we're going to solve this, and I think the collaboration across the board has been unprecedented. Just as many communities, states, and locals are also coming together - for our organization and our companies, they're competitors in the marketplace - but these competitive interests have been set aside to advance the efforts in combating the virus, and it's really been a team effort.

We've been working closely with U.S. government, global health authorities - that includes everyone at the FDA, NIH, the World Health Organization - and state and local governments as well. We're sharing what we've learned from clinical trials in real time with state governments and other companies so that no one is wasting effort. If we find that something isn't working, we're sharing that knowledge because the goal here is to get something into the market that works, and competition to be first has gone by the wayside in the spirit of public health, and in companies we've talked about earlier, sharing their capacity to ramp up production once we get the medicine or vaccine on the market. This is really important because I don't think any one manufacturer could have this capacity to produce and meet the demand that currently exists.

And as you know, we're also working with government and insurers to make sure that once we get treatments and vaccines available that they're going to be affordable and accessible to patients. So many people are struggling with the economic downturn, and we've seen how states and state budgets are struggling as well, and we want to ensure that what we develop will be accessible, affordable and available. Our companies are committing millions to those direct monetary and income contributions to support our communities around the world battling COVID.

Laura Blake: America's biopharmaceutical companies are already ramping up production capacity in anticipation of the discovery of an effective treatment or vaccine. We're at an advantage due to decades

of scientific research cultivated from experiences with similar viruses, such as SARS and influenza. These previous public health emergencies have helped put the infrastructure and partnerships in place to enable a more rapid response to emerging threats like COVID-19.

Regarding costs, we know that PhRMA has invested a lot in research and development, but what might be expected of states and their residents when a vaccine or treatment is approved and available?

Julia Worchester: Sure, I know folks listening will certainly join me in looking forward to that day when we have an approved vaccine so we can get back to some semblance of normalcy. And obviously, many listening to this podcast are responsible for their state's economic health as well as physical health, and we recognize that there are concerns that exist about access and affordability. We are working to make sure that twin treatments and vaccines are available and that they're affordable for patients.

I would say that if you look at the track record of other pandemic situations, companies have priced the products responsibly. We don't expect there to be an affordability problem at this time, and ultimately, decisions on pricing are made by individual companies. I would note that many companies have already publicly stated how they're donating their existing medicine and focused on making sure vaccines are at an affordable price or distributed at a not for profit basis.

But of course, many patients will be struggling with how they're affording their medicines that they're taking today for things like diabetes, hypertension, or mental health. And our companies are making great strides in enhancing their patient support programs to ensure that patients also get access to the medicines they need now, and will continue to provide support to communities in the states as well. State agencies are doing phenomenal work ensuring patient access to their medications, and I'd also like to mention that we have our website with our medication tool. It's a great repository where people can go to find out information about what programs exist. It's called the Medicine Assistance Tool, and you can find it at mat.org.

Laura Blake: We've definitely seen states taking the lead when it comes to COVID-19. At last count, there were more than 3,200 bills in 52 states and territories related to COVID-19. Based on everything we just discussed, what does all this mean for state policymakers moving forward?

Julia Worchester: Well, we're definitely going to be busy. The recovery from this devastating economic impact of this pandemic will be over the course of many years, and we've seen a lot of that direct impact right now. It's just not going to end anytime soon. Our State Policy and Government Affairs teams as well as our Science and Regulatory Affairs teams have been working with legislators across the country all summer and fall to provide proactive policies to get to some of the underlying affordability challenges that we know so many patients face to ensure that when they go to the pharmacy counter to pick up their medicines. What can we do to reduce the prices there in a way that also balances our ability to continue to innovate?

The U.S. system thankfully has allowed us to be available to address the global pandemic by investing billions of dollars and go all-hands-on-deck, which is incredibly important. We want to continue to do the work with the state legislatures and enact more proactive reforms that would do a better job at helping patients afford their medicines, so we've initiated a platform in many states and in a handful of policy issues, one of which is when our companies is associated with an insurance company over the price of a medicine.

We offer pretty big discounts and rebates to the insurance companies to buy medicines in bulk. Sometimes these rebates don't often make their way to the patient who's picking up their medicine at the pharmacy counter, and if they did get the benefit of those discounts, they'd save a lot of money, oftentimes 50% or more. So, that's an area that we think that is ripe for states to review in 2021 and after the transition at the White House.

If our goal is actually to reduce costs that patients pay, our companies offer direct assistance in the form of coupons to patients who struggle with the cost of one or more of their medications. Also, unfortunately, they don't always count towards assistance in their deductible or getting their maximum out of pocket costs. A handful of states are enacting this legislation, and we really hope that more will happened in the 2021 state legislative sessions.

These are all patient-centered ideas to help those in need, and I thank you for asking this question because it's important to recognize the importance of the entire system and what we have in the US that does encourage innovation and does encourage companies to do the kind of research that they do. It provides incentives and sustains that incredible innovation and progress that we've seen over the last few years.

Laura Blake: So, speaking of incentives, a recent poll from the Pew Research Center finds about 51% of those surveyed would definitely or probably get a COVID-19 vaccine if it were available today. That number is unfortunately significantly less than the 72% who said they would take the vaccine back in April. That just begs the question, what is PhRMA doing to combat vaccine hesitancy?

Julia Worchester: This is definitely something we want everyone in public health and across the broad spectrum of our industry in the medical industry - we want to instill confidence in the potential vaccine or vaccines going into 2021. Incoming president elect Biden has stated that this is first on his priority list when he takes office on January 20. We want to remind the American public that our industry is working around the clock to research and develop safe and effective vaccines to prevent COVID-19. These decades long investments have been made in new technology, research, treatments, and have prepared the industry to act swiftly without cutting corners to respond to this pandemic.

To help assure rapid availability of any future approved or authorized vaccines, biopharmaceutical companies are scaling up that capacity and exploring a whole new world of potential vaccines. All the vaccine candidates will be subject to the same regulatory standards as other vaccines and biological products, including standards for safety, purity, and potency. We want to remind people that COVID

vaccines are being developed through rigorous research and development processes and that the clinical trials are being conducted to meet the highest scientific and ethical standards and will test tens of thousands of subjects. The safety and efficacy of any COVID vaccine will continue to be studied after authorization and approval.

Biopharmaceutical companies are committed to having diversity in participants in clinical trials for these vaccines, including different ages, genders, races, medical backgrounds, and to identify and address potential barriers to enrollment in these clinical trials. And last, the industry is working with governments and insurers to ensure that when it's approved, they will be available and affordable for everyone.

Laura Blake: So, while I've got you here, in the remaining time I'd like to talk briefly about access and what resources are available for patients who are having trouble accessing their medications, especially during COVID. Julia, can you provide any insight on this?

Julia Worchester: Absolutely. As a reminder, America's biopharmaceutical companies are expanding access programs through our assistance programs to help more people with over 950 public and private partnerships through the Medicine Assistance Tool, which is easily accessed at mat.org and is also available in English and Spanish.

PhRMA and Healthcare Ready joined forces at the start of this pandemic and continue to facilitate the financial support and in-kind donations of PPE, medicines, and critical medical supplies. State governments and policymakers can go to healthcareready.org for more information.

And last, for daily updates, go to pharma.org/coronavirus for up-to-date member company efforts, fact sheets, incredible infographics, and information about how the industry is fighting to combat COVID-19.

Laura Blake: Julia, thank you so much for your insights and for being here today. As we're wrapping up the podcast, do you have any key takeaways or closing remarks for us?

Julia Worchester: Laura, it's been such a pleasure and so great chatting with you today. I've personally never been more proud to work for the biopharmaceutical industry during this challenging time because science is how we're going to return to normal together. And together we're all going to combat this virus. Thank you so much for having me.

Laura Blake: COVID-19 caught the average American off guard. However, the biopharmaceutical industry immediately jumped into action based on previous public health emergencies that helped put the infrastructure and partnerships in place to enable a more rapid response to the current pandemic.

As the world continues to feel the impact of the coronavirus, industry leaders are working around the clock to identify and develop a safe and effective treatment or vaccine while also researching and developing new therapies to treat those infected with the virus.

As we wait for an effective treatment, please continue to practice social distancing, wear a mask, avoid handshaking or hugging, avoid crowds and non-essential travel, and work from home when possible.

Once again, I'd love to thank Julia Worcester for providing such great insights with us today. I'd also like to thank all the listeners for taking the time to hear this important discussion. Don't forget to subscribe to, like, or share our podcast. You can also email us by visiting womeningovernment.org.

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444 NORTH CAPITOL STREET NW

SUITE 401

WASHINGTON, DC 20001

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