Doshi public comments for FDA VRBPAC meeting, October 26, 2021
Comment submitted to docket https://www.regulations.gov/document/FDA-2021-N-1088-0001

Dear members of the VRBPAC,

For identification purposes, my name is Peter Doshi. I am on the faculty at the University of Maryland and an editor at The BMJ. I have no relevant conflicts of interest and my comments are my own.

The decision before the committee today—to endorse or reject Pfizer's EUA application for its covid vaccine in children 5 to 11 years of age—puts the committee in a very difficult spot.

If the evidence were clear cut that the benefits outweigh the risks, the committee's work would be easy. But the reality is that that evidence is not there. Pfizer's pivotal trial in children under 12 years of age did not even report on vaccine efficacy, only immunogenicity, and Pfizer has acknowledged that we simply do not know how antibody response correlates with protection from severe disease:

> "We actually looked at our breakthrough cases in our placebo-controlled phase 3 study, and have compared the antibody titers where we had the opportunity in individuals that got the disease versus the ones that didn't, and we were also unable to really come up with an antibody threshold. So I think there's probably a much more complex story and not easily just addressed with neutralizing antibodies."
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> Pfizer SVP Kathrin Jansen
> FDA VRBPAC meeting, September 27, 2021
> (Video begins at 5:37:13 - https://youtu.be/WFph7-6t34M?t=20233)

It may take a long time to determine whether, and how, the benefits can be shown to outweigh the risks.

But there is a very real social backdrop here. There are two major segments of American society – one that eagerly anticipates the time when vaccines for their children are available, and another, also large, proportion of the American population that is not anywhere close to being ready to vaccinate their children.

Let's be realistic. An EUA will almost certainly result in mandates across the country. It doesn't matter that fact sheets for EUA covid-19 vaccines, for example, by law say, in black and white that it is the recipient's choice whether or not to receive a covid-19 vaccine. We have seen what happened. EUA vaccines became mandated despite all this.

The committee's decision then, either up or down on the EUA, will create major winners and major losers, deepening the divide already splitting our country.

I chose to speak today to suggest to the advisory committee that there may be a third way, a way to make both parties happy. And that is by rejecting the EUA, but making a strong recommendation for Pfizer and the FDA to set up a robust Expanded Access program.

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Why is Expanded Access the right way to go? Because it decouples "access" from "authorization" or "approval." It ensures that those who want the vaccine for their children can get it—but for those who do not want it, there will be no mandates. It will remain their choice.

Here's how it could work. The Expanded Access program would offer the vaccine to all parents who express an interest in the vaccine and sign an informed consent. That document would make clear the state of the evidence—namely, that FDA does not yet know whether the benefits outweigh the risks. Parents comfortable with this can proceed to access vaccine.

Expanded Access, I propose, is the way to thread the needle, **enabling access but ensuring people retain the right to choose** what is right for themselves and their families.

Sure, Expanded Access wasn't designed with this kind of thing in mind. But the EUA process wasn't designed for entire population deployment of unapproved products, either. It's time to get creative.

So I urge members of the VRBPAC to: (1) reject the EUA and instead promote an Expanded Access program and (2) state clearly that EUA products should not result in mandates.

Thank you for your attention.