Doshi public comments at FDA VRBPAC meeting, April 6, 2022
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 and my comments today are my own.

[next slide please] Last November, The BMJ reported the disclosures of a whistleblower named Brook Jackson, who worked for Ventavia, a contract research company that ran three of the clinical trial sites for Pfizer's vaccine. Jackson alleged the company had falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events. She provided The BMJ with company emails, internal documents, text messages, photos and recordings of her conversations with company employees.

[next slide please] This photo, for example, shows vaccine packaging materials that are only supposed to be seen by unblinded staff, just left out in the open.

[next slide please] And unblinding may have occurred on a far wider scale. Here you can see the document containing the instructions Ventavia staff were given to file each trial participant's randomization and drug assignment confirmation sheet into each participant's chart. This contained unblinded information.

[next slide please] Unblinding, as I think everybody knows, creates serious concerns about data integrity. Once this massive error was discovered, Ventavia asked staff to go through each and every chart to take out the randomization and drug assignment confirmations. You can see here an email from Ventavia's COO reacting after discovery of the problem: they had not even realized that the drug assignment confirmation contained unblinding information.

[next slide please] In the heat of a pandemic, it's not hard to imagine that corners were cut and mistakes were made. Some mistakes are benign, but others carry serious consequences to data integrity. One hopes Ventavia is an extreme outlier, but we need more than just hope. We need evidence that the data were dealt with properly. We need regulatory oversight. But despite whistleblower Brook Jackson's direct complaint to the FDA, FDA never inspected Ventavia. In fact, FDA only inspected 9 of the trial's 150-plus sites before approving the vaccine. Just 9 sites. And Pfizer continues to use Ventavia for trials.

[next slide please] What about Moderna? FDA had over a year and inspected just one – ONE – of the trial's 99 sites. How can FDA feel confident in the Moderna data based on a 1% sample?

[next slide please] Data integrity requires adequate regulatory oversight. Trustworthy science requires data transparency. It's been over a year, but anonymised participant level data remain inaccessible to doctors, researchers, and the public. The public paid for these products, and the public takes on the balance of benefits and harms post vaccination. The public has a right to data transparency, and FDA has an obligation to act. Thank you.