BMJ's Peter Doshi Tells FDA About Serious Concerns Over Pfizer Trial Data and Lack of FDA Oversight

Description

UK: Dr. Peter Doshi is an editor at the British Medical Journal ("BMJ"). He dialled in to the most recent FDA committee meeting on vaccines and related biological products to give them his views regarding the integrity of the Pfizer "vaccine" trials.

On 2 November 2021, the BMJ published information disclosed to them by whistle-blower Brook Jackson, a former regional director for Ventavia Research Group. Ventavia is a company that was contracted by Pfizer to help with the decisive trial.

Jackson provided BMJ with company documents, audio recordings, emails and photographs to support her claims. She told BMJ: "The company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial."

By The Naked Emperor

I have written a few posts about Dr. Peter Doshi as he seems to be a man of integrity, reporting on issues that most mainstream publications don't or won't. Dr Doshi is an associate professor of pharmaceutical health at the University of Maryland School of Pharmacy, as well as a senior editor at the British Medical Journal. "His research focuses on the drug approval process, how the risks and benefits of medical products are communicated, and improving the credibility and accuracy of evidence synthesis and biomedical publications."

In the most recent US Food and Drug Administration ("FDA") Vaccines and Related Biological Products Advisory Committee meeting in the US, 6 April 2022, Dr. Doshi dialled into the Open Public Hearing Session. This is where members of the public can present their own information to the FDA. The committee was meeting to discuss considerations for the use of Covid vaccine boosters and the process for Covid vaccine strain selection to address current and emerging variants.

Dr. Doshi told the FDA about Brook Jackson, a whistle-blower from Ventavia, which ran Pfizer's

vaccine trials. He discussed how unblinding of trial participants seems to have occurred and how this creates serious concerns about data integrity. Dr. Doshi also highlighted the lack of FDA inspection.

The video for the FDA meeting is below. We have embedded the video to begin with Peter Doshi's statement (start 5:34:44). But all of the public presentations are interesting and these begin at around 5:15, wrote The Naked Emperor.

US FDA: Vaccines and Related Biological Products Advisory Committee, 6 April 2022

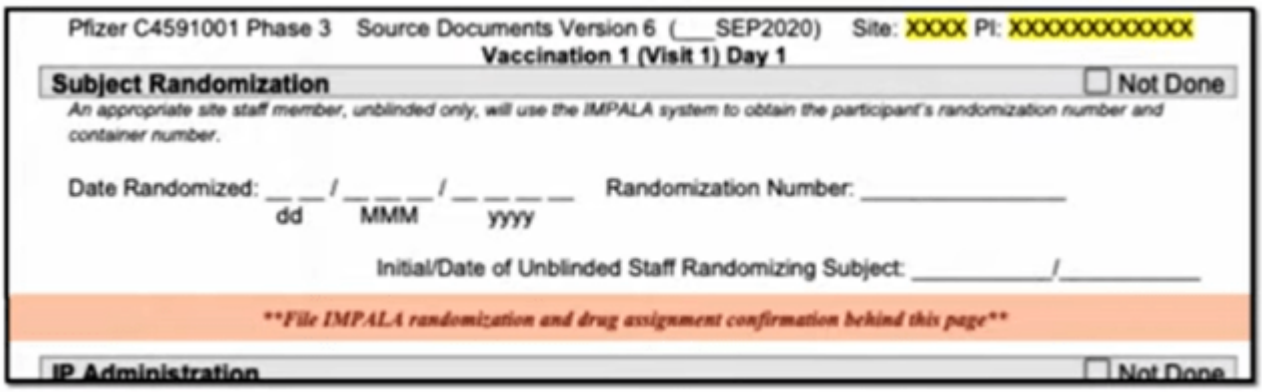
A transcript of his comments is below.

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.

Last November, The BMJ reported the disclosures of a whistle-blower 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."

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

An 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 randomisation and drug assignment confirmation sheet into each participant's chart. This contained unblinded information.



Pfizer C4591001 Phase 3 Source Documents Version 6 (___SEP2020) Site: XXXX PI: XXXXXXXXXXXX

Vaccination 1 (Visit 1) Day 1

Subject Randomization ☐ Not Done

An appropriate site staff member, unblinded only, will use the IMPALA system to obtain the participant's randomization number and container number.

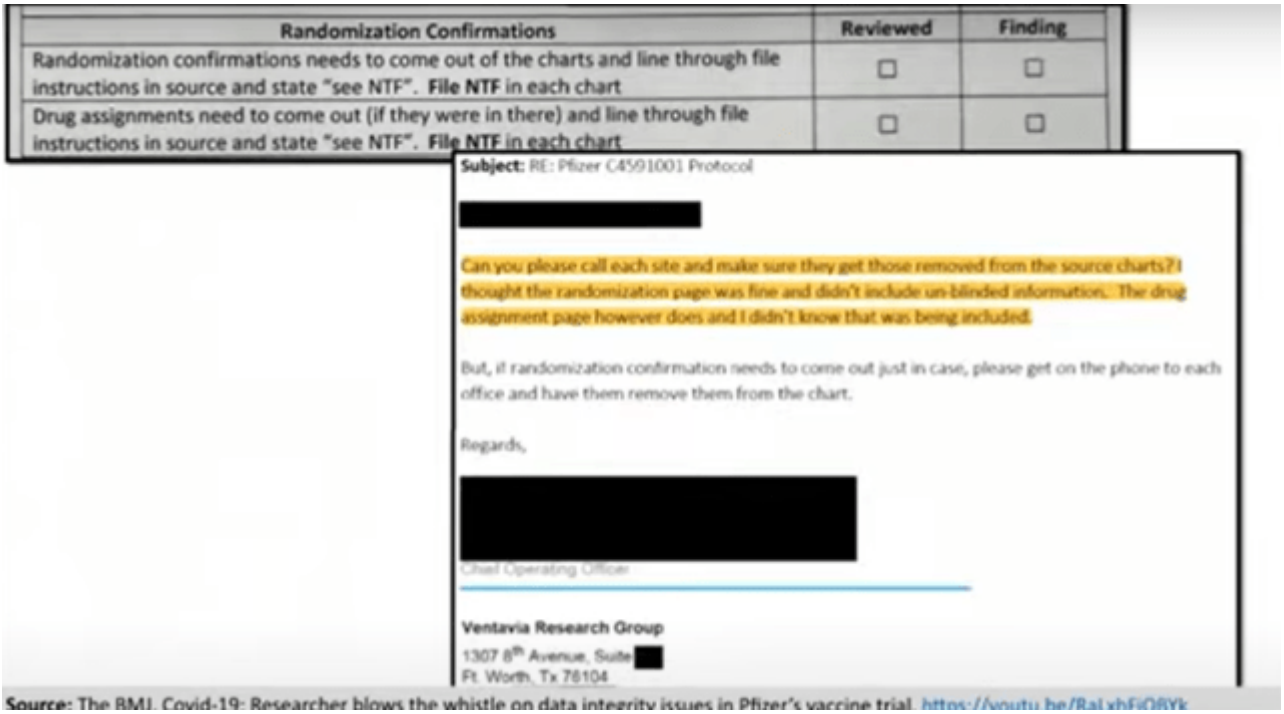
Date Randomized: __ __ / __ __ __ / __ __ __ __ (dd / MMM / yyyy) Randomization Number: _____

Initial/Date of Unblinded Staff Randomizing Subject: _____/_____

File IMPALA randomization and drug assignment confirmation behind this page

IP Administration ☐ Not Done

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 randomisation and drug assignment confirmations. You can see here an email from Ventavia's COO reacting after discovery of the problem. They had not even realised that the drug assignment confirmation contained unblinding information.



Randomization Confirmations	Reviewed	Finding
Randomization confirmations needs to come out of the charts and line through file instructions in source and state "see NTF". **File NTF** in each chart	☐	☐
Drug assignments need to come out (if they were in there) and line through file instructions in source and state "see NTF". **File NTF** in each chart	☐	☐

Subject: RE: Pfizer C4591001 Protocol

[redacted]

Can you please call each site and make sure they get those removed from the source charts? I thought the randomization page was fine and didn't include un-blinded information. The drug assignment page however does and I didn't know that was being included.

But, if randomization confirmation needs to come out just in case, please get on the phone to each office and have them remove them from the chart.

Regards,

[redacted]

Chief Operating Officer

Ventavia Research Group

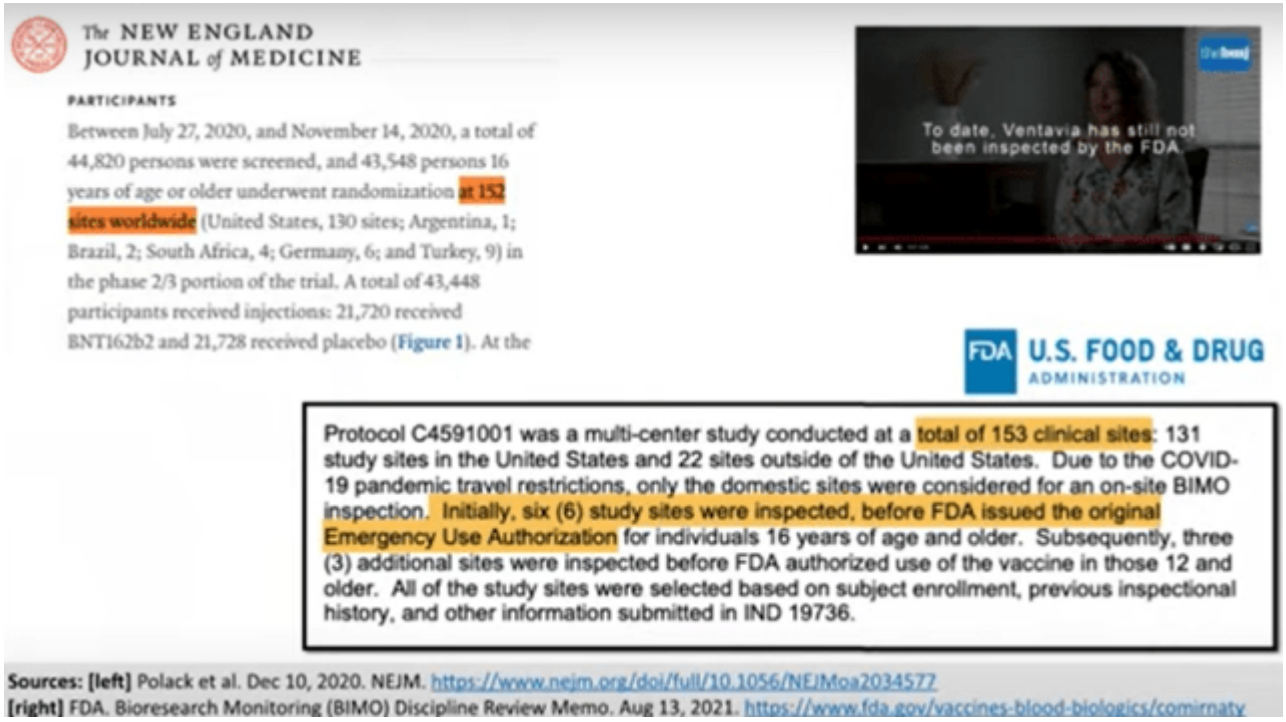
1307 8th Avenue, Suite [redacted]

Ft. Worth, Tx 76104

Source: The BMJ. Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial. https://youtu.be/BaLxbFiO8Yk

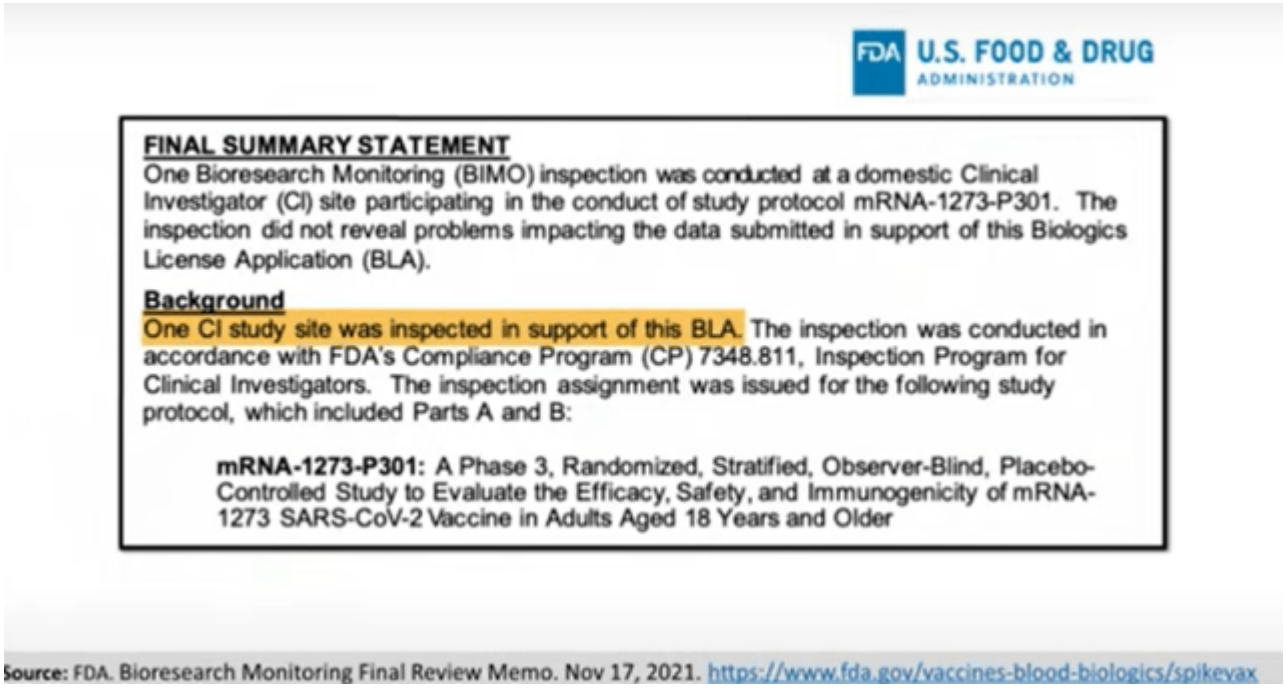
In the heat of a pandemic, it's not hard to imagine that corners were cut and mistakes were made. Some mistakes are benign but others carry serious consequences to data integrity. One hopes Ventavia is an extreme outlier, but we need more than just hope. We need evidence that the data were dealt with properly. We need regulatory oversight. But despite whistle-blower 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.



Sources: [left] Polack et al. Dec 10, 2020. NEJM. https://www.nejm.org/doi/full/10.1056/NEJMoa2034577
[right] FDA. Bioresearch Monitoring (BIMO) Discipline Review Memo. Aug 13, 2021. https://www.fda.gov/vaccines-blood-biologics/comirnaty

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?



Source: FDA. Bioresearch Monitoring Final Review Memo. Nov 17, 2021. https://www.fda.gov/vaccines-blood-biologics/spikevax

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.

by Rhoda Wilson

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