



Senate Committee on Health, Education, Labor, and Pensions

An Update from Federal Officials on Efforts to Combat COVID-19

May 11, 2021

10:00 A.M., 106 Dirksen Senate Office Building

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Purpose

The purpose of this hearing is for the Senate Committee on Health, Education, Labor, and Pensions to examine the current updates and guidance on COVID-19 from federal officials from the NIH, CDC, FDA, and HHS.

Key Takeaways

- The deadly outbreak in India is a reminder of the impact of COVID-19 variants. A strong public health infrastructure supported by both public and private entities is necessary to ensure proper preparedness and emergency response.
- Policies that protect intellectual property were key in the rapid development and production of COVID-19 vaccines were. Innovation must continue to be supported to ensure the country's preparedness.
- The FDA's continued rigorous oversight of manufacturing facilities is essential to ensure quality and safety of vaccine production.
- Bolstering outreach and public health messaging can improve vaccine hesitancy to get the country to herd immunity. Closing gaps in information and data collection is necessary to maintain public confidence in federal agencies, especially when issuing guidance on outdoor mask mandates, indoor social distancing measures, school re-openings, and summer camp openings. Consistency and clarity is key to building confidence.
- While there has been an increase in vaccine confidence amongst marginalized and vulnerable communities, health equity will continue to be at the forefront of all COVID-19-related initiatives.

Members Present

Chairwoman Murray, Ranking Member Burr, Senators Paul, Casey, Collins, Baldwin, Cassidy, Murphy, Kaine, Murkowski, Braun, Hassan, Marshall, and Rosen

Witnesses

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

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

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

Rochelle Walensky, MD, MPH, Director, United States Centers for Disease Control and Prevention, Atlanta, GA

Opening Statements

Chairwoman Murray (D-WA) said over half the adult population has gotten at least one vaccine dose and communities are working to safely reopen. Even if they are encouraged by the progress, more work lies ahead. To truly end the pandemic, vaccines must be widespread. Data shows that vaccinations are lagging in some areas, especially in marginalized communities. They must address systemic inequities and everyone must have the opportunity to get vaccinated. There is also a slowing of vaccination rates and they must ensure people are getting reliable information on vaccines, especially from voices they trust. The Biden administration continues to release funds from the American Rescue Plan to strengthen the response, especially for supporting community-based workforces and rural areas. They must also acknowledge that this is also a global fight. The deadly outbreak in India is a heartbreaking reminder of the danger of viral variants and overwhelming healthcare systems. These moves will save lives in India and around the world. The country must be prepared for the next Public Health Emergency and ensure capacity for emergency response.

Ranking Member Burr (R-NC) said there have been many lives lost and shutdowns have impacted the lives of Americans. Now more than ever, there is reason for hope. The Centers for Disease Control and Prevention (CDC) projects declines in deaths and hospitalization rates. Manufacturers were able to produce vaccines and are able to produce them for countries in need. Industry answered the call to bring these life-saving products. Now, the Biden administration has agreed to just hand this property over. There is a way to operate without impacting innovators of the vaccine. Waiving intellectual property rights will undermine innovation and will leave the country less prepared. This information can be used to predict the road ahead and now, supplies are starting to exceed demand. Addressing vaccine hesitancy is important. They must reassure Americans that vaccines are safe and they save lives. The framework has always been flexible, and it must be kept this way.

Testimony

Dr. Rochelle Walensky said the dedicated professionals at the CDC have been working diligently to update guidance based on the latest scientific evidence. She is pleased to report to downward trends in hospitalization and deaths. These trends are hopeful and they must remain diligent on the surveillance and prevention efforts. Since January, they

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have increased genomic sequencing and are prioritizing health equity. Investments are centered on health equity. In addition, CDC continues to update guidance to be clear that vaccines will help life return back to normal. With these cases trending down and vaccinations increasing, they are cautiously optimistic. However, countries are suffering and they will not end this pandemic without working with other countries to fight COVID. She said the CDC will continue to follow the science and encouraged all people to get the vaccine.

Dr. Anthony Fauci stated they have a strategic plan to combat the pandemic. He will focus on the issue of vaccines. The decades of investment in biomedical research led to the extraordinary feat of rolling out vaccines so quickly. The clinical trial network set up decade ago from influenza and HIV set up the infrastructure for this vaccine rollout. The real world effectiveness is even more impressive than the results of clinical trials. Many studies showed that the mRNA vaccine has been highly effective in individuals and can protect against variants. The goal of 70% adults receiving the vaccine is an attainable goal. They are in a race between the vaccine and the virus. Based on experience, he feels confident that the country can return back to normality.

Dr. Peter Marks said that the Food and Drug Administration (FDA) announced the expansion of the Pfizer vaccine to include adolescents as young as 12 years-old. The FDA also evaluated cases of COVID amongst adolescents and found that the vaccine was effective in preventing illness. They plan to convene a meeting on June 10, 2021, to provide a status update on the Emergency Use Authorization (EUA) for individuals 12-17 years of age, as well as to discuss data needed to support an EUA and a full Biologics Licensing Application for children younger than 12. They continue to work with partners to work on critical priorities. Recently, the surveillance systems have detected blood clots and thrombosis in some vaccinated individuals, and the FDA modified this accordingly. They will continue to monitor the safety of vaccines, as well as tackling the emergence of variants. Working with partners will help administer booster vaccines, if needed. Additionally, moving forward, the FDA is monitoring quality assurance and hopes that every person will get vaccinated.

Dr. David Kessler stated that the most important thing is getting a vaccine to everyone who wants one. The current vaccine supply exceeds demand, and they must achieve vaccinating 70% of the population. There are many reasons why people have not been vaccinated, as many are afraid of the unknown. Data supports that vaccines are safe and effective, which prevents hospitalization. They are working to make vaccines more available to providers and in rural areas, as well as have data on the effectiveness of vaccines for children under 12. Data is also being collected on the need for boosters and the threat of variants. It is essential for the U.S. to share vaccines with other countries in the world. The country also needs to hasten the search for an antiviral, as there are still people who are vulnerable. Lastly, they need to build a program for pandemic preparedness and build upon the lessons learned to date.

Questions and Answers

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Chairwoman Murray said the outbreak in India underscores the need for a public health infrastructure. She asked what can be learned from the outbreak in India and be applied to the U.S. **Dr. Fauci** said never to underestimate the surge of viruses. India opened up prematurely which has led to devastation. Public health preparedness is a lesson learned and they must continue to build up public health infrastructure. This requires a global response, especially against the variants. **Chairwoman Murray** asked about findings of cross-contamination during vaccine production and what steps are being taken to ensure the quality and effectiveness of vaccines. **Dr. Marks** said that the FDA is ensuring deficiencies are remediated and that producers are meeting quality standards. They will take the approach of using inspectional tools to ensure the quality of these products. **Chairwoman Murray** said that children can get sick and spread the virus, and asked what parents can do to protect their children. **Dr. Walensky** said that they encourage children to ask for the vaccine and parents should get their children vaccinated.

Ranking Member Burr asked about the shipment of vaccines to other countries. **Dr. Kessler** said that they have shifted doses of AstraZeneca to Mexico and Canada. **Ranking Member Burr** asked about clarification of the Baltimore facility creating the AstraZeneca shot. **Dr. Marks** said that the facility has been producing the AstraZeneca vaccine. He said that there have been efforts to clear those doses as quickly as possible. **Ranking Member Burr** said that current success has relied on leveraging partnerships to scale up production manufacturing. He inquired about waiving intellectual property that may affect innovation in the future to scale. He asked if the private sector should be able to continue innovation. **Dr. Kessler** said that they know a waiver alone will not result in the scale and speed to result in the capacity of production for vaccines needed to end of the pandemic. That is why working with the private sector will be needed to increase vaccine distribution. **Ranking Member Burr** asked about how many of the 33 million people who tested positive for COVID have actually been vaccinated. He said that this is important because some of these people already have protection from already having COVID. They must calculate this number and take into account for herd immunity.

Senator Casey (D-PA) said that there are over 11 million doses in the vaccines for children program that have been missed. Now, there is more of a need for parents to understand what vaccines their children need. He noted that the American Rescue Plan has funds allocated to improving vaccine hesitancy and asked about funding to ensure children and adolescents are caught up on routine vaccines. **Dr. Walensky** said that many routine vaccines went unused this year, and there is no data on using the COVID vaccine alongside routine vaccines. There is a need for outreach to ensure vaccine confidence, as well as data to co-administer these vaccines. There is no sense on the timing for funding. **Senator Casey** said Pfizer is seeking full licensure of their vaccine and asked what full licensure means. **Dr. Marks** said that full licensure is when a manufacture submits with a full data package that includes long-term safety and efficacy studies. These vaccines were expedited not by cutting corners, but going through a development plan where manufacturing was going on simultaneously as clinical trials.

Senator Paul (R-KY) said they do not understand the origins of the virus and said the Wu Han Virology Institute was studying coronavirus' effects on humans. The collaboration between the U.S. and the Virology Institute continues. He asked if the National Institutes of Health (NIH) funding should continue to support the virology institute. **Dr. Fauci** said that Senator Paul was incorrect and the grant was not for the lab. **Senator Paul** asked if he supports money being sent to the lab in China. **Dr. Fauci** said that it would be irresponsible to not investigate the bat virus. **Senator Paul** asked if the COVID-19 virus could not have escaped though serial passage. **Dr. Fauci** said he is in full support of investigation of the virus origin and the NIH has not funded the gene-of-function lab.

Senator Smith (D-MN) commented that they must acknowledge the incredible vaccine roll out process. She said getting vaccines into arms has been a learning process. She asked what the CDC is doing to deploy initiatives to increase access vaccines. **Dr. Walensky** said that money has been spent to make it easy to access to vaccines and ensure that pop-up sites and mobile units are deployed to expand reach. The CDC has released ethnic and minority data to increase access.

Senator Collins (R-ME) said that the CDC has always been the gold standard, but now it is not anymore. She said that the CDC has contradicted scientific guidance and confidence. The first issue is on school re-openings and the lack of science-based initiatives. The second is on mask-wearing and the CDC announced that less than 10% of transmission was occurring outdoors. There is not a single documented COVID case from the outdoors. The third is guidance on summer camps. These matter because it undermines public confidence. She asked why the CDC is not following the standard protocol. **Dr. Walensky** said that the CDC engages with stakeholders who use guidance before it is finalized, and the school re-openings were corresponded with 50 stakeholders. Immunocompromised children were taken into account, and the request was to address how immunocompromised teachers should behave using science. A meta-analysis was conducted to come up with the statistic that less than 10% of transmission occurs outdoors. The camp guidance is intended to allow kids to return back to camp.

Senator Kaine (D-VA) said that there are going to be two challenges, the first being mental health and second being long COVID. He asked how funds are being utilized to handle long COVID. **Dr. Fauci** said that the NIH has been given money to address the acute manifestations of COVID. The symptoms are common and can last for a very long time. They must research the underlying causes. **Senator Kaine** said that they are not at a point where the PHE is over. There is a focus on mental health efforts and keeping healers healthy. **Dr. Walensky** said that it is hard to understand the trauma that first responders have experienced. There are collaborations to develop support tools for mental health for the society at large.

Senator Cassidy (R-LA) said there is frustration between the public and the CDC. He asked if previous infection confers immunity. **Dr. Fauci** said that it does, and that a study has shown that vaccinating someone who has been previously infected does improve immunity. **Senator Cassidy** said that immunization mimics a previous infection, even

though literature shows that there is an increase in side effects. **Dr. Marks** said that there are studies going on to analyze antibody titers in already infected people. **Senator Cassidy** asked if people can go back to work without a mask. **Dr. Walensky** said that they are working to review guidance. They could check antibodies on all who are vaccinated, but this data has not been collected. **Senator Cassidy** said that there is increased frustration and there needs to be updates on recommendations.

Senator Baldwin (D-WI) stated that she is encouraged by the genomic sequencing of COVID. She asked how health departments are making use of genomic sequencing funding and asked about new variants. **Dr. Walensky** said they are now sequencing at a much higher rate now, as well as bolstering this infrastructure to do this at the local level. There must be a bolstered infrastructure to address future public health threats. **Senator Baldwin** asked how increases in COVID-19 worldwide threatens the progress made in the U.S. **Dr. Fauci** said that as long as there is a dynamic of worldwide spread, there is a danger of variants being generated and the threat of coming to the U.S. There is a responsibility to the U.S. first, but we must also take part in a multifaceted effort to help other countries. **Senator Baldwin** said meeting folks where they are is the next phase of the vaccination process, and asked how they are minimizing the potential of wasted doses. **Dr. Kessler** said that tradeoffs have been made, but is in awe of the contributions have been made to be able to bridge the barriers that people have.

Senator Murkowski (R-AK) said that Alaska was successful in getting vaccines out quickly, but that meant it also had to contend with vaccine hesitancy sooner. She said that people are looking to what friends and family are doing when it comes to taking cues on getting the vaccine. She asked how the tourism industry can get back to a place where people can start entering the state. She asked about guidance on tourism and cruise lines. **Dr. Walensky** said that there have been calls with the cruise line industry to bolster tourism guidance.

Senator Murphy (D-CT) said that there is a lot to be learned about the gaps in information and asked about outdoor transmission rates. He asked how they close the gap in information. **Dr. Walensky** said that they are responsible for putting out guidance for individuals and the public health in general. The meta-analysis put forward indicating that less than 10% rate from outdoors has been conducted and they are continuing to collect more information on outdoor transmission rate. **Senator Murphy** asked what they can expect for booster shots. **Dr. Kessler** said they are in the process of analyzing the duration of immunity, increasing age, variants and other factors. They are collecting data on the vaccines and there needs more time to determine the need for booster vaccines.

Senator Braun (R-IN) said more resources must be put into rural areas and asked about zeroing in on the distance between people indoors and outdoors, from 6 feet to 3 feet. **Dr. Walensky** said that resources are funding Federally Qualified Health Centers and rural centers. Studies have been conducted on the 6-foot and 3-foot guidance and as science emerged, guidance has been following the guidance. With regards to natural immunity, data is being conducted to learn more about genomics and variants. They continue to

ensure testing and vaccinations. **Senator Braun** asked about the impact of pulling the Johnson and Johnson vaccine given the low of rate of incidence of adverse events. **Dr. Fauci** said that it was not a setback and it underscores how seriously safety is taken. The FDA and the CDC looked at the data to alert providers and patients on treatment. It underscored how seriously they took safety. **Senator Braun** asked how many shots are needed to achieve herd immunity. **Dr. Fauci** said that herd immunity is a concept and it is hard to pinpoint a number. The threshold is unknown for this virus.

Senator Hassan (D-NH) said that many families are looking for guidance to protect children under the age of 12, especially as public health restrictions are being lifted. She asked about advice for families to protect their kids from the virus as they wait for emergency authorization. **Dr. Fauci** said that following the CDC guidance is important as is keeping up to date on the evolution of guidance. He said that clinical trials are being done on children under 12. **Senator Hassan** stated they have heard encouraging news on the vaccines, but Americans may need booster shots. The price must reflect the investments made by American taxpayers. What steps should Congress take to ensure boosters are made available for citizens? **Dr. Kessler** said that they do have the funds to purchase the next round and if there are boosters, they will be free. **Senator Hassan** asked about building up herd immunity. **Dr. Walensky** said that states have gotten money on surveillance and testing.

Senator Marshall (R-KS) asked if there is a possibility that COVID is man-made. **Dr. Fauci** said that may be a possibility. **Senator Marshall** asked about the conflict of interest of funding for labs. **Dr. Fauci** said that he has no problem with the compliance of funding for labs. **Senator Marshall** asked about the risk of dual applications by military and foreign actors, particularly for national security. **Dr. Fauci** said that in any research they do, they publish the research so other parties can use the data. They have committees who review research, which provides a considerable amount of oversight on grants and research. The pause was lifted because they established a committee that looks at Potential Pandemic Pathogens, or P3CO. **Senator Marshall** asked if COVID is the product of lab manipulation and if NIH was involved. **Dr. Fauci** said the NIH did not fund this research.

Senator Rosen (D-NV) said the NIH had launched a billion dollar initiative on targeting long COVID. She asked about the research gaps that remain on learning about the long-term effects of COVID. **Dr. Fauci** said that they have initiated studies and cohort capacity building for these studies. This involves multiple NIH institutes and they have started the applications for these studies. **Senator Rosen** asked about therapeutics that exist to help long haulers. **Dr. Fauci** said they do not understand the mechanism, so only symptomatic treatments exist for now.

Chairwoman Murray asked how the federal government has been working to decrease health inequities. **Dr. Kessler** said that there has been a drop in deaths amongst the Hispanic and African-American community. There has been an increase in confidence of the vaccine amongst these populations. Equity is the center of the response.

Ranking Member Burr said that in addition to the Baltimore emerging facility, other AstraZeneca manufacturers are being held. He asked about the inspection concerns on these supplies. **Dr. Kessler** said there are two other facilities that are manufacturing, but all issues are being investigated. **Ranking Member Burr** asked about the vaccines being delivered to Mexico and asked about adverse effects of these vaccines. **Dr. Marks** said no, there have been no reports. **Ranking Member Burr** asked about the percentage of employees at the agencies who have been vaccinated. **Dr. Fauci** said there is no concrete number, but he thinks a little more than half. **Dr. Marks** agreed and **Dr. Walensky** said she does not know. **Ranking Member Burr** said that they are the face of why people should get vaccinations, and they should know these exact percentages. He asked if the CDC Director should meet with private innovators to help modernize the CDC. **Dr. Walensky** said that much of what they need to do is collaborate with academia, nonprofits, and private sectors. She would be willing to engage in these conversations if it's of a relevant subject matter. **Ranking Member Burr** said that language has been changed on the guidance and asked about this change on school re-openings. **Dr. Walensky** said they engaged many stakeholders to issue this guidance, and in doing so, they failed to comment on what if teachers were immunosuppressed. The CDC scientists provided the guidance. **Ranking Member Burr** asked about requiring teachers to be vaccinated and issuing vaccines. **Dr. Walensky** said that she encourages teachers to get vaccinated and said she would have to confirm the latest issue of vaccination guidance for teachers.