



U.S. Senate Committee on Health, Education, Labor & Pensions
Examining Our COVID-19 Response: An Update from Federal Officials
Thursday, March 18, 2021
10 a.m., 216 Hart Senate Office Building

Purpose

The purpose of this hearing was to hear from federal public health leadership about current vaccination efforts, increasing vaccine confidence, and recently released CDC guidance relating to vaccinated individuals.

Key Takeaways

- Getting individuals vaccinated with any FDA authorized vaccine is still the top public health priority.
- Vaccine hesitancy could be the biggest hurdle to achieving herd immunity and is a major concern in the next 30 to 60 days.
- The CDC will continue to issue guidance on vaccinated individuals, safety standards for school re-openings and travel guidelines.
- Long-term, officials are focused on monitoring variance in the virus to ensure that the vaccines developed, authorized and eventually approved remain effective.
- Strategies to achieve equitable vaccination include placing vaccine sites in disproportionately impacted communities and increasing the number of people able to vaccinate individuals.

Members Present

Chairman Murray, Ranking Member Burr, Senators Baldwin, Paul, Murphy, Collins, Kaine, Cassidy, Hassan, Murkowski, Casey, Braun, Smith, Marshall, Rosen, Tuberville, Moran, Lujan

Witnesses

Anthony Fauci, MD, Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health

David Kessler, MD, Chief Science Officer, COVID-19 Response, United States Department of Health and Human Services

Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, United States Food and Drug Administration

Rochelle Walensky, MD, MPH, Director, Centers for Disease Control and Prevention

Opening Statements

Chairman Murray (D-WA) said the committee had its first meeting with federal officials a year ago and since then, the difference between the administrations' responses to COVID-19 is obvious. The efforts from the current administration have been progressing and now the nation is looking to make everyone eligible for vaccines by May 1. The federal government needs to increase vaccine distribution equity as well as address vaccine hesitancy. Further, Congress

needs to support home and community based services and community health centers and ensure that the recently passed investments strengthen in the long term. Right now, Congress needs to focus more on vaccine accessibility for vulnerable communities such as communities of color, rural communities, disabled communities and seniors. That's why it is important to pass the Public Health Infrastructure Saves Lives Act to help the country build back stronger. It is important that this committee continues to hold hearings, talks to experts and work across the aisle to keep families and communities safe from future emergencies.

Ranking Member Burr (R-NC) said continuity will be critical to move forward. America needs to reopen schools and businesses and open global commerce. The recent reports about the CDC's testing is wrong and furthers where collaboration needs to be supported. As such, it is important that our government leans on private partnerships like Roche to have access to rapid diagnostics and to create a new surveillance system that couples traditional de-identified data with other data like weather patterns to get a true picture of the threats on the ground. The CDC should not hoard the money provided through COVID-19 relief legislation and it should not build internal systems for them to turn obsolete. While previously working with Dr. Fauci in NIH, the agency cast the widest net possible to have access to innovation, which is what the country needs to do today. Moving forward, the country needs to focus both on what is known and what is not known. The pandemic has altered the model at the FDA and the agency should not go back to its previous approach. The Emergency Use Authorization (EUA) standard calls for the benefit to outweigh the risk. The FDA should take the opportunity to use real world information to respond to the drug applications that will be coming to its desk. Operation Warp Speed, now called The Operation, was and continues to be a huge success and needs to be supported. It has been remarkable to see the private sector to partner with their competitors to make vaccines. These practices need to be upheld in the future.

Testimony

Dr. Anthony Fauci said the NIH has had a four step strategic plan: improve fundamental knowledge of COVID-19; develop diagnostics and assays; characterize and test therapeutics; and develop safe and effective vaccines. The future of therapeutics relies on identification of the virus. The country did develop vaccines very quickly but the true development started decades ago in NIH with a larger number of grantees to study new vaccine platforms. Moving forward, there needs to be strong partnerships between the government and the private sector. The new variants are very concerning but can be countered in two ways: first, vaccinations through maximizing immune response against wildtype virus and boost with variant-specific vaccine and second, public health measures such as masks, keeping distance, avoiding congregate settings, and washing hands.

Dr. David Kessler said the strength of private partnerships should continue to be supported. There are three critical initiatives HHS has been focusing on. First, there is a need to evaluate the data on the safety and effectiveness of vaccines in adolescents. Second, questions about variants must be addressed. Third, further research address questions about possible booster vaccinations for the future need to be supported. Studies are underway to ensure that there will be an adequate supply of booster vaccines prior to there even being a need.

Dr. Peter Marks said with the urgency called for, the FDA has authorized emergency use for three vaccines based on the agency's standards for safety and effectiveness. The agency has been working on promptly approving new products. The FDA also recently approved new temperature storage requirements for the Pfizer vaccine. The FDA has been working with the CDC, CMS, VA, and other academic and non-governmental agencies to be successful. The systems that are currently being used could be leveraged to track safety of products.

Dr. Rochelle Walensky said that while there has been a decrease in deaths, the country needs to stay cautious. There have been increased efforts to rapidly scale up sequencing to respond to the new COVID-19 variants. Further, the CDC has been focused on evidence-based approaches to reduce cases and deliver an equitable response. Since 2009, the country has faced four significant public health threats. While urgency demanded quick responses, none resulted in long-term changes. If the country doesn't act with permanent fixes, it will face another public health emergency unprepared. The CDC has had four goals during the pandemic that have been the foundation of its response efforts. First, the CDC leads with science. Second, the agency strives to expand the reach of lifesaving vaccines and improve vaccine confidence. Third, health equity must be at the intersection of everything we do for public health. Fourth, there must be sustainable public health infrastructure funding.

Questions and Answers

Chairman Murray asked what the biggest challenge ahead is. **Dr. Fauci** said it is multifaceted, but the biggest issue is staying ahead of the virus itself by vaccinating people as quickly as possible. **Chairman Murray** asked how the CDC is encouraging citizens to get vaccinated. **Dr. Walensky** said there is a need to understand why people are vaccine hesitant. The CDC held a vaccine forum recently with community leadership to all share approaches and best practices. **Dr. Kessler** said we are quickly moving into an issue of having too much supply and too little demand. The country is approaching 100 million shots in arms, which is a remarkable number. Leadership needs to continue to confidently say to the American public these are safe vaccines.

Ranking Member Burr asked if the country can reach herd immunity without vaccinating children. **Dr. Fauci** said it is unknown where that magical point of herd immunity is, but if the majority of the country is vaccinated, herd immunity can be reachable. **Ranking Member Burr** asked what the biggest challenges in the next 30, 60, and 90 days are. **Dr. Kessler** said that within the context of the next 30 to 60 days, the biggest barrier will be vaccine hesitancy. **Ranking Member Burr** asked what steps the FDA is taking so products passed under emergency use don't have to be reapproved in the future. **Dr. Marks** said for the first couple of variants, the FDA will need clinical studies, but it is possible that once the Agency understands how these perform, it may not need studies for people. **Ranking Member Burr** asked if Dr. Walensky could understand why were the American people confused when it took 3 months for CDC to issue guidance for vaccinated people. **Dr. Walensky** said the CDC has been working at a speed that correlates with accurate science, and as more people get vaccinated, more guidance will be released. Additionally, there needs to be an understanding that as the country has more transmissible variants, the target for herd immunity changes.

Sen. Baldwin (D-WI) asked how the CDC is using the \$1.7 billion from American Rescue Plan to respond to new variants and how many positive test samples ought to be sequenced to have a

firm grasp on variants. **Dr. Walensky** said from the original 2,000 samples, the agency is now testing up to 10,000 a week for sequencing. The additional \$1.7 billion is essential to fund jurisdictions to have sequencing capacity and to scale up the CDC's own capacity. **Sen. Baldwin** asked what the early obstacles were that made the FDA have an over-reliance on international partners. **Dr. Marks** said there was a critical shortage of supplies to make vaccines. Learning for the future, the country needs to rely on more advanced technologies. **Dr. Kessler** said the BARDA team has been searching the globe for supplies. In the American Rescue Plan, there is a specific provision to enhance the ability to have adequate supplies prior to the needing them. **Sen. Baldwin** requested a report on the Strategic National Stockpile.

Sen. Paul (R-KY) asked what specific studies can be cited that say the public should be wearing masks until 2022. **Dr. Fauci** said that when talking about infection, the conversation must always include the growth of variants, which dissolves immunity memory. Wearing masks protects the public from the risks of new variants. **Sen. Paul** asked if wearing a mask is theatre and why the NIH is making policies off of conjecture. **Dr. Fauci** said when a person gets infected from the wildtype, the original variant, they will only have antibodies for that specific variant. When someone is infected by new variants, it is almost like they have never been infected before.

Sen. Murphy (D-CT) asked what the differences is between Pfizer and AstraZeneca to pursue a non-profit model. **Dr. Kessler** said it is confusing and can affect pricing. **Sen. Murphy** asked why the vaccine price may be 3 to 4 times higher than they are today and said that the companies' contracts should be disclosed. **Dr. Kessler** said the President believes very firmly in affordable vaccines.

Sen. Collins (R-ME) said the CDC needs to push for open schools now. **Dr. Walensky** said it is urgent, but the country needs to proceed with caution. A study in Wisconsin noted that with 92% of students and teachers wearing masks and lowering the number of children in the classroom, schools can reopen. The guidance specified that schools that are doing well should continue to be open while schools that are closed should work to find a strategic plan.

Sen. Kaine (D-VA) asked how the committee should be investing in the response for the two long-term consequences of COVID-19: the mental health pandemic and the long-term health impacts of those who were infected with the virus. **Dr. Fauci** said for long-term health effects, NIH has invested over \$1 billion on behalf of Congress to study these effects. **Dr. Walensky** said cohort studies need to be supported for both issues.

Sen. Cassidy (R-LA) asked if a surrogate marker can be identified in infected individuals to showcase that they are protected from the virus, specifically since testing on kids may not showcase antibodies since kids are not susceptible to infection. **Dr. Fauci** said there are current efforts to collect data from trials in adults to find a marker. Since COVID-19 is different, leadership must take precautions when comparing it to influenza.

Sen. Hassan (D-NH) asked how the federal government will partner with states to ensure access to vaccines for those with disabilities and older adults. **Dr. Kessler** said increasing the number of access points and increasing the number of vaccinators and working on the information systems

is the best approach. **Sen. Hassan** asked if there are additional steps that should be taken now to ensure Americans have timely access to boosters and have the knowledge of the importance in taking them. **Dr. Kessler** said there has to be a plan to meet the varying needs of people and the country needs to make sure there are enough vaccines. **Dr. Fauci** said that, considering the degree of variability for vaccinations, the minimum cut off where individuals absolutely have to start getting boosters is unknown yet. The NIH has to follow vaccinated people for months to track the strength of antibodies.

Sen. Murkowski (R-AK) asked for guidance on how the CDC order relates to the conditional order. **Dr. Walensky** said this decision is an interagency decision and the process for studying reopening is moving forward. **Sen. Murkowski** asked how to address those who are against vaccinating. **Dr. Walensky** said it is important to further understand why individuals are vaccine hesitant and the CDC will release additional guidance as more individuals are vaccinated. In the context of travel, last week was the busiest travel week since before the pandemic and the agency is actively looking at releasing guidance on how to travel safely.

Sen. Casey (D-PA) asked if federal agencies commit to making vaccine distribution transparent for states and local health department. **Dr. Walensky** said The Operation is responsible for deciding how many vaccines are distributed. Governors now have three weeks to prepare for the number of vaccines they will receive. **Dr. Kessler** said the Administration has committed to transparency. **Sen. Casey** asked how the challenges for the future are ranked. **Dr. Fauci** said the first concern is declaring victory prematurely.

Sen. Braun (R-IN) asked if attention needs to be turned to therapeutics if the vaccinations aren't as effective as previously thought. **Dr. Fauci** said the magical terminology of herd immunity could be reached without meeting the arbitrary percentage but it depends on many variables. It is important to focus on how every day there are 2 to 3 million more people vaccinated. It isn't necessary to reach 85% herd immunity for the population to return to normal. **Sen. Braun** asked if it's 2 to 3 million or 4 to 5 million that need to be vaccinated. **Dr. Fauci** said there is no plan right now, but the agency is working on it. **Dr. Marks** said getting to high antibodies levels will mean the country is not decimated by another variant. **Sen. Braun** asked if therapeutics should be prioritized over vaccines. **Dr. Marks** said for a global pandemic, vaccinations need to be prioritized. **Dr. Fauci** said the idea of prevention that has been used for HIV isn't applicable to a virus such as COVID-19.

Sen. Smith (D-MN) asked how to address the challenges of equitable distribution of vaccines. **Dr. Walensky** said the CDC had a vaccine forum a few weeks ago to establish trusted partnerships for vaccination efforts with community members. **Sen. Smith** asked how to address individuals who are shopping for a specific vaccine dependent upon effectiveness rates. **Dr. Fauci** said all three vaccines have high efficacy rates. It isn't appropriate for consumers to shop around for a specific vaccine. The most important thing is to get vaccinated as quickly as possible. The particular kind isn't necessarily relevant.

Sen. Marshall (R-KS) asked how to get kids back into schools. **Dr. Fauci** said the most important thing to do is to get children back into school safely. **Sen. Marshall** asked if the benefits outweigh the risks. **Dr. Fauci** said the recent CDC guidance is focusing on just that.

Sen. Marshall asked if leadership is comfortable with what is going on at the border. **Dr. Fauci** said NIH isn't aware of what is going on at the border. **Dr. Walensky** said the CDC is aware of Customs and Border Protection site density issues and the agency is providing technical guidance to make sure they are as safe as possible.

Sen. Rosen (D-NV) asked if people are dying because they do not have access to therapeutics. **Dr. Fauci** said therapeutics are for early disease, but there is logistical difficulty in getting people early enough for the therapeutics to work. **Sen. Rosen** asked how NIH is evaluating the troubling long-term health consequences of COVID-19. **Dr. Fauci** said NIH is using \$1.15 billion to follow cohorts of individuals to determine long-term effects. Too much is still unknown about the underlying pathogenic mechanism to devise effective therapeutics.

Sen. Tuberville (R-AL) asked for true feedback from the witnesses since both politicians and citizens know very little about how to respond to COVID-19. He said the feedback and guidance need to be consistent. **Dr. Fauci** said that when staying consistent, it is important to remember that recommendations are given based upon what is going on in the present moment. Therefore, the recommendations may change with the situation.

Sen. Moran (R-KS) asked if the NIH's other responsibilities have stayed strong during the pandemic. **Dr. Fauci** said things aren't exactly the way they were prior to COVID-19, largely within the clinical setting, but the agency is working hard to ensure all projects are not slipping. **Sen. Moran** asked for the CDC to create timely guidance for vaccinated people. **Dr. Walensky** said vaccinated people can visit with unvaccinated people as long as they aren't within a high-risk group. A vaccinated individual doesn't have to quarantine if they have been exposed to an infected individual. Guidance for travel will also be coming forward soon.

Sen. Lujan (D-NM) asked if wearing masks will help stop the spread of infection. **Dr. Fauci** said it would. **Sen. Lujan** asked how to increase the country's equitable response. **Dr. Fauci** said having community vaccine centers that are represented by vulnerable communities and increasing the number of vaccinators. **Sen. Lujan** asked how to use the Social Vulnerability Index (SVI) as a mechanism to address vaccine disparities in collaboration with FEMA. **Dr. Walensky** said the CDC is in partnership with FEMA and is using SVI to collected data but more efforts need to be done.

Chairman Murray (D-WA) asked for an update on the FDA authorized vaccines and therapeutics for children. **Dr. Marks** said all three manufacturers have or are starting trials on adolescents, so there is hope that the younger population will be vaccinated by fall. **Chairman Murray** asked what the CDC doing to stream data reporting and to ensure data points on race and ethnicity is accurate. **Dr. Walensky** said the organization is working to increase data collection. Previously, some states had data use agreements that did not allow them to collect racial data points. Additionally, many citizens do not report the race and ethnicity information so the agency is looking to make the race and ethnicity question mandatory. Electronic case reporting forms have been doing better to connect vaccine reports to their medical record, a process that is occurring in Cerner and Epic.