Doshi public comments at FDA VRBPAC meeting, September 17, 2021
3 minutes.

Hi, I'm Peter Doshi, thanks for the opportunity to speak. **[Hopefully you can see my title slide with 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, which is labeled "Slide A"] I want to start off by asking: just what problem is this third dose aiming to solve? If we have a "pandemic of the unvaccinated," as our public health officials have repeatedly stated, why would a quote "fully" vaccinated person need a third dose?

[next slide B please] The briefing documents suggest the rationale for boosters is waning immunity, but the lowest vaccine efficacy figure mentioned is 83.7%. And last month, FDA approved Pfizer's vaccine stating that efficacy against symptomatic covid is 91%. Sure, a third dose might nudge up efficacy numbers. But so, too, might a fourth dose and a fifth dose. The thing is, the two-dose regimen efficacy numbers are already way higher than the 50% bar that FDA set in June last year for an approvable vaccine.

Before contemplating the licensure of dose 3, shouldn't FDA first require evidence that the 2-dose regimen no longer meets the efficacy bar the agency just weeks ago said it met? If vaccine efficacy is now below 50%, let's see the data.

[next slide C please] Now let's discuss safety. When discussions about a third dose began in July, CDC deputy director Dr. Jay Butler said it was vital to find out if the third dose increased adverse reactions—particularly severe ones.

Unfortunately, we're still in the dark. Pfizer's booster application reports on just 329 people, with no control data. Now there *is* a Pfizer ongoing placebo-controlled randomized trial of boosters in 10,000 people not discussed in the briefing documents. But this trial is unlikely to satisfactorily characterize booster safety. First, the trial is too small and enrollment's limited to "healthy participants." Second, we really need to know how safe boosters are in people who already had bad reactions to dose 1 or 2. But such people are obviously *less likely* to volunteer to participate in this trial, so we won't have the data to answer the question. Yet if the booster is approved, such people will surely be mandated to receive a third dose.

[final slide D please] I'll end with a question. Last week three medical licensing boards said that they could revoke doctors' medical licenses for providing covid vaccine misinformation. I'm worried about the chilling effect here. There are clearly many remaining unknowns and science is all about probing unknowns. But in the present supercharged climate—and I'll point out that multiple members of this committee are certified by these boards—I want to ask FDA: what is FDA doing to ensure that those advising it are able to speak freely, without fear of reprisal?
Thank you for your attention.