Doshi public comments at FDA VRBPAC meeting, June 10, 2020
5 minutes.

Hello, I'm Peter Doshi, thanks for the opportunity to speak. **[If you could please advance to my title slide showing my financial disclosures]** For identification purposes, I am on the faculty at the University of Maryland and an editor at The BMJ. I have no relevant conflicts of interest.

[next slide please, labeled "Slide A" at the top-right] So the question is: what is the evidence in children thus far? Let's take Pfizer's trial of 12-15 year olds which supported the recent EUA. In this trial, harms outweighed the benefits. The placebo group was better off than the vaccine group. I know that's a blunt way to put it, but the reason is because efficacy benefits were **rare** whereas side-effects were **common**. I'll explain that.

In terms of benefits, the reported 100% efficacy was based on 16 covid cases in the placebo group versus none in the fully vaccinated group. But there were around 1000 placebo recipients, so just 2% got covid. Put another way, 2% of the fully vaccinated avoided covid, whereas 98% of the vaccinated wouldn't have gotten covid anyways. But on the other side of the ledger, side-effects were common – it's on my slide – 3 in 4 kids had fatigue and headaches, around half had chills and muscle pain, around 1 in 4 to 5 had a fever and joint pain; the list goes on.

In sum, all fully vaccinated 12-15 year olds avoided symptomatic covid, but most wouldn't have gotten covid even without the vaccine—so the benefit is small. But it came at the price of very common side-effects that were mild to moderate in severity, and lasted for a few days.

And then are long-term effects about which we still know nothing. I'll come back to this point.

[next slide, slide B please] Why do so few vaccinated children enjoy **any** efficacy benefit? As I said, one reason is that few kids got covid, at least during Pfizer's trial. Also, many infections are asymptomatic. But another reason is that many children are post-covid at this point. The CDC estimates some 25 million US children were infected by March 2021. That translates into 23% of kids 0-4 years old and 42% of children 5 to 17 years as being post-covid. And I say 'post-covid' because the evidence to date suggests that the immune response following natural infection is robust and long lasting. I think this is why so few vaccinated kids reap any benefit.

[next slide, slide C please] Now let's talk about long-term harms. There's a view out there that serious side effects always occur within 6 weeks of dosing. Well, it's just not so simple. The fact is that historically, side effects were **not** always discovered so quickly. For Pandemrix, an influenza vaccine, cases of narcolepsy in adolescents were first reported around 9 months after vaccines were given. And now, with covid vaccines, it wasn't until this month, 4 or 5 months into the vaccination campaign in Israel, that myocarditis was recognized as a harm in young men. So it's not simply a matter of how long after dosing did these adverse events occur. The crucial question is when were these adverse events **noticed, researched, and established as linked to** the vaccine. The pharmacovigilance timeline matters. Unless you recognize harms soon after they occur, you can't use that knowledge to prevent harm in the next person about to get the vaccine.

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And on long-term harms, we know nothing. All we can do is theorize, say by considering the mechanism of action, vaccine biodistribution, and other essential studies that we outlined in our June 1 Citizen Petition.

[next slide, slide D please] Next I want to address this idea of vaccinating children to protect adults. I encourage the advisory committee to read Dr. Lavine et al.'s editorial who explain why "vaccinating children is likely to be of marginal benefit in reducing the risk to others." And even if you think a small benefit is better than nothing, let's not forget that it's an unproven hypothetical benefit. We need confirmatory evidence, not just assumptions.

And then there's the ethics and the law. FDA can only indicate a product for use in a given population if benefits outweigh risks in **that same population**. So if benefits don't outweigh risks in children themselves, it can't be indicated for children, full stop. Whether vaccinating children might help adults is a moot point.

[final slide, slide E please] In summary, we must avoid a fiasco. EUA criteria are not met because there's no emergency for children; thus far, risks outweigh benefits and we know nothing about long term safety other than history's lesson to be very cautious.

Does this mean we should prevent parents desiring to vaccinate their children? No. Access does not require an EUA or BLA. Rather, an **expanded access program** can thread the needle, providing access to vaccines while being honest about the evidence, that it has not been demonstrated that benefits outweigh risks. FDA approval must represent a high bar of robust evidence, otherwise the whole point of regulation is lost.

Thank you for listening.