



SENATE HELP COMMITTEE

“THE PATH FORWARD: A FEDERAL PERSPECTIVE ON THE COVID-19 RESPONSE”

JULY 20, 2021 – 10:00 AM

OVERVIEW

On Tuesday, July 20, the Senate HELP Committee held a hearing to receive an update from federal health officials on efforts the Biden Administration is undertaking to combat the coronavirus pandemic, progress that has been made, and challenges the U.S. and the world are facing.

Members asked about sequencing to detect the presence of variants; vaccine efficacy; booster shots; breakthrough infections; Strategic National Stockpile; gain of function research; disinformation on technology platforms; substance use disorder and overdose deaths; mental health; CDC's mask guidance for schools; Provider Relief Fund; vaccine outreach; and vaccine confidence, among other things.

Federal health officials urged Americans to get vaccinated; touted the benefits of the COVID-19 vaccine, particularly against the Delta variant; noted that when they see studies showing that vaccine efficacy is waning, they will make the decision that booster shots are necessary; warned that the mental health effects of this pandemic will linger for a long time and must be addressed; spoke about the need to use culturally appropriate messaging in all of our vaccination efforts; indicated that disinformation on technology platforms has negatively impacted the response to the pandemic; and stated that it's critically important for schools to be open for full, in-person learning this fall.

OPENING STATEMENTS

- [Chairwoman Patty Murray \(D-WA\)](#)
- [Ranking Member Richard Burr \(R-NC\)](#)

WITNESS PANEL

- [Rochelle Walensky](#), MD, MPH – Director, CDC
- [Anthony Fauci, MD](#) – Director, National Institute of Allergy and Infectious Diseases, NIH
- [Janet Woodcock, MD](#) – Acting Commissioner, FDA
- [Dawn O'Connell](#) – Assistant Secretary for Preparedness and Response, HHS

QUESTION AND ANSWER SUMMARY

Sen. Patty Murray (D-WA) – What is the one thing everyone can do to keep us from returning to the early days of this pandemic?

Full panel said get vaccinated.

Sen. Murray – How do you assess the duration of vaccine efficacy and the impact of variants on that efficacy?

Dr. Fauci – There are two ways that are actively being used. The first is laboratory data. There are correlates of immunity that have been established. For example, you have a level of measurable neutralizing antibody, which is the easiest measure. We know from studies, clinical trials, and animal studies that when you go below a base line level, you are much more vulnerable to getting a breakthrough infection. The second is watching and following cohorts of people to see if you have an increase in breakthrough infections. We know according to the clinical trial that the mRNA vaccines are 93% to 94% effective in preventing clinically recognizable disease. If you see a fall below that into the 80% to 70% range, then you know you've reached a point when the durability needs a boost.

Sen. Murray – We don't have any data that we're seeing that, correct?

Dr. Fauci – No, we don't. There is some preliminary data that we've heard about from Pfizer from studies they've done in Israel and in their own studies, which seem to indicate that there is waning immunity. We have a lot of cohorts that we're following that will be able to amplify on that data and give us much more in terms of making a decision.

Sen. Murray – How will the Administration be able to make a decision that booster shots are needed?

Dr. Fauci – Just by following the cohort studies. Dr. Walensky has in her domain a number of cohort studies that will inform us. In the meantime, we at NIH are doing studies now to determine when you give a booster how high do you get it and what kind of cushion do you get for antibody responses.

Dr. Walensky – We have numerous cohort studies that represent tens of thousands of people across the U.S. These include data from 14,000 nursing home facilities and long-term care facilities. We have a heroes cohort made up of over 5,000 essential workers that are getting weekly PCR testing. We have healthcare worker cohorts. We have cohorts across the country where we're following this data and looking at it every several weeks to understand what the vaccine efficacy is. Fortunately, we're anticipating this will wane and not plummet. As we see our waning, that will be our time for action.

Sen. Richard Burr (R-NC) – Has Israel given us transparency into their data? Do we really need to wait for CDC to complete its data? Do you think you’ll come to a different conclusion than Israel did?

Dr. Walensky – We have to have collaboration across the globe because this is a global problem. We’ve already had two conversations with Israel. We’ve had data sharing from our cohorts as well as from their cohorts. We’ve also been in discussions with the U.K. to see what data they have because they’re several weeks ahead of us in the Delta variant. We intend to leverage all of the data we have around the world to share liberally with other countries in hopes that they will share with us.

Sen. Burr – Is there reason to believe the Israeli data is flawed?

Dr. Walensky – We are in epidemiologic discussions. There are numerous cohorts in Israel. We have seen some of their data. They’re actually continuing to analyze the data. We’re in those active epidemiologic discussions.

Sen. Burr – CDC’s recently updated mask guidance for schools says communities should use local outbreak data to make decisions. Yet, I would challenge you that if only 844 cases have been sequenced, those local people don’t have the data they need to make the determination as to what the policy is going to be at the local level. Would you agree?

Dr. Walensky – That discussion is based on cases. Not based on variants. We’re getting data from around the country based on variants as well from the local health departments as well as academic centers and commercial labs. The recommendations for schools was based on test positivity and positive cases, not necessarily based on variants.

Sen. Burr – Shouldn’t transparency from the local health departments about variants in their local community be important to the decisions about what they do in their schools?

Dr. Walensky – Absolutely. We have data by region about variants that are posted on our website. Not only are we looking at test positivity down to the county level but variants that come in from each of the individual states, academic partners, and the labs.

Sen. Burr – What are your plans to address the pressure that the flu is going to cause on the system?

Ms. O’Connell – That’s something that the ASPR team has been considering and planning for over the last several months. There is now an interagency process set up by the White House Supply Chain Coordinator that ASPR has been actively participating in and working with the manufacturers of both flu vaccines and COVID-19 vaccines on to make sure the supplies are there so we have access to both vaccines as we move into the fall. That’s something we will continue to monitor and recalibrate to make sure we can do both at the same time. Right now, our planning assessment says we can but I will continue to monitor that.

Sen. Tim Kaine (D-VA) – You stated in your opening statement that the overwhelming majority of deaths now are in people that are not vaccinated. What is the statistic?

Dr. Walensky – In a five month study from January to May, it was 99.5% in numerous states.

Sen. Kaine – Can you tell us what CDC and other partners are doing to look at the resurgence of a spike in overdose deaths in the past year?

Dr. Walensky – There have been two things in the last decade that have decreased life expectancy – COVID-19 and overdose. We are now seeing a collision of those two things happen at the same time. There was a 29% increase in overdose deaths. We are actively working to not only study overdose deaths and overdose hospitalizations but also look at surveillance, look at infectious diseases associated with injection drug use, promote syringe services programs and naloxone programs, provide services and programs around the country for mental health and substance use disorders, toolkits for suicide prevention in youth, parental toolkits, etc. We're actively doing the surveillance and studying of this as well as the outreach in the communities for the prevention side.

Sen. Rand Paul (R-KY) – Knowing it is a crime to lie to Congress, do you wish to retract your statement from May 11 when you claimed that NIH never funded gain of function research in Wuhan?

Dr. Fauci – I have never lied before the Congress and I do not retract that statement. This paper that you're referring to was judged by qualified staff up and down the chain as not being gain of function. You don't know what you're talking about. I resent the lie that you're propagating because if you look at the viruses that were used in the experiment that were given in the annual reports and published in the literature, it is molecularly impossible to result in SARS-CoV-2. You are implying that what we did was responsible for the deaths of individuals. I totally resent that. If anyone is lying here, it is you.

Sen. Tina Smith (D-MN) – Is there anything more you would like to say to counteract these attacks on your integrity that we have just witnessed?

Dr. Fauci – This is a pattern that Sen. Paul has been doing at multiple hearings based on no reality. He keeps talking about gain of function research. This has been evaluated multiple times by qualified people to not fall under the gain of function definition. I have not lied before Congress.

Sen. Smith – Is it correct that the COVID-19 vaccine protects against the Delta variant?

Dr. Fauci – It protects against the clinically apparent disease and it protects extremely well against hospitalization and deaths.

Sen. Smith – If you're not vaccinated given how contagious the Delta variant is, would it be fair to say you're very likely to get infected?

Dr. Fauci – Certainly when you look at the capability of this virus to transmit from people to people. Obviously you have to be in an environment where the virus is present so if you're in an area where you have a high level of infection in the community and a very low percentage of vaccinated people, the chances of getting infected are reasonably high.

Sen. Smith – How do you think about the side effect risks of the COVID-19 vaccine compared to the risks of not being vaccinated?

Dr. Fauci – It refers to the risk benefit ratio of getting a vaccination. Every time this has been evaluated with so many other vaccines, there is no intervention that is without some time getting an adverse event. When you have that situation, you balance the rarity or uncommonness of a particular uncommon event with the advantage that you're protecting yourself against the actual disease against which you're vaccinated. Thus far, whenever this has come up about an adverse event, it has been evaluated, perhaps even a warning has been given, but it's always weighed on the part of saying that the benefit of the vaccine outweighs the risk of the adverse event.

Sen. Smith – Are there a larger number of younger people getting hospitalized today versus a year ago or six months ago?

Dr. Walensky – We have seen hospitalizations go up for every age bracket recently as cases go up. As there are more cases now among younger people, we're seeing more younger people in the hospital.

Sen. Jerry Moran (R-KS) – What is the plan to get HHS to perform better or more quickly so providers have the necessary information and comfort level to take the steps necessary to prevent the spread of the virus and care for the health of Americans and others? There is \$24 billion left unspent in the Provider Relief Fund. We've been anxiously awaiting assistance and care for facilities that care for our senior populations and there's still no answer in that regard. Do you have any comments on that? I would like more certainty from HHS on the spending of those dollars.

Ms. O'Connell – We'll take the comments that you've made and bring them back to the Secretary and other HHS senior leadership to ensure the money is moving quickly and that the guidance comes out expeditiously. We want to do all we can to support your constituents. It's helpful to know this has been a problem.

Sen. Moran – What are the necessary steps to mitigate a mental health and drug overdose crisis? What should Congress and other institutions be doing to prepare for a future pandemic?

Dr. Fauci – I think the lesson that we've learned from this is to realize the important mental health impact that this outbreak has had, not only in the suffering from the disease itself, but from the extraordinary disruption of our society. Even when we get this under control, the mental health effects of this are going to be continuing for months, if not years. When the outbreak is over, the mental health effects are not going to be over. They're going to linger and that's what we need to address.

Sen. Jacky Rosen (D-NV) – Are there any plans for the CDC, or in coordination with other agencies, to restart the pharmacy partner program that sent teams directly to every nursing home with a less than 90% vaccination rate for residents and staff?

Dr. Walensky – We recognize this challenge and we're with you. In fact, we have 10 CDC people deployed to Nevada right now working to assist. Part of the long-term plan in working to vaccinate our long-term care facilities is to have a longitudinal plan because there is quite a bit of turnover in patients and we want to make sure there are always vaccine doses available. We need to work to get our staff vaccinated as well. Staff in these facilities are often 20% less vaccinated than the residents themselves. We're working on confidence in those areas and specifically strike teams within long-term care facilities to assist in getting vaccine to those places that aren't reliant on a one-time mass vaccination but have a longitudinal plan to make sure vaccines are always available in the long term.

Sen. Rosen – Some recent research is showing that COVID-19 vaccines may actually improve symptoms for some patients with long haul COVID-19. What do we know about this so far? How common is a vaccine to be a strong prevention tool and to also work therapeutically in this case? What else should we be studying?

Dr. Fauci – There have been anecdotal reports of people who have been infected, developed long COVID-19, and their symptoms have been improved upon getting the SARS-CoV-2 vaccine. That has not been proven under the scrutiny of a clinical trial. Right now, we're looking at individuals who have in fact recovered and seeing if vaccination does improve. Even though the anecdotal cases suggest that, I don't think we can say anything definitively from a scientific standpoint but that's something that is being looked at.

Sen. Mitt Romney (R-UT) – Is there a place for people to go to find out what the data show for the side effects of vaccines by age group, how many serious complications there are for people of different ages, and compare that with the serious implications of getting COVID-19?

Dr. Walensky – That’s exactly what we’re doing. When people don’t want to get vaccinated, it could be for a whole host of reasons. At the CDC, we have vaccine confidence consults. We have state departments and local health departments who can call into us and tell us the things they are hearing on the ground, ask for specific data in real time, and empower people with the information through trusted messengers.

Sen. Romney - Is that information being collected?

Dr. Walensky – Absolutely. We have numerous large-scale mechanisms by which to collect these data. We have the first ever v-safe monitoring program, the vaccine adverse reporting system, and the vaccine safety data link so we can check numerators, denominators, and get estimates. We’re covering the gamut.

Sen. Romney – How long is it going to take before we have sufficient information for Americans who want to get a booster shot to do so?

Dr. Woodcock – The agencies represented here are all monitoring this extremely carefully. At the moment, the people getting sick are the people who haven’t been vaccinated.

Sen. Romney – The data coming in from Israel is showing that people who have double vaccines are still susceptible to the Delta variant, serious disease, and death. They’re showing that if they get a booster, that is dramatically reduced. Why should we not have people who are elderly or have other compromised conditions to be able to get that booster?

Dr. Woodcock – We are looking at all that. Remember that the vaccines that are under emergency use authorization require an additional authorization for a booster.

Sen. Romney – How long is that going to take? We have people who want to get a booster.

Dr. Woodcock – Pfizer has publicly announced that they’re going to submit an amendment to their emergency use authorization as well as their data along with data from Israel to potentially make a case for a booster. The FDA will be looking at that.

Sen. Maggie Hassan (D-NH) – What is your best guidance regarding COVID-19 mitigation taking into account the needs of people with disabilities?

Dr. Walensky – We have dedicated resources specifically to disabled communities, especially those who are unable to come out and get vaccinated.

Sen. Hassan – Sen. Cassidy and I recently introduced bipartisan legislation that would improve transparency into the Strategic National Stockpile (SNS), authorize transfers of expiring products, and assist states in establishing and maintaining their own stockpiles in order to avoid the kinds of challenges we faced last year. What steps are you taking to improve the SNS? Will you continue to work with us on this bipartisan legislation to make further improvements?

Ms. O’Connell – This is a place where I tend to spend a lot of time in my new role. I’m pleased to report that ASPR has spent and invested over \$10 billion in supplemental funds to restock the SNS. We currently have 35 times the number of n95 respirators we had at the beginning of the pandemic, 17 times the number of gloves, 8 times the number of masks, and of the n95 masks, all 12 contracts are with American manufacturers.

Sen. Hassan - Will you work with us on the bipartisan legislation Sen. Cassidy and I have introduced?

Ms. O'Connell - I would love to.

Sen. Hassan – When do you believe parents and families can expect clinical trials to yield the type of data needed to pursue authorization for use of COVID-19 vaccines in children under the age of 12?

Dr. Fauci – We'll have enough data likely by late fall or early winter. That doesn't mean it will all of a sudden be allowed to happen. That will be a regulatory decision that the FDA will have to make.

Sen. Roger Marshall (R-KS) – What are the additional benefits of the COVID-19 vaccine to a child who has already had the virus?

Dr. Walensky – It very much depends on the variant that child has had and whether they could potentially be infected or reinfected. We fall into this flawed thinking that only 400 of these 600,000 deaths have been in children. Children are not supposed to die so 400 deaths is a huge amount for a respiratory season.

Sen. Marshall – How many children under the age of 18, without a preexisting condition, have died from COVID-19 in this country?

Dr. Woodcock – I don't have that data in front of me.

Dr. Walensky – I don't know.

Sen. Marshall – Can you talk about the S2 unit and explain the significance of the furin cleavage site, the double arginine CGG codon, and how that works?

Dr. Fauci – The furin cleavage site is a site of a set of amino acids, which is at the point where the enzyme furin can cleave it so the virus can bind to the receptor cell and then enter the cell. It is seen on a number of viruses including SARS-CoV-2 and it's also seen on other beta coronaviruses. The double CGG codon is unusual but is also seen on a number of beta coronaviruses. It is not a common codon for the amino acid in question but it is seen in coronaviruses.

Sen. Marshall – Dr. David Baltimore, a Nobel laureate, stated that when he first saw the furin cleavage site with the arginine codon, he told his wife it was the “smoking gun for the origin of the virus. These features make a powerful challenge to the idea of a natural origin for SARS-2. Would you agree or disagree with Dr. Baltimore?

Dr. Fauci – Dr. Baltimore has backtracked on that statement and said he wished he had not used the words smoking gun when it was pointed out to him that this is seen in a number of coronaviruses, including one of the common cold coronaviruses.

Sen. Marshall – So, you disagree with him?

Dr. Fauci – I agree with his second statement where he backtracked and said he wished he had not used the words smoking gun.

Sen. Robert Casey (D-PA) – What types of data is CDC collecting to track breakthrough infections? How are both CDC and NIAID using data to monitor outcomes in patients with breakthrough infections?

Dr. Walensky – There are different ways we are capturing these data and they all fit together into a puzzle. One of these is passive surveillance where folks give us data when they breakthrough and the hospital systems provide us data when they know somebody is admitted and has a history of vaccination. We want to know about those cases to the greatest extent possible, and we want to have a sample of the virus so we can understand the viral load and sequence it. However, that's limited because it doesn't give us the denominator. In order to do real effectiveness studies, we need to have both the numerator of the cases as well as the denominator. We don't know who else might have been reporting or what we might have missed in that process. We are doing many of those studies across the nation. We have those geographically sampled. We have a long-term care facility study where we're getting data from over 14,000 long-term care studies, we have a health worker study, we have an essential worker study, and we have numerous other cohorts, 19 academic medical centers, and 187 hospitals to monitor the numerator of how many people are breaking through, how serious their infection is, as well as the denominator of how many people were vaccinated overall. This helps us understand the percentage of people that are breaking through.

Dr. Fauci – When you talk about breakthrough infections, people need to appreciate that the original data from the clinical trial, the efficacy data, was based on preventing clinically apparent disease, not preventing infection such as asymptomatic infection. When you hear about breakthrough infection, that doesn't necessarily mean the vaccine is failing because it's still holding particularly true with regard to protection against severe disease leading to hospitalization and deaths. We will be following for two years the 30,000 people that are in clinical trials to be able to determine what percent are breaking through in the context of the Delta variant.

Sen. Bill Cassidy (R-LA) – Have inventory management systems been implemented to minimize the wastage in the SNS?

Ms. O'Connell – Yes. We are looking at that. One of the things we're pursuing is the model of the vendor managed.

Sen. Cassidy – Is there any effort to rotate out soon to expire vaccine that doesn't appear it is going to be used into a setting where it could be used quite rapidly?

Dr. Woodcock – We have been working on this and have been advising states that have repositories to hold on to that vaccine. This is because unlike most medical products you're used to, the manufacturers are making stability determinations on the fly. We've extended the date already for one of the vaccines and we may be able to keep extending it as there is longer stability observed.

Sen. Cassidy – Are there contractual obstacles to implementing inventory management systems and rotating out soon to expire vaccines into settings where they can be used rapidly? Someone told me that the contracts with the drug companies would not allow the transfer of the product to another setting such as Mexico and would have to be tossed instead.

Dr. Woodcock – My understanding is that it's possible under the emergency use authorization to do exports but we can get back to you on that because it isn't an FDA issue.

Sen. Cassidy – It seems to me that the issue of whether or not we need a booster would be ascertainable by whether or not we can see a response of antibody to rechallenge within the window period of the virus between onset and exposure. If the antibodies after reexposure to the vaccine mimicking an infection shoot up rapidly, we’ve got protection. Are any studies taking place along these lines?

Dr. Woodcock – Absolutely. Both within the government and within the companies. The agencies are monitoring this very carefully and we’re sharing all the data.

Sen. Cassidy – What is the delay in knowing this?

Dr. Woodcock – As Dr. Fauci said, when immunity wanes to the point that you need to give a booster.

Sen. Ben Ray Lujan (D-NM) – Federal investment in community health centers increased Hispanic vaccination rates. Did this investment in this community save lives?

Dr. Walensky – Absolutely.

Sen. Lujan – What is the plan to build on the success of using culturally appropriate outreach and messaging to boost Hispanic vaccination rates?

Dr. Walensky – I think we need to use culturally appropriate messaging in all of our vaccination and healthcare efforts. Our vaccination toolkits are available in more than 20 languages. We are continuing to do outreach by trusted messengers in their own language in culturally sensitive ways. We are seeing that it is working and we were able to increase vaccination rates in Hispanic communities from 8% to 19%.

Sen. Lujan – The Administration has enlisted black owned barber shops and faith-based community outreach to promote the shots and even serve as vaccination sites to increase Black vaccination rates. Does the Administration have plans to employ targeted outreach to the Hispanic community?

Dr. Walensky – The Administration is working to reach people where they are and understand what specific communities need, and have trusted messengers.

Sen. Lujan – Has disinformation on technology platforms negatively impacted the response to the pandemic?

Full panel responded yes.

Sen. Lujan – What can the federal government do to decrease COVID-19 infections in border communities?

Ms. O’Connell – It’s a question of liability that needs to be worked through when sharing vaccines with other countries. It is important that we offer tests and vaccines where we can to prevent the spread of COVID-19 in the border communities.

Sen. Lujan – How can the federal government better coordinate internationally to ensure foreign regulatory bodies have the data and the vaccine supply that can be approved locally?

Dr. Woodcock – We have collaborations with regulators around the world. We are actively reaching out to other foreign regulatory authorities to give them information about what we’ve done to review vaccines and what we know about them.

Sen. Mike Braun (R-IN) – Was NIAID one of the organizations Facebook consulted with when deciding what speech to filter through?

Dr. Fauci – To my knowledge, that is not the case. When you say, consulting with my agency regarding what speech to filter through, I don't ever recall or have ever heard any discussion about filtering speech.

Sen. Braun – Did they consult with you on any topics? Have you been in contact with them to give them your personal opinion on this or that?

Dr. Fauci – I don't know what you mean by this or that. There was one communication or two perhaps with Mark Zuckerberg in which he emailed me and wanted to know if there was anything he could do to promote vaccination and make sure people wear masks. Mostly it was about propagating a public health message. It had nothing to do with the origins of the virus at all.

Sen. Braun - Do you consult with Mark Zuckerberg on a regular basis via email or do you have his cell phone number for instance?

Dr. Fauci – You probably know that because you're asking the question. In fact, there is an email exchange or two between myself and Mr. Zuckerberg. I'm not sure if I have his cell phone number but I can look.

Sen. Braun – The White House has recently said they are wanting to flag problematic posts. Would you be the one that would try to come up with whatever posts that are out there that need to be flagged as misinformation?

Dr. Fauci – I have not at all been involved, even indirectly in that. This is beyond my area of expertise. I develop vaccines to save lives. I don't get involved in flagging things.

Sen. Braun – Would you be in favor of mandating a vaccine for COVID-19 or any of the variants as mandatory for getting into grade school?

Dr. Walensky – First we need to see the clinical data, understand the risks and benefits, and see the long term data so I think that's premature at this point.

Sen. Braun - What additional data would be needed?

Dr. Walensky – We don't have clinical trial data in the school-aged population yet.

Dr. Fauci – You need to make decisions based on data. We don't have that data. When we do, we can address the decision.

Sen. Tammy Baldwin (D-WI) – How is ASPR working to secure supplies of raw materials like meltblown to make us better prepared for the future?

Ms. O'Connell – We just had OMB recently release \$2 billion, which is going to go to, among other things, expanding access to raw materials for vaccines. That's one of the first efforts that it's going to be used for. It will also go to making sure we have full finish capacity, needles and syringes, and it's just the start. We're very anxious to get these contracts awarded and moving. Of course, that's not enough but that's where we are right now. We've also spent other supplemental funds on producing gowns and other personal protective equipment (PPE) in the U.S. We're continuing to do that domestic manufacturing but we also have this industrial base expansion for vaccine capacity right now.

Sen. Baldwin – Can you assure me that the Administration is doing all it can to encourage the production of smaller vials and smaller batches of vaccines as soon as possible? What is your anticipated timeline for changes like this?

Dr. Woodcock – To do that we need to get the manufacturers to change how they're manufacturing the drug and what the storage conditions might be. Heroic efforts are being made to try and get vaccines that don't require deep freezing storage conditions that could then be broken up into smaller groups and stored in a pediatrician's office refrigerator. Those efforts are arduously going on but they're highly technical. I think the government and the manufacturers are both united in realizing this is necessary.

Sen. Tommy Tuberville (R-AL) – What would you say to those that look at the CDC and say the agency needs a bit of restructuring? What would you do differently?

Dr. Walensky – I came in on January 20 and we've made a lot of progress to do everything we can to address this virus. A lot has changed just in the last six months. We need a public health infrastructure in this country that allows the CDC and our states and local health departments to be prepared for a pandemic. In that process of restructuring, we need long-term disease diagnostic funding that isn't like a rollercoaster that comes with one infectious disease threat and disappears when that disease threat is gone. We are going to be dealing with this for a long time. We will have long COVID, we will have boosters to be thinking about, and we will be dealing with mental health issues.

Sen. Tuberville – What would you say to the vaccine hesitant people who don't feel comfortable taking a vaccine that hasn't been fully FDA approved?

Dr. Woodcock – We did not cut any corners in these 30,000 patient trials, 44,000 patient trials and all the surveillance that you've been hearing about potential rare side effects. These vaccines have received the full court press as far as evaluation and study and they've gone through the FDA process and to the CDC's advisory committee. That said, it is public that one of the companies put a marketing application before us and we're going to do everything we can to review that in a timely manner.

Sen. Tuberville – What kind of timeline do you think we'll have a full approval within?

Dr. Woodcock – I can't talk about that.

Sen. Tuberville – Unless this Administration acknowledges the efforts of the last one, a large part of Americans are going to continue to feel like nothing is positive and they're not going to take the vaccine. Do you understand what I'm saying? Is there a unifying message we can put out?

Dr. Fauci – Having been present through the last year, which was when COVID-19 began and the last year of the former Administration, I can tell you that without a doubt the former Administration deserves a considerable amount of credit for the effort that was put into Operation Warp Speed, which allowed the rapid development and testing but also the implementation of the vaccine. With regard to a unifying message, I think we need to appreciate that we are dealing with a common enemy – the virus. The virus doesn't know if you're a Republican, Democrat, or Independent. The virus just knows that it makes people ill and it kills people. We have an extraordinarily efficient tool against that common enemy and I would hope that common message would be let's get together and utilize that tool, the vaccine, to crush that virus.

Sen. John Hickenlooper (D-CO) – What should schools be thinking about and who should they be talking to so that kids are fully protected by the time they start school in the fall?

Dr. Walensky – I think it's critically important that schools be open for full, in-person learning in the fall. We have learned enough over the past year to know what we need to do to keep our children safe. We believe that based on the science that we can keep them safe in those settings. The best thing would be to have everyone vaccinated that can be vaccinated, surround unvaccinated children who are not yet eligible by people who are vaccinated to protect them, and unvaccinated children should wear masks. We are going to see upper respiratory infections in schools in the fall. We are going to have to understand what is COVID, what is influenza, and what is a cold.

Sen. Hickenlooper – Some of the FDA's reports on Aduhelm, Biogen's new Alzheimer's drug, are very concerning. Last week, there was an extra panel convened by the Institute for Clinical and Economic Review, which unanimously concluded that the drug wasn't efficacious and did not provide a benefit for patients with Alzheimer's and certainly wasn't worth the price tag. Can you specify how differently the FDA should have looked at this?

Dr. Woodcock – A lot of the confusion is in some of the controversies. This is an accelerated approval. That means it was approved on a surrogate endpoint that is reasonably likely to predict clinical benefit. The ICER conclusion that you just referred to is not surprising because they haven't definitively shown benefit. Congress has urged us to use the accelerated pathway for life threatening diseases that don't have any effective therapy. Alzheimer's is one. Part of the issue is that it was brought to an advisory committee and proposed for traditional approval – not on a surrogate endpoint. The advisory committee conclusively shot that down so the agency went back and looked at all the data on the surrogate endpoint, which is clearing out all the amyloid plaque from the brain. They found that correlated with benefit of slowing decline of deterioration of thinking. Looking at other programs with other antibodies that do the same thing, they concluded that this clearing out of the plaque was reasonably likely to predict benefit. That's how we approved HIV drugs from the very beginning. That's also how we approve many drugs for rare diseases.

Sen. Burr – It's my understanding that CDC is only tracking breakthroughs that result in hospitalization. Is that accurate?

Dr. Walensky – That's passive surveillance. It's not the best way to track breakthroughs and one of the limitations of our passive surveillance system. That is one of the reasons why we're collecting longitudinal data in tens of thousands of people, some of whom are getting weekly PCRs so we can test for asymptomatic breakthroughs as well.

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Please click [here](#) for the archived hearing.