**Transcript: FDA commissioner Dr. Marty Makary on "Face the Nation with Margaret Brennan," June 1, 2025**

MARGARET BRENNAN: Welcome back to Face the Nation. We're joined now by FDA Commissioner Dr. Marty Makary. Good morning.

FDA COMMISSIONER DR. MARTY MAKARY: Good morning.

MARGARET BRENNAN: Good to have you here in person.

DR. MAKARY: Good to be here.

MARGARET BRENNAN: So I want to get through a lot here, but one of the things we've noticed is this new COVID variant that seems to be circulating in Asia. I believe it's NB.1.8.1. It's a variant under monitoring. What do we need to know?

DR. MAKARY: Yeah so this appears to be a subvariant of JN.1, which has been the dominant strain so it's believed that there is cross-immunity protection. The COVID- COVID virus is going to continue to mutate, and it's behaving like a common cold virus. It's now going to become the fifth coronavirus that's seasonal, that causes about 25% of the cases of the common cold.

MARGARET BRENNAN: So you're thinking of it as like a flu-type variant, just a normal fluctuation.

DR. MAKARY: The flu mutates about 34 times more frequently than COVID. The COVID variant mutation rate appears to be a little more stable, but the international bodies that have provided some guidance on which strain to target, have suggested that either JN.1 or any of these subvariants would be reasonable strains to target.

MARGARET BRENNAN: So you don't seem overly concerned about that. I want to get now into some of the recommendations that have been very specific this week from the CDC and you with the HHS Secretary in this video announcement on Tuesday where Secretary Kennedy said the CDC was removing the COVID vaccine for healthy children and healthy pregnant women from its recommended immunization schedule. He then had a memo to the CDC rescinding recommendations for kids' vaccines, saying the known risks do not outweigh the benefits. Then late Thursday, the CDC said quote "shared clinical decision-making," which I think is just talking to your doctor should determine whether kids get vaccinated. Can you clearly state what the policy is? Because this is confusing.

DR. MAKARY: Yeah, we believe the recommendation should be with a patient and their doctor. So we're going to get away from these blanket recommendations in healthy, young Americans because we don't want to see--

MARGARET BRENNAN: For all vaccines?

DR. MAKARY: We don't- well on the COVID vaccine schedule, we don't want to see kids kicked out of school because a 12-year-old girl is not getting her fifth COVID booster shot. We don't see the data there to support a young, healthy child getting a repeat, infinite, annual COVID vaccine. There's a theory that we should sort of blindly approve the new COVID boosters in young, healthy kids every year in perpetuity, and a young girl born today should get 80 COVID mRNA shots, or other COVID shots in her average lifespan. We're saying that's a theory, and we'd like to check in and get some randomized, controlled data. It's been about four years since the original randomized trials, so we'd like an evidence based approach. Dr. Prasad and I published this in the New England Journal of Medicine last week, and we're basically saying we'd like to bring some confidence back to the public around this repeat booster strategy theory, because--

MARGARET BRENNAN: Your statement was not about repeat boosters. It says the vaccine is not recommended for pregnant women, the vaccine is not recommended for healthy children. That's different than annual boosters.

DR. MAKARY: Yeah at this point we're dealing, you know, it is a booster strategy- people would be getting the updated shot. So whether or not a young, healthy--

(CROSSTALK)

MARGARET BRENNAN: But what about kids who haven't gotten a shot?

DR. MAKARY: So we'd like to see the data. We'd love to see that- that data. It doesn't exist.

MARGARET BRENNAN: No, no, no, but on a practical level, for a parent at home, hearing you, trying to make sense here.

DR. MAKARY: Yeah. We're saying, take it back to your doctor.

MARGARET BRENNAN: Their child has not been vaccinated. Are you recommending that their first encounter with COVID be an actual infection?

(END CROSSTALK)

DR. MAKARY: We're not going to push the COVID shot in young, healthy kids without any clinical trial data supporting it. That is a decision between a parent and their doctor. And just so, I don't know if you know the statistics, but 80 for 88% of American kids, their parents, have said no to the COVID shot last season. So America, the vast majority Americans, are saying no. Maybe they want to see some clinical data as well. Maybe they have concerns about the safety--

(CROSSTALK)

MARGARET BRENNAN: I don't want to crowdsource my health guidance. I want a clear thing--

DR. MAKARY: The worst thing you--

MARGARET BRENNAN: --I wouldn't go with popularity--

DR. MAKARY: The worst thing--

MARGARET BRENNAN: --I'm going with, as you're saying, data--

DR. MAKARY: --Yeah so let's see the data.

(END CROSSTALK)

MARGARET BRENNAN: Okay. So the CDC data said 41% of children aged six months to 17 years hospitalized with COVID between 2022 and 2024 did not have a known underlying condition. In other words, they looked healthy--

DR. MAKARY: So--

MARGARET BRENNAN: --and COVID was serious for them.

DR. MAKARY: So first of all, we know the CDC data is contaminated with a lot of false positives from incidental positive COVID tests with routine testing of every kid that walks in the hospital--

MARGARET BRENNAN: You don't trust the CDC data?

DR. MAKARY: --When I go to the ICU, when I walk to the P- the we know, We know that data, historically under the Biden administration, did not distinguish being sick from COVID or an incidental positive COVID test. When you go to an ICU in America and you ask, how many people are in the ICU that are healthy, that are sick with COVID, the answer I get again and again is, we haven't seen that in a year or years. And so the worst thing you can do in public health is to put out an absolute universal recommendation in young, healthy kids. And the vast majority of Americans are saying, no, we want to see some data. And you say, Forget about the data. Just get it anyway.

MARGARET BRENNAN: Okay, so on data and transparency for decades, since 1964 it was the Advisory Committee on Immunization Practices, ACIP that went through this panel recommendation. People watched these things during COVID. The report was then handed up. It offered debate, it offered transparency, and it offered data points that people could refer back to. Why did you bypass all of this and just come down with a decision before the panel could meet and meet that data?

DR. MAKARY: That panel has been a kangaroo court where they just rubber stamp every single vaccine put in front of them. If you look at the minutes of the report from, they even say we were- generally want to move towards a risk stratified approach.

MARGARET BRENNAN: So why not let them do that in June?

DR. MAKARY: So in the meantime, we don't want an absolute recommendation for healthy kids to get it. They can do it, and that committee-committee will meet and make recommendations. But you look at the minutes of the last couple of years, they say we want a simple message for everybody, just so they can understand it. It was not a data based conversation. It was a conversation based on marketing and ease and and I've written an article titled "Why the people don't trust the CDC," and it's in part from that blanket strategy–

MARGARET BRENNAN: You're telling them not to right now. You just said don't trust the CDC.

DR. MAKARY:  We're saying it's going to be between a doctor and a patient until that committee meets or more experts weigh in, or we get some clinical data. If there's zero clinical data, you're opining. I mean, you're just, it's a theory, and so we don't want to put out an absolute recommendation for kids with no clinical data at this point.

MARGARET BRENNAN: So you made this pronouncement as well on pregnant women. There is data. Researchers in the UK analyzed a series of 67 studies, which included 1.8 million women, and the journal BMJ Global Health published it. People can Google it at home, and it says the COVID vaccine in pregnant women is highly effective in reducing the odds of maternal SARS-CoV-2 infection, hospital admission and improves pregnancy outcomes with no serious safety concerns. This is data that shows that it is recommended or could be advised, for pregnant women to take this vaccine. Why do you find otherwise?

DR. MAKARY: There's no randomized control trial. That's the gold standard. Those 67 studies are mixed. The data in pregnant women is different for healthy versus women with a comorbid condition. So it's a very mixed bag. So we're saying your obstetrician, your primary care doctor, and the pregnant woman should together decide whether or not to get it. 12% of pregnant women last year got the COVID shot. So people have serious concerns, and it's probably because they want to see a randomized trial data, the randomized trial of pregnant women–

MARGARET BRENNAN: But in the meantime, the world moves on, and you published in the New England Journal of Medicine on May 20. In that report, you referenced, you listed pregnancy as an underlying medical condition that increases a person's risk for severe COVID. You said that. So then seven days later, you joined in this video announcement saying you should drop the recommendation for the COVID vaccine in healthy pregnant women. So what changed in the seven days?

DR. MAKARY: In the New England Journal medicine, we simply list what the f- what the CDC has traditionally defined as high risk, and we're just saying, decide with your doctor. We're not saying the other–

MARGARET BRENNAN: But doctors want data and information as well from you–

DR. MAKARY: and the randomized trial– so here's the data on pregnant women. A randomized control trial was set up, and it was closed without any explanation. We wanted to see that trial complete so women can have information that in a randomized control trial, which is the gold standard, this is what the data shows. We don't have those data.

MARGARET BRENNAN: All right. It is still unclear what pregnant women now should do until they get the data that you say--

DR. MAKARY: I'd say talk to their doctor.

MARGARET BRENNAN: When do they get the data you're promising? All these controlled studies.

DR. MAKARY: In the absence of data, they should talk to their doctor--

MARGARET BRENNAN: So no date?

DR. MAKARY: --and their doctor will use their best wisdom and judgment.

MARGARET BRENNAN: FDA Commissioner, thank you for trying to help clear this up.

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