The Washington Post Democracy Dies in Darkness

An FDA adviser said we need to give kids vaccines to fully understand their safety. Here's the crucial context.

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The Food and Drug Administration's advisory committee Tuesday provided a pretty resounding endorsement for giving a coronavirus vaccine to children ages 5 to 11. It voted 17 to 0 in favor of what is known as emergency-use authorization, with one member abstaining.

This paves the way for the agency to make the Pfizer-BioNTech vaccine available to that age group for the first time, possibly as soon as next week.

But even as that news landed, some are pointing to a few less-than-resounding comments from one of the advisory committee members. While voting for the authorization, Eric Rubin acknowledged that it was "a much tougher one, I think, than we had expected coming into it." He also said that "we're never going to learn about how safe this vaccine is unless we start giving it."

Those latter comments, in particular, have begun circulating widely in conservative media and among vaccine skeptics. Some have likened them to House Speaker Nancy Pelosi's (D-Calif.) statement that Congress had "to pass [Obamacare] so that you can find out what's in it." Others have suggested the authorization would be akin to turning children into guinea pigs.

But the comments — and the situation — deserve some context.

First, here's a look at the fuller comments from Rubin, who is a professor at Harvard University and also editor in chief of the New England Journal of Medicine (with key parts **bolded**):

> **This is a much tougher one, I think, than we had expected coming into it.** The data show that this vaccine works and it's pretty safe … **And yet, we're worried about a side effect that we can't measure yet, but it's probably real.** And we see a benefit that isn't that same as it is in older patients. …
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> It's a very, sort of, personal choice. If I had a child who was a transplant recipient, I would really want to be able to use a vaccine. And there are certain kids who probably should be vaccinated. The question of how broadly to use I think is a substantial one. And I know it's not question, and I know we're kind of punting that to ACIP.
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> **But I do think that it's a relatively close call.** As Dr. [Ofer] Levy just said, and Dr. [Hayley] Gans said, it really is going to be a question of what the prevailing conditions are. **But**

> **we're never going to learn about how safe this vaccine is unless we start giving it. That's just the way it goes.** That's how we found out about rare complications of other vaccines like coronavirus vaccine. And I do think we should vote to approve it.

It's true that what Rubin is saying here is significant and noteworthy. It acknowledges there's plenty we don't yet know, given the limited time and scale of what we've been able to study. Other members of the committee acknowledged the difficulty of this decision, as well, pointing to the fact that it involved relying upon studying a few thousand children when deciding whether to authorize the vaccine for potentially millions.

It's basically tailor-made for vaccine skeptics such as Tucker Carlson and Sen. Ron Johnson (R-Wis.). That goes double given the sensitivity of vaccinating young children — an issue on which there is more skepticism in the broader populace — and the looming debates over school vaccine mandates.

But that mandate question is also an important one to emphasize. What the FDA is considering here, after all, is not forcing any children ages 5 to 11 to take the vaccine; rather, it's about giving parents the option. Emergency-use authorizations are, by definition, about deciding whether the benefits of a given treatment outweigh the risks during a public health emergency. It's necessarily a situation in which difficult decisions need to be made without the kind of extensive studies everyone would prefer were done.

California recently became the first state in the country to say it would mandate the coronavirus vaccines in schools, but it will do so only after the vaccines receive full authorization for the given age groups. So nobody will be forced to get the vaccine until we get the more extensive data that will come, as Rubin notes, after "we start giving it."

The situation is the same with broader vaccine mandates for adults, which have come after the FDA gave the Pfizer-BioNTech vaccine its full authorization this summer — when we had a much fuller picture beyond the early studies.

The side effect Rubin and others mentioned Tuesday is myocarditis, an inflammation of the heart muscle that disproportionately impacts adolescent boys and young men, generally after the second dose of the vaccine.

As Stat News reported recently:

> Because myocarditis occurred only rarely in clinical trials, it's difficult to estimate exactly how often it occurs. In its briefing documents, the FDA said that myocarditis and pericarditis, a related inflammation of the heart's lining, were reported to the U.S. government's Vaccine Adverse Events Reporting System (VAERS) at a rate of 71.5 cases per million in vaccinated males ages 16 to 17 and 42.6 cases per million in males ages 12 to 15. That equates to about one case per 12,000 for 16- to 17-year-olds and one case per 24,000 for 12-to-15-year-olds.
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> But the FDA also analyzed a database of claims from Optum, part of the insurer UnitedHealth Group. In that database, the estimated excess risk of myocarditis and pericarditis approached 200 cases per million in fully vaccinated males aged 16 to 17, and 180 cases per million in vaccinated males aged 12 to 15 years of age. That's about one case per 5,000 vaccinated boys.

In other words, the risk of this condition, while remaining rare, goes up for boys. And combining that with the generally better health outcomes for younger people and children who contract the coronavirus, some experts on the advisory committee acknowledged it was a tighter cost-benefit analysis to approve the vaccine on an emergency

basis than they've previously confronted.

Stat's report also got at the details of that newest cost-benefit question. FDA modeling showed that most of the time, vaccination would prevent between 200 and 250 hospitalizations per 1 million boys ages 5 to 11. It estimated the constant rate of hospitalizations for myocarditis would be significantly less — about 98 per million.

But when cases were low, it would have kept as few as 21 boys per million of that age group out of the hospital. Again, from their report:

> So normally, even in the highest-risk group, the number of Covid-related hospitalizations prevented would be double the number of hospitalizations due to myocarditis. But when the virus is under control, the number of myocarditis-related hospitalizations in boys in this age group would be slightly more than Covid-related hospitalizations because Covid-19 cases would be so low.
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> The FDA argues that even in this case, outcomes for those hospitalized with Covid-19 would be worse than those with myocarditis, and that it chose to model a high rate of myocarditis, meaning the condition may be less common.

This gets at Rubin's point about which children might be better candidates for vaccination: "If I had a child who was a transplant recipient, I would really want to be able to use a vaccine. And there are certain kids who probably should be vaccinated. The question of how broadly to use I think is a substantial one."

The fact that this cost-benefit calculation and whether we need broad-scale vaccination for children was discussed in detail as part of these deliberations would seem to be a good thing when it comes to transparency and instilling confidence in the process. Despite vaccine skeptics criticizing the media for supposedly being unwilling to question the vaccines, Rubin's comment was included in much of the coverage of the FDA's decision Tuesday.

That said, some of those who have long searched for something to back up their vaccine skepticism — despite all the data we now have demonstrating their safety and effectiveness for the approved groups — have shown they will grasp at much of anything in their pursuit. This will surely be high on that list, even as it involves merely giving parents the chance to make the decisions for themselves.

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