Doshi comments to "Whistling at the Fake" conference, May 6, 2022
7-10 minutes.

Thank you for the invitation. I am an academic, I work at the University of Maryland School of Pharmacy and also for The BMJ as a medical journal editor. So I come from the world of medicines – drugs, vaccines, and the approval process.

I was asked to speak about The BMJ's investigation into poor practices occurring at a Texas company that was contracted to work on the Pfizer covid vaccine trial in the second half of 2020. So I will present that story, as well as the aftermath which ties into the issue of misinformation—but perhaps in an unexpected way.

[next slide] The story came to us from a whistleblower named Brook Jackson, who worked for a contract research company called Ventavia, that ran three of the clinical trial sites for Pfizer's vaccine. Ventavia enrolled more than 1,000 participants into the 44,000 person trial.

Jackson alleged that Ventavia had falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events. But Jackson didn't just bring allegations to us, she provided The BMJ with company emails, internal documents, text messages, photos and recordings of her conversations with company employees. So it was a very solid case.

[next slide] This photo, for example, shows vaccine packaging materials just left out in the open. This is not good.

This was a blinded trial, which means to ensure the validity of the results, neither patients nor investigators should know whether the participant got vaccine or placebo.

But these cartons clearly identify whether something is vaccine or placebo, and the patient's ID number is written on it.

The way this was supposed to work is that the only people who could see this were the unblinded …

That is sort of a visually arresting way to understand how unblinding could occur.

[Next slide] But here you will see that at Ventavia, 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. Again, this is unblinded information that allows one to figure out whether the person got vaccine or placebo, and staff were being instructed to place a copy of this sheet in participants' charts.

[next slide] 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. What's clear is that

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Ventavia management had not, until the whistleblower started raising questions about this, even realized that the drug assignment confirmation contained unblinding information.

[next slide] In the heat of a pandemic, it's not hard to imagine that some places were not doing science quickly, but perhaps rushing faster than was acceptable. Places where corners were cut and mistakes were made. Some mistakes are benign, but others carry serious consequences to data integrity.

I very much hope that Ventavia is an extreme outlier, but the public needs more than just hope. We need evidence that the data were dealt with properly. Pfizer has said it didn't identify any issues that would invalidate the data, but what we really need to know is what does an independent regulatory think.

That is what regulatory oversight is for. But unfortunately the reason Jackson the whistleblower came to us is precisely because the FDA did not thoroughly investigate.

Despite a direct complaint that Jackson made 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] That was the BMJ story. The BMJ commissioned an award winning investigative reporter to write the story and we published on 2 November, following legal review, external peer review and the eyes of numerous editors. And it received record traffic. Millions of reads. For those of you that know about Altmetrics, it has the second highest Altmetric in history.

[next slide] But a week later, readers began reporting a variety of problems when trying to share our article. Some reported being unable to share it. Many others reported having their posts flagged with a warning about "Missing context ... Independent fact-checkers say this information could mislead people." Those trying to post the article were informed by Facebook that people who repeatedly share "false information" might have their posts moved lower in Facebook's News Feed. Group administrators where the article was shared received messages from Facebook informing them that such posts were "partly false."

[next slide] This was all triggered by a "fact check." But it really is an unbelievable fact check. The title itself is nonsensical. "Inaccurate, incompetent and irresponsible," is how our editors in chief described it. It called the BMJ a "news blog." It published the story on its website under a URL that contains the phrase "hoax-alert".

But most importantly, it failed to provide a single assertion of fact that The BMJ article got wrong. Instead, it took to undermining the credibility of the whistleblower as if the story somehow just rested upon her word, and not the many actual trial documents The BMJ obtained from the whistleblower. But this fact check is what led to Facebook taking these actions against our article.

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[next slide] And despite our appeals to Lead Stories and Facebook, including an open letter to Mark Zuckerberg, the errors relating to Facebook's tagging of our article have not been corrected. Zuckerberg didn't respond.

I think this whole case highlights an important and concerning intersection where whistleblowers and fact checking meet in an unexpected, and unfortunate, way. The BMJ published fully fact checked journalism based on a trove of materials brought to it by a whistleblower, documenting serious problems occurring at certain trial sites involved in one of the world's most important clinical trials. The story thus affirms the crucial role of whistleblowers, but the story – or post publication story - also shines a light on the power of fact checking companies to shape the social media environment in ways that are not healthy and should worry readers.

I think this story suggests we need to take a broad view of the problem of misinformation.