



House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Leading the Way Forward: Biden Administration Actions to Increase COVID-19 Vaccinations

March 17, 2021

10:00 A.M., Virtual Hearing via Cisco WebEx

Purpose

The purpose of this hearing is to examine the federal government's response to the COVID-19 pandemic and the federal government's procedure for manufacturing, disseminating and administering COVID-19 vaccines.

Key Takeaways

- Witnesses emphasize the integrity of the clinical trials and drug approval processes for the COVID-19 vaccines and the need for public education efforts to address vaccine hesitancy.
- Equitable vaccine dissemination remains a priority as vaccinations are scaled-up.
- More data is required to accurately characterize the long-lasting health effects of the virus in individuals who have recovered.
- There are ongoing studies and clinical trials providing data on new vaccines, the efficacy of remdesivir as treatment, and additional treatment therapies in the pipeline.

Members Present

Chairwoman DeGette, Ranking Member Griffith, and Representatives Pallone, McMorris-Rodgers, Kuster, Dunn, Rice, Burgess, Schakowsky, Long, Tonko, Joyce, Ruiz, McKinley, Schrier, Palmer, Trahan, and O'Halleran.

Witnesses

Rochelle P. Walensky, M.D., M.P.H.

Director

Centers for Disease Control and Prevention

Anthony D. Fauci, M.D.

Director

National Institute of Allergy and Infectious Diseases

National Institutes of Health

Peter Marks, M.D., Ph.D

Director

Center for Biologics Evaluation and Research

US Food and Drug Administration

Opening Statements

Chairwoman DeGette (D-CO) stated that with this hearing, the subcommittee continues its evaluation of the federal government's response to the COVID-19 pandemic. The subcommittee

intends to continue evaluating the current pandemic and ensuring the nation's preparedness for any future pandemics. This subcommittee has held two previous hearings on the COVID-19 pandemic, including state responses and COVID-19 vaccine manufacturers. Today, the subcommittee will hear from senior Biden Administration leadership. 532,000 Americans lost their lives and millions of Americans have lost their jobs due to the pandemic. The Chair has several questions for the witnesses including how the nation can ensure vaccination administration is equitable, what is the status of vaccine research for children, and how will the US will restore the Centers for Disease Control and Prevention (CDC) as a world leader in scientific discovery and voice. The American Recovery Act of 2021 (ARP) will further boost testing and vaccine distribution across the country. The veil is being lifted on COVID-19, but the nation must remain vigilant.

Ranking Member Griffith (R-VA) said just over a year ago, the World Health Organization (WHO) recognized COVID-19 as a global pandemic. According to a New York Times article, one in three Americans have lost a loved one to the virus. However, because of the success of Operation Warp Speed and the efforts from the private sector, there are three vaccines with emergency authorizations from the Food and Drug Administration (FDA). While the vaccine rollout was slow to start, supply and distribution of COVID-19 vaccines have increased. More people have been vaccinated than have been infected with the virus in the US. States have expressed that supply of vaccines has been the greatest barrier to increased administration.

Chairman Pallone (D-NJ) thanked the witnesses for making the time to be with the Committee. Congress has been working hard to expand availability of the COVID-19 vaccine around the country. Last week, President Biden signed the ARP providing additional funding for COVID-19 vaccine distribution. While the vaccine distribution under the Trump Administration was slow due to poor planning, the Biden Administration has made major strides to increase coordination for the distribution of the vaccine. The Administration prioritizes equitable distribution of the vaccine. The ARP also provides funding to support the safe reopening of schools. More than 70 million adults have received at least one dose of COVID-19 vaccine. While the nation is making significant strides in addressing the pandemic, it will take a collaborative effort to reduce the spread of disease.

Ranking Member McMorris-Rodgers (R-WA) thanked the panel for joining the hearing. Regarding the development and distribution of the vaccines, President Biden came into office and inherited a plan from the Trump Administration. As the Biden Administration took office, Democrats continued to spread misinformation about the success of Operation Warp Speed. This model should be looked at for future innovation in healthcare. School closures are having a devastating impact on children. The mental health crisis due to school closures will be a worse pandemic than COVID-19, however schools remain closed. This is unacceptable. Schools remain closed due to fear and politics, not scientific research. Both Dr. Fauci and Dr. Walensky have stated that schools should reopen.

Testimony

Dr. Rochelle Walensky said taking on the role of the Director of the CDC during the pandemic has not been an easy task. CDC staff is tirelessly working to provide guidance to the nation, and

world, during the pandemic. Half a million loved ones have died because of the pandemic. While there have been reductions in deaths and transmission, the nation must continue to be cautious. We are in a race to stop transmission and new variants has made this more challenging. The CDC is scaling up genomic sequencing. As disease transmission is monitored, vaccines are being distributed throughout the nation. As of March 16, more than 110 million doses have been administered, and over 72 million people have received at least one dose of the vaccine. This is a remarkable accomplishment, and yet we have so much more to do. The CDC is working with states and local governments to establish confidence in the public. COVID-19 has highlighted longstanding health disparities, and health equity must remain a cornerstone of the nation's public health work. Since 2009, the US has faced four significant infectious disease events. None of these events have resulted in significant changes in the US public health infrastructure. CDC is leading with science and will continue to be the leading resource for the nation.

Dr. Anthony Fauci said we have made substantial progress leading to the FDA approval for remdesivir which has made a significant improvement in treating patients with severe COVID-19. Other clinical trials have demonstrated effectiveness to improve 28-day mortality of the disease. New research is being done to identify the replication cycle for SARS-CoV-2. Vaccine research for the COVID-19 vaccine began decades ago with investments in critical infrastructure. We now have three vaccines that are highly efficacious and safe. New data about other vaccines will also be made shortly available. The sequence of the virus was made public in January. In July, two of the three vaccines began a phase three trial, and within 11 months, the vaccine was being distributed. Viral variants will be the next hurdle.

Dr. Peter Marks stated all of the FDA efforts are in close collaboration with other federal agencies. With the urgency, the FDA has provided emergency use authorization (EUA) for three COVID-19 vaccines, relying on the agencies rigorous standards for vaccines. Normally, the process for developing vaccines is much slower. These vaccines were developed without cutting corners, and no vaccines were distributed without having undergone thorough evaluation from the FDA and other public experts. The FDA took steps to facilitate transparency. The three authorizations make available vaccines that have clear and compelling efficacy, meeting FDA's standards for safety. All of the vaccines have surpassed the standard of being more than 50% more effective than the placebo. Though there may be some differences among the vaccines, they were not compared to other vaccines. FDA is collaborating with CDC, the Centers for Medicare and Medicaid Services, and other academic and non-government data systems to monitor vaccines. The efforts are in addition to the active monitoring of the manufacturers. These systems can also be leveraged to monitor vaccines in specific populations. In February 2021, the FDA updated guidance documents about the new variants of COVID-19. The agency is pivoting to most appropriately respond and protect the nation as the virus adapts.

Questions and Answers

Chairman Pallone emphasized that when being critical of the Trump Administration, the criticism comes from his experience of the Administration. When engaging with Operation Warp Speed leadership, states were leading the efforts. In contrast, the Biden Administration is leading with more of a national coordinated effort. **Chairman Pallone** asked how the ARP funding for public health infrastructure and schools will speed up the distribution of vaccines and support

schools reopening. **Dr. Walensky** stated the CDC is working with the states to organize grants for community organizations. The agency has also provided resources to urban and rural communities and is scaling up vaccine efforts with a focus on equity. The CDC is distributing resources to schools to increase space, testing and ventilation. **Chairman Pallone** asked how funding supports FDA development and monitoring of COVID-19 vaccines? **Dr. Marks** said database surveillance systems will be used to assess the safety and effectiveness of vaccines. **Chairman Pallone** asked when younger children be vaccinated and how this impacts spread? **Dr. Fauci** said studies are currently being conducted for high school and school-age children. The trials must demonstrate the vaccine will provide an appropriate immune response. Dr. Fauci anticipates high school students will likely be able to be vaccinated in the fall prior to the start of school and younger children will be vaccinated early in 2022.

Ranking Member Griffith said President Biden has announced adults will be eligible for vaccinations in May. He asked what the barriers are for actually meeting the goal of vaccinating those that want the vaccine. **Dr. Walensky** stated though there are numerous barriers, there will be an adequate supply of vaccines for adults by the end of May. The nation needs vaccinators, places where people can be vaccinated, and the public must want to get vaccinated. **Ranking Member Griffith** stated there are differences in approval for vaccines, specifically the AstraZeneca vaccine. The Administration is stockpiling the AstraZeneca vaccine, he asked how old the stockpile is and if it will expire. **Dr. Fauci** said in Europe, many countries do not want to use the AstraZeneca vaccine, however scientists believe the issue is not with the adverse events of blood clotting, and the vaccine should be used. In April, there will likely be enough data to approve the vaccine in the US. **Ranking Member Griffith** stated 17 million doses have been administered and 0.002% had blood clotting, he asked if this is unusual. **Dr. Fauci** stated this is correct, the presence of clotting is not more than you would anticipate in the general population. **Dr. Marks** stated the FDA does not necessarily have an expiration date for vaccines being held in stability studies. The FDA anticipates the vaccine would be available for Americans.

Chairwoman DeGette said pandemic preparedness is an important issue for the nation. She asked how Congress could aid in vaccine distribution efforts. **Dr. Fauci** said we are still in the middle of a serious outbreak. He is concerned we will prematurely pull back on prevention methods. We have plateaued at 50,000 new cases a day. In the future, his concern is that the nation does not appropriately remember the impact and preparedness to prevent a future similar outbreak. Many of the successes of the vaccine is due to support from Congress. **Chairwoman DeGette** said over the last Congress, a number of the CDC's recommendations were subverted or influenced by non-science based principles. She asked how the CDC is restoring the importance of scientific evidence. **Dr. Walensky** stated the CDC is working to ensure all guidance follows scientific requirements. **DeGette** asked how new variants will impact need for booster vaccines. **Dr. Marks** stated as new evidence is gathered, the FDA will ensure vaccines protect against new variants. Additionally, the FDA is monitoring how trial participants maintain protection from the virus to help inform when a new booster may be required. The agency is beginning to get new readouts from databases about the safety of data, which is already being made available.

Ranking Member McMorris-Rodgers stated mental health issues are surging among young Americans. She asked if the mental health crisis is a public health crisis. **Dr. Walensky** stated that she agrees that mental health challenges presented by the pandemic are serious and must be addressed. **Ranking Member McMorris-Rodgers** stated that numerous studies and scientific bodies have stated that three feet of distance is appropriate. Six feet of separation is a significant barrier for school reopening. **Dr. Walensky** stated that CDC guidance is intended to lean-in in how Wisconsin schools are acting and that students are less likely to wear masks correctly. In Massachusetts, three feet of distance was acceptable to prevent the spread of COVID-19 when there is appropriate mask wearing. The CDC is looking to update guidance and looking to do it soon.

Rep. Kuster (D-NH) stated long hauler COVID-19 is a significant issue, infections that persist with COVID-19 for several months. The medical costs and testing for these patients is significant. More than 50% of COVID-19 patients experience lingering symptoms for more than 90 day after initial exposure. She asked what is known about long COVID-19. **Dr. Fauci** said these are people whose symptoms are real. Several common symptoms persist including profound fatigue, tachycardia, brain fog and irregular temperature. The National Institutes for Health (NIH) has appropriated \$1.15 billion to study the underlying cause and pathogenesis of long COVID-19. **Rep. Kuster** asked if the CDC is also working on long COVID-19. **Dr. Walensky** stated the CDC is in collaboration with the NIH working on gathering more data.

Rep. Dunn (R-FL) stated the early actions from the Trump Administration led to the current success, and the Biden Administration built on the successes and have delivered on increased vaccine distribution. He supports nationwide opening of schools. The medical community must better understand the COVID-19 immunity. He asked if there are changes in travel recommendations for those who are vaccinated. **Dr. Fauci** stated the CDC has released preliminary recommendations about fully vaccinated individuals. **Dr. Walensky** stated conversations for travel recommendations are in the beginning stages. **Rep. Dunn** stated dialysis patients are the most vulnerable, and have been overlooked in the prioritization of vaccinations. He asked the witnesses to address this population. **Dr. Walensky** stated the CDC is working on a program to target dialysis patients.

Rep. Rice (D-NY) asked how current investments will build back a more resilient public health infrastructure. **Dr. Walensky** stated that over 50,000 public health jobs have been lost over the past decade. Part of the public health infrastructure is in the workforce. Additionally, the US needs to develop epidemiological databases and to develop public health labs. **Rep. Rice** stated there is vaccine resistance that must be addressed. She asked how we can address vaccine hesitancy and fears. **Dr. Fauci** stated the agency has been engaging with communities to identify concerns and explain the facts about the vaccine. The Administration is explaining the approval of the vaccines is informed by independent scientists. **Rep. Rice** asked if the agency is aware of the long-term health implications for COVID-19. **Dr. Fauci** stated there are two types of long-term concerns, those that have long-term symptoms, or those that have significant organ damage and dysfunction.

Rep. Burgess (R-TX) asked if Operation Warp Speed was a national effort. **Dr. Fauci** stated it was a national effort, a collaboration among numerous agencies. **Rep. Burgess** asked how Congress can alleviate vaccine hesitancy. **Dr. Fauci** said, through the ARP, additional funding is important to ensure appropriate distribution of vaccines. On the public relations side of vaccine hesitancy, if members of congress are vaccinated publicly, it could help with vaccine hesitancy. **Rep. Burgess** asked about the purchasing contracts with manufacturers. **Dr. Fauci** stated there was an option to purchase additional vaccines. **Rep. Burgess** asked Dr. Walensky about the vaccine distribution and spending plan and if it was modeled after a plan developed in October 2020 by the Trump Administration. **Dr. Walensky** said there are similar concepts considered at the CDC in 2020 and as well as what was considered in 2021. Vaccine hesitancy is not one thing, there are many different kinds of vaccine hesitancy. To address hesitancy, we must understand how to best address the different types of hesitancy.

Rep. Schakowsky (D-IL) said there is a looming crisis that has not been sufficiently addressed. As long as the virus flourishes everywhere, it will remain a threat. Progress on vaccination has been widely uneven across the world. **Dr. Fauci** said this is critically important to the worldwide effort to stop the spread of COVID-19. Once the US is vaccinated, efforts will be made to share vaccine surplus with other countries.

Rep. Long (R-MO) said additional transparency about the distribution of the vaccine to states is needed. He asked what the current process is to community with states about distribution. **Dr. Walensky** stated the Administration is hosting a weekly call with state governors about the state of the pandemic and the distribution plan. States have three weeks lookout about the number of vaccine distribution. **Rep. Long** asked what the CDC can do to increase transparency for states and what the CDC is doing to ensure rural communities have access to the vaccine. **Dr. Walensky** stated the CDC is working with states to ensure they know how vaccines are distributed. The CDC is investing significant funding to ensure equitable distribution of the vaccine. The federal pharmacy program is distributing vaccines in hard to reach communities. Most Americans live within 5 miles of pharmacies.

Rep. Tonko (D-NY) stated vaccines in vials do not protect people. He asked when we can expect all American adults to be fully vaccinated and achieve herd immunity. States are responsible for administering vaccines, he asked how the Administration is directing states to prioritize certain populations. **Dr. Walensky** said it will be determined based on how eager Americans are in getting vaccinated. The agency is investing in educational programs to inform Americans about the need to be vaccinated. **Dr. Fauci** said whatever vaccine we can get to people, will be critical. We do not know about how many Americans it will require to reach herd immunity. **Rep. Tonko** asked about the impact of herd immunity and vaccinating children. **Dr. Fauci** reiterated that the US should focus on vaccinating as many people as possible. **Rep. Tonko** asked about the Administration's plan about the surplus of vaccines. **Dr. Marks** said there may be some concern about giving boosters and having adequate supply of vaccines. There may be some wisdom in having some supply on hand in the US.

Rep. Joyce (R-PA) asked Dr. Fauci to expand on innovation of intranasal vaccines and if they should be considered for the next generation of vaccines. **Dr. Fauci** said there has been interest

in these types of vaccines for respiratory vaccines. There is research already being conducted with support by the NIH. **Rep. Joyce** asked if we should evaluate less invasive vaccines to support vaccination of children. **Dr. Fauci** said the NIH will be pursuing alternative methods of vaccine for SARS-CoV-2, as well as other vaccines.

Rep. Ruiz (D-CA) said the vaccination rates among white people is much higher compared to minority populations. He applauds the Biden Administration for the focus of equity on the pandemic response. Equity requires prioritizing high risk people and vaccinating these people in the community. He asked what the plan is to ensure vaccines are distributed in communities hardest hit and not just low-risk affluent communities. **Dr. Walensky** said the pharmacy group within the CDC has great connection with the pharmacies. The CDC is collaborating with those pharmacies to ensure the vaccinations are reaching the vulnerable communities.

Rep. McKinley (R-WV) said that President Biden stated that everyone should wear masks until everyone is vaccinated. He asked if Dr. Fauci agrees with this statement. **Dr. Fauci** said he is unaware of the statement from President Biden. **Rep. McKinley** said 288 children have died from COVID-19. The spread of the virus in schools is minimal with appropriate protective measures. He asked if the CDC will update school reopening guidelines this week. **Dr. Walensky** said the CDC has published guidance to reopen, and schools that are currently open and doing well should not close. **Rep. McKinley** said thousands of people gathered last year to protest racial injustice. Many public health professionals supported the protest. He asked Dr. Fauci if he agreed with these statements. **Dr. Fauci** said he recommends people follow the standard public health guidelines at all times.

Rep. Peters (D-CA) said equity is a key tenant of the Biden Administration's COVID-19 strategy. He asked Dr. Walensky to explain how vaccination centers are determined. **Dr. Walensky** said the CDC works collaboratively with the Federal Emergency Management Agency to identify areas of high census and high social vulnerability and the amount of vaccine that can be supported and distributed. **Rep. Peters** said he is concerned about the quality of data that is being produced, and there is no standardization from state to state. He asked what guidance the CDC has developed for state and local governments to report data. **Dr. Walensky** said the data infrastructure was insufficient at the beginning of the pandemic. The CDC is working with states to unify the data coming in to support the pandemic response. The CDC does not receive individual line item data, the privacy of data is held at the state-level.

Rep. Schrier (D-WA) said, as a doctor, she recommends patients take any of the vaccines that are available. She asked Dr. Fauci if he agrees. **Dr. Fauci** said he vehemently agrees. All three are superb at preventing hospitalizations and deaths. **Rep. Schrier** said with variants, there are concerns the virus can get ahead of the vaccines. She asked if at-home testing is an important tool in the pandemic response. **Dr. Fauci** said he agreed and effective tests should be readily available and distributed across the nation. **Rep. Schrier** asked how home testing could not only help schools open safely, but also stay open. **Dr. Walensky** said there is less transmission among children. Once we have teachers vaccinated, testing in the schools can be used to identify potential infections and keep schools open. **Rep. Schrier** asked the witnesses to agree to coordinate and collaborate to get at-home tests in homes. The witnesses all agreed.

Rep. Palmer (R-AL) said nasal vaccines should be prioritized for development because the vaccines do not have storage requirements and are often more easily administered. He asked if trials for such vaccines are part of Operation Warp Speed. **Dr. Fauci** said Operation Warp Speed does not include these vaccines, the clinical trials receive funding from the NIH or CDC.

Rep. Trahan (D-MA) said the impact of COVID-19 on children must be better understood. Earlier in this hearing it was indicated that high school students may be vaccinated in early fall. She asked Dr. Walensky to expand on what parents need to know about risk of transmission for children. **Dr. Walensky** said as we want to lean in to day-to-day activities, it depends on how much disease is in the community. As community transmission is lowered with increased vaccination rates among adults, in conjunction with testing measures, schools will become safer for children. **Rep. Trahan** said there is a need to strengthen mental health resources for youth. She asked what efforts are underway to understand and respond to youth mental health challenges. **Dr. Fauci** said the National Institute of Mental Health is taking this issue very seriously.

Rep. O'Halleran (D-AZ) said the vaccines gives America hope. Looking forward, the nation must be ready to respond to other variants. In the ARP, Congress allotted \$1.7 billion to the CDC for SARS-CoV-2 sequencing and surveillance. He asked the witnesses as a Congress to start looking at preparing for future public health responses. **Dr. Fauci** said one of the things Congress has already done with the ARP, is investing in response planning that will benefit the nation in responding in future pandemics.