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British Medical Journal: "COVID-19 Vaccines and Drugs Were Developed at "Warp Speed""

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FDA oversight of clinical trials is "grossly inadequate," say experts

On 25 September 2020, the US Food and Drug Administration (FDA) received a complaint by Brook Jackson who had been working for Ventavia Research Group, a Texas based company hired to run clinical trials for Pfizer's covid-19 mRNA vaccine. Jackson, a regional director, had witnessed problems at three trial sites she was overseeing and complained to an FDA inspector about a range of problems including falsified data, unblinded patients, and inadequately trained vaccinators who were slow to follow up on adverse events. "I thought that the FDA was going to swoop in and take care of everything. What I was reporting was so important," Jackson told The BMJ. The FDA did not, however, inspect the trial sites in question.

This lack of oversight was not an isolated case, *The BMJ* has learnt. Regulatory documents show that only nine out of 153 Pfizer trial sites1 were subject to FDA inspection before licensing the mRNA vaccine. Similarly, only 10 out of 99 Moderna trial sites2 and five of 73 remdesivir trial sites3 were inspected.

Now, facing a backlog of site inspections, experts have criticised the FDA's oversight of clinical trials, describing it as "grossly inadequate." They say the problem, which predated covid-19, is not limited to a lack of inspections but also includes failing to notify the public or scientific journals when violations are identified—effectively keeping scientific misconduct from the medical establishment.

The FDA is "endangering public health" by not being candid about violations that are uncovered during clinical trial site inspections, says David Gortler, a pharmacist and pharmacologist who worked as an FDA medical reviewer between 2007 and 2011 and was then appointed as a senior adviser to the FDA commissioner in 2019-21.

“The lack of full transparency and data sharing does not allow physicians and other medical scientists to confirm the data independently and make comprehensive risk-benefit assessments,” continues Gortler, who is now a fellow at the Ethics and Public Policy Center thinktank in Washington DC.

Paused during the pandemic

Between March and July 2020, at the peak of pandemic restrictions, the FDA paused its site inspections and only “mission critical” inspections were carried out. Gortler says, however, that this was the time that the FDA should have ramped up its oversight, not scaled back, especially since covid-19 products were being developed at warp speed and intended for millions of people. “The drug companies took appropriate measures to keep staff safe, which is exactly what the FDA could and should have done,” said Gortler.

A former staffer in the FDA’s Office of Criminal Investigations was also concerned about the agency’s failure to fully tackle Jackson’s complaint about falsified data in Pfizer’s mRNA vaccine trial. In an email dated March 2021, they wrote, “Having worked at the FDA, I see it as surprising, for many reasons, that the agency turned a blind eye . . . They likely feared the criticism they undoubtedly would have received for holding up a vaccine (which they knew they would eventually approve anyway) at the expense of untold lives lost.”

The former FDA employee, who signed a non-disclosure agreement and did not respond to interview requests, went on to write, “My point here is that instead of the regulators protecting the public, they were complicit. At the time, they may have been doing what they believed to be the right thing under extraordinary circumstances. But now, they may soon have some explaining to do.”

The FDA told *The BMJ* it takes oversight of clinical trials seriously and had adapted to travel restrictions, publishing draft guidance4 for remote regulatory assessments. This guidance describes virtual inspections using live streaming and video conferencing and requests to view records remotely.

Gortler, who is a credentialed FDA inspector, laughed at the proposition. “You can’t do a remote inspection. That’s like saying I’m going to arrest somebody remotely. You have to be there on site and look at every nuance such as cleanliness, organisation, staff coordination—even their body language. During a pandemic, the FDA could’ve put inspectors in hazmat suits if they wanted to, there’s no excuse for not going onsite.”

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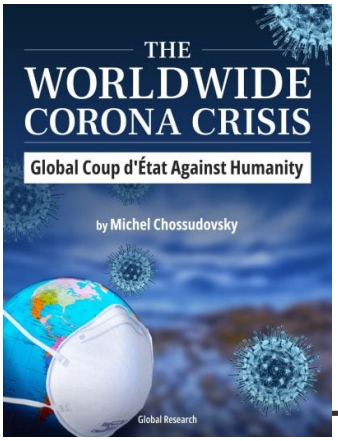

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