Marianne O'Hare: Welcome to Conversations on Health Care. This week we welcome Dr. Rochelle Walensky, Director of the Center for Disease Control and Prevention on a recent announcement of a shakeup of the agency to address failures in the pandemic.

Dr. Rochelle Walensky: So the strategy now is to tailor vaccine for giving us the largest breadth of response.

Marianne O'Hare: Lori Robertson joins us from FactCheck.org and we end with a bright idea improving health and wellbeing and everyday lives. Now, here are your hosts, Mark Masselli and Margaret Flinter.

Mark Masselli: CDC director, Dr. Rochelle Walensky, recently said, "To be frank, we are responsible for some pretty dramatic and pretty (inaudible 00:00:38) mistakes during COVID from testing to data to communications. It's the agency's responsibility to learn from those lessons and do better."

Margaret Flinter: Dr. Walensky has an ambitious plan to reset the CDC. And. of course, it can't be happening soon enough as we are facing new hurdles. She's been in the post since 2021, and we always appreciate her taking time to speak with us.

Mark Masselli: Yeah, thank you so much Dr. Walensky for being a guest again on Conversations on Health Care.

Dr. Rochelle Walensky: Always delighted to be with you. Thanks for having me.

Mark Masselli: Yeah, we're experiencing a BA.5 outbreak as we talk with you. Soon, you and your colleagues will announce the decision on new COVID Booster shots. I'm wondering if you could share with our listeners the process that you'll take to review the data to make sure that it's safe and secure for the American public.

Dr. Rochelle Walensky: Yeah, well, maybe first I will say we have now given over 600 million doses of this vaccine in this country, so we have an extraordinary safety profile probably unlike any we've seen with any vaccine in history. What will happen over the next several weeks is Pfizer and Moderna have put forward applications for this new booster for the fall a Bivalent booster, which is part prototype the original strain and part BA.5. As they do so, the FDA's Advisory Committee will review those data, the FDA will authorize that should the FDA make the decision to authorize that vaccine. Then it'll come to our Advisory Committee on Immunization Practices and then I will put forward a recommendation for its use. That is the process in the weeks ahead and looking forward to being able to execute on that based on the conversations.

Margaret Flinter: Well, you have questions flying at you every day at CDC, and certainly one of the big ones seems to be the opinions about when's the best possible time to get a COVID booster shot? Should somebody get it as soon as possible, when they -- when and if they become approved, or should they wait until cases rise in the fall and winter, as we've seen in the earlier winters of the pandemic in order to maximize immunity when it's really needed? Is that part of CDCs role too to weigh in on timing and try and educate the public as to what is maximally effective for them?

Dr. Rochelle Walensky: Yeah, one of the things I will say is as we've rolled out our guidance we have been --- for our vaccination, we have been --- the data on what these vaccines are good at and doing has changed over time. Right now we know specifically with the Omicron variant, while they are good at preventing infections, they are very good, exceptionally good, at preventing severe disease and death. In fact, even to this day as we have over 350 deaths a day still, with this BA.5 variant as you noted, the people who are seeing most at risk of severe disease and death continue to be those who are unvaccinated or under vaccinated.

I've always said there is no bad time to become up-to-date on your COVID checks. If you haven't gotten a booster in the year of-- calendar year of 2022, and you're eligible for a booster, there's no bad time to get one. We are going to be reviewing data on these updated boosters, as I mentioned coming soon. But if you are in a place where you feel like you're at high risk of severe disease, if you're over the age of 50, if you're especially over the age of 65 and there's a lot of infection in your community, you may want to go ahead and not wait for that booster. The information from that booster, get the one that is available to you now and then we'll have further recommendations about when you can get an updated booster in the fall.

What I really want to avoid is somebody who was waiting two weeks and happened to get severely ill in that interim period of time when they could have avoided that by getting the prototype booster now. My party line is never a bad time to get a booster if you're eligible. If you get one today, and you should if you're eligible, that doesn't necessarily mean you won't have a recommendation for another one in the fall.

Mark Masselli: Well, that's great Dr. Walensky. Just one more question on this because there are other scientists that say the government is moving too fast and they believe the existing vaccines provide

strong protection against severe disease. Some say the new booster raises questions because it involves studies on mice instead of humans. I'm wondering if we could give you a chance to respond to those criticisms.

Dr. Rochelle Walensky: Yeah, and maybe this goes back to the safety of those vaccines, which we know based on hundreds of millions of people who have received them are extraordinarily safe. As we have updated these booster shots for the fall, the data that we are looking at is related to very, very small changes in the mRNA sequence, and really shouldn't impact safety at all. We're not expecting it will impact safety.

There's always a question here of being too slow versus too fast. I think one of the challenges is if we wait for those data to emerge in human data, not just mice data, in human data, we will be using what I would consider to be a potentially outdated vaccine. Maybe it's best, and I believe it is best, to use a vaccine that's tailored for the variant that we have right now. We do know that the variant -- over 88% of the sequences that we're seeing right now are BA.5, over 98% are either BA.4 or BA.5.

The strategy now is to tailor vaccine for giving us the largest breadth of response, ideally one that would have less waning over time, and that is by targeting what I would say is the most proximal variant, the one that we have closest to us, which is BA.4 and BA.5. I believe there's significant upsides to doing that with this updated Bivalent Vaccine, and very little downside in doing so. While we -- I have heard those critics before, but I actually think in a time of we could either be too slow or too fast, I really would love to be ahead of this variant this season.

Margaret Flinter: Well, August is wrapping up, Labor Day is right ahead of us, and we understand that federal officials are preparing for a Labor Day kickoff for booster vaccine campaign. We saw plan online to talks about leveraging partnerships and engaging trusted messengers, which really was the foundation of so much of what we did in the communities, I think, throughout the country over these last two years. But still, we've hit walls around getting everybody to be vaccinated even with the primary series and pure as you've noted with the booster doses. Is there anything new, dare I say radical or new different, you feel that there's element to the approach that you're going to take that may really capture people's attention at this point?

Dr. Rochelle Walensky: Yeah, I think, first of all we've recognized that we need to have

ease in messaging. We really need to have people understand the communications of who should get what when, and so that is certainly something that is high on our mind. I don't want to get ahead of when, this is actually going to happen when we'll hear from the FDA, when we'll hear from the ACIP, but what I will say is time and time again, we've learned that we can make the recommendations, but it's you the trusted messengers, the people who work with folks who trusted all day every day on the ground who have been the reliable go to through not just COVID-19, but through prior health challenges, through prior health care, you are the people who can deliver those messages for us and who we will continue to rely upon. One group also that I think is going to be critically important is our children. We do have vaccine now for even our youngest down to six months old. Yet the uptake of that has been slow. As we get our children back to school, we do really want to send a message that we know how we can keep them safe.

We've seen incredible safety benchmarks from even down to the youngest, and we'll continue to relay those data as well so people know that they can rely on the safety of these vaccines. When it comes to our children, COVID-19 during the pandemic has been one of the top five killers of our children and in the age demographic under the age of 18 and the number one infectious cause of death during the pandemic.

Mark Masselli: In addition to the internal review that you initiated, the General Accounting Office will soon release a report on CDC that is expected to be very tough. What do you think the GAO report will show? In the interest of transparency, will you be able to release the entire contents of your own study that you initiated?

Dr. Rochelle Walensky: Yeah, so I can't actually speak to the GAO report prior to it being public. But I can certainly speak to our review, and maybe I'll just say that we took on two parallel processes. We took on a process that was led by Jim Macrae that really looked at our COVID-19 response, how do we operate during a pandemic, if you will, and what are our -- what did we do well, and what are some of the challenges that we had and how can we learn the lessons of our response in our everyday operations at CDC.

We also wanted to take at the same time a review of our just baseline systems, processes, policies, that may not incentivize people to work in the optimal way that they do., and so we took on both of those reviews. We engaged in over 170

interviews with key stakeholders, both within the agency, within our response, but then importantly outside the agency, government officials, prior CDC directors, other public health leaders to really understand their perspective. These are key stakeholders who understand CDC, utilize CDC, depend on CDC. In both of those processes we've synthesized a lot of the work that we have ahead and those will become public in the week ahead.

Margaret Flinter: Well, we certainly know Jim Macrae well from the Community Health Center world. We're glad to see that he was working on that review, but we had ---.

Dr. Rochelle Walensky: And a dear colleague.

Margaret Flinter: Yeah, dear colleague. We had the opportunity recently to speak with one of your predecessors, Dr. Tom Frieden who I thought had an interesting idea. He suggested that it would be a good idea for you to hold a press conference. I think he even said it hour long press conference, if I'm not mistaken, with all of the CDC experts to discuss boosters, the new school guidelines and any other questions that would help us towards this goal of more transparency and perhaps more engagement of the public. Would you be open to that kind of press conference? Do you think it might accomplish some good in terms of giving people a chance to really hear from you and your colleagues directly?

Dr. Rochelle Walensky: Yeah, one of the things that we learned through this review from both Jim and our own review is that there was a hunger for more contact with our subject matter experts, discussion with our subject matter experts, press conferences with health reporters so that they could asks sort of nitty-gritty health related questions rather than sort of just made overall press reporters. We've taken that to heart. You have probably seen through our monkeypox response we've have had many more press conferences in that regard. We have done more with regard to and did one when we released our COVID-19 guidance. Certainly something that is on the table, and as part of really learning from what we have from the review itself is that we have been engaging in more and more of these press conferences with subject matter expertise at CDC.

Mark Masselli: I think one thing that the public may not know is that while CDC receives a good amount of money, it doesn't have a lot of flexibility in that expenditure. Let's say you could go to Capitol Hill and make anything happen, what's the one wish you'd want the budget gods to grant you right now?

Dr. Rochelle Walensky: Well, I can't synthesize it down to one wish, but I will give you maybe top two or three. One, is we really need sustainable longitudinal budget lines that don't wax and wane from crisis to crisis. The infrastructure in public health, our core capabilities, our workforce, our laboratory, our data systems, we need a sustainable investment that I would say is disease agnostic, one that doesn't necessarily wax and wane as we talked about. We are now looking at how we can utilize COVID dollars to help monkeypox resource efforts. Those are the kinds of things that I think are really challenging, and it needs to be sustainable. It can't be borrowing from a prior challenge, so that I think would be one big one, again, disease agnostic, sustainable resources.

The other is that there are challenges in this review specifically we identified challenges that didn't allow us to be as nimble as we otherwise might have wanted, didn't allow us to see a full scope of everything that we wanted. There are of course challenges related to our data authorities. We wait for data to come in from our state and local jurisdictions, our partners, but we can't compel those data to come in, so we can't always see where all the cases of monkeypox are or where all of the vaccines are or the ethnic and racial diversity of who has been vaccinated. We can't compare those. Now those data are starting to come in as you've probably seen.

We have challenges with the Paperwork Reduction Act and the delays that we have in setting up studies because of the Paperwork Reduction Act. Challenges related to our human resource authorities, how quickly we can hire, how quickly we can deploy even during a pandemic. Some of these are -- their nitty-gritty authorities who are kind of in the weeds here, but they have really hampered our ability to be nimble in a time where it was so important to be nimble.

Margaret Flinter: Well, I think in many ways you've answered the question that was on the tip of my time, but I'm going to ask you to expand upon that a little bit anyway. Certainly, we did learn a lot wherever you were, in health care or just wherever you were, during COVID. Then monkeypox appeared on our horizon unexpectedly, I would say from our perspective. We ran into some of the same issues around getting access to testing the vaccine shortage issues and some confusing messages I think as we tried to explain to people different strategies for stretching the vaccine supply. How do you think we're doing with monkeypox across the country and really taking the learning from previous experiences and getting it out there, particularly, I think, in terms of education, vaccines and

testing?

Dr. Rochelle Walensky: Yeah, I mean, I think it's interesting to think about what are the parallels and what are the differences with these two outbreaks, or in one pandemic, one outbreak. Certainly, one of the things that I think is very similar is though we knew a lot about monkeypox by virtue of the fact that we had been studying at the CDC for decades, which I think really helped us jumpstart things. Most of the American public did not know about monkeypox, and most clinicians did not know about monkeypox, so we were scientifically more attuned and knew more about monkeypox, but we needed to educate America, all of America, what is this disease? What should you be on the lookout for? How is it transmitted? That was a huge heavy lift early on as this outbreak was taking hold.

The testing component was different. We again, we had a test for this. We had sequences published within days of finding the first case that were on our website -- published sequences as well, actually they were on our website within days, so that people could easily find them. We scaled up our laboratory testing. We were talking to commercial labs within days of that first test to be able to scale up laboratory testing, but we had to educate America that not everyone can walk in and get a monkeypox test, you actually need to have a rash in order to be able to get a test. Then we needed to work closely with our state and local health departments as to how and who should be able to send those monkeypox tests and how can we make sure that we're getting the right people to get those tests and get those results back faster.

One of the challenges that we've had at CDC is again how slow the data were to come in. How slow we were to receive data from our local jurisdictions to be able to then feed it back to the American people and back to our local jurisdictions, and that is not -- this is a partnership with the local jurisdictions that we are fostering. One of the things we've learned from their review is how much we need to work more closely with our local jurisdictions and our partners in those ways. But we need to have data systems that allow fluid flow of those data.

We were getting case reports, in some cases by e-mail, and some cases by Excel, and in some cases by Cloud, that's not a productive way to be able to import our data. That's really one of the core public health infrastructures that I think we need to bolster in the years ahead to make sure that our data systems can receive those data fluidly so we can feed them back out.

Mark Masselli: So important data unites us, anecdotes divide us, so having that information is so important. Let me ask you about because I think we're all sorting out Dr. Fauci's upcoming departure from government service, what that will mean. You've worked with him, he's a friend. What's the -- maybe share with us a little bit about his departure, but what's the biggest piece of advice he's given you through the years?

Dr. Rochelle Walensky: Maybe what I will just say is I have had the great gift and fortune of knowing Dr. Fauci for about 20/25 years. He has been a mentor to me, he has been a colleague to me and I've had the great gift of working with him closely over the last year and a half. He's a giant public servant. He has incredible expertise and incredible wisdom. Maybe what I will just say is I wish him the very best of luck in his exciting next chapter, which is I'm understanding not retirement, but just the next chapter. I'm really thrilled for him and wish him only the very best.

Margaret Flinter: Hear, hear. And Dr. Walensky, many thanks for your time today, and thank you for our audience for being here. You can learn more about so many things and learn more about Conversations on Health Care by signing up for our e-mail updates at www.chcradio.com. Dr. Walensky thank you so much for taking the time to share your thoughts with us.

Dr. Rochelle Walensky: Always good to be with you. Thanks for having me.

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Mark Masselli: At Conversations on Health Care we want our audience to be truly in the know when it comes to the facts about health care reform and policy. Lori Robertson is an award winning journalist and Managing Editor of FactCheck.org, a nonpartisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in US politics. Lori, what have you got for us this week?

Lori Robertson: Numerous studies have found that COVID-19 vaccination is safe during pregnancy and doesn't raise the risk of miscarriage. Results from the Pfizer-BioNTech clinical trial are consistent with those findings. In the trial for the Pfizer COVID-19 vaccine there were just three spontaneous abortions or miscarriages reported among 50 participants who became pregnant and received the vaccine during the trial. The miscarriage rate was normal and wasn't more than the rate among those who received the placebo.

Estimates vary but miscarriage before 20 weeks is common

and occurs in some 10% to 20% of known pregnancies. But a false claim has been spreading through social media that during Pfizer's main clinical trial 44% of the pregnant women who were vaccinated miscarried. That's wrong. The statistic comes from a faulty tally of miscarriages that counted each miscarriage twice and included miscarriages from people in the placebo group.

The claim originates from a post on the DailyClout, a website run by Naomi Wolf and author and former Democratic consultant who is trafficked in conspiracy theories. The August 12 post is no longer on that website, but as we often find, once a claim is made it can take on a life of its own on other websites or in social media post. The post claimed that according to a Pfizer document that was made public through a Freedom of Information Act request, there were 22 instances of miscarriage out of the 50 subjects in the trial, who reported pregnancy after the first dose of the vaccine. But there are only 11 unique miscarriages listed in the Pfizer document. Each miscarriage was counted twice because they appear in two different tables. And those 11 miscarriages are for all participants, vaccine and placebo recipients combined.

We at FactCheck.org cross checked the information with a document that shows whether a participant was assigned to the placebo or vaccine group. We found that three of the 11 miscarriages were among vaccine recipients. The remaining eight miscarriages were in the placebo group, which also reported one induced abortion. The 44% statistic is false. Since the Pfizer trial, other studies have looked at vaccination and pregnancy. Victoria Male, a lecturer in Reproductive Immunology at Imperial College London has been tracking this research. She told us that none of the eight studies looking at miscarriage found an increased rate of miscarriage associated with COVID-19 vaccination. Those studies included nearly 72,000 people who were vaccinated during pregnancy. That's my fact check for this week. I'm Lori Robertson, Managing Editor of FactCheck.org.

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Marianne O'Hare: FactCheck.org is committed to factual accuracy from the country's major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you'd like checked, e-mail us at www.chcradio.com we'll have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

Mark Masselli: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives. Over the past few decades kids have been getting less and less physical activity throughout the school day and as budgets have been tightened, and achievement requirements of increased Phys Ed has become less prevalent in many schools. The University of Michigan researchers wanted to find a creative and effective solution that would increase kids movement and increasing sedentary lifestyles without disrupting the school day.

Dr. Rebecca Hasson: We looked at the scientific literature in terms of prolonged sitting, and they have demonstrated that if you just do two minutes of activity, a small burst,. get up do some movements, sit back down activity and that small of a dose can have dramatic improvements on health, on cognition, on learning. We decided to develop an intervention, a program, that would allow children to get these small burst of activity throughout the day.

Mark Masselli: Dr. Rebecca Hasson is Principal Investigator for InPACT, interrupting of prolonged sitting with activity. She wanted to find out if just two to three minutes short burst of physical activity five times a day would impact the kids' cumulative movement. The research showed that kids of all shapes and body types found that program easy to participate in.

Dr. Rebecca Hasson: We typically see in PE or recess lower participation in girls compared to boys, but in classroom activity breaks you actually see similar rates of participation, if not higher rates of participation in girls compared to boys. We also saw that for children who are carrying a few extra pounds that those children also were exercising at a high intensity. Even children with asthma, they were even able to do the activity breaks at a higher extent than the children without asthma.

Mark Masselli: Dr. Hasson, a kinesiologist said they wanted to design the intervention that would be easy for teachers to adopt and manage, so they created videos designed to get kids moving quickly. Then allow them to quickly ease back into their learning mode.

Dr. Rebecca Hasson: We created a compendium of 200 activity breaks that are just three minutes long. The teachers had a variety of different types of activities, whether it was jumping jacks, leapfrogs, something that will get their heart rate in the target heart zones. We got a lot of positive responses, particularly for the videos from the teachers, because it was really easy to implement.

Mark Masselli: Kids burned on average about 150 more calories per day, and at the end of the week, had accrued a significant amount of physical activity.

Dr. Rebecca Hasson: The kids when they left the laboratory, when they went home, they still continued to be physically active. We had these little accelerometers, they measure movement at the hip and so it tells us how many calories were the kids burning away from the laboratory and how much physical activity were they getting.

Mark Masselli: A low cost easily adoptable fitness intervention for kids, allowing short burst of physical activity throughout the school day, enhancing fitness, empowering kids to move more, positively impacting the learning experience. Now that's a bright idea.

[**Music**]

Mark Masselli: I'm Mark Masselli.

Margaret Flinter: And I'm Margaret Flinter.

Mark Masselli: Peace and health.

Marianne O'Hare: Conversations on Health Care is recorded in the Knowledge and Technology Center Studios in Middletown, Connecticut, and is brought to you by the Community Health Center now celebrating 50 years of providing quality care to the underserved where health care is a right not a privilege, www.chc1.com and www.chcradio.com.