Whistleblower Lawsuit Accuses Pfizer of Fraud During COVID Vaccine Trials

A whistleblower lawsuit alleging fraud during Pfizer's COVID vaccine trials will be allowed to move forward after a district court judge unsealed a complaint filed more than a year ago, along with 400 pages of exhibits.

The U.S. Justice Department, which represents the FDA, said it will not get directly involved in the case, but reserved the right to intervene at a later date. The government's lawyers didn't explain why they did not intervene and the FDA, which is supposed to investigate alleged clinical trial fraud, hasn't responded.

Brook Jackson filed a lawsuit in January 2021 under the False Claims Act accusing Pfizer and two of its contractors, Ventavia Research Group and ICON PLC, of "cutting corners in clinical trials" and falsifying clinical trial documents in their "race to secure billions in federal funding and become the first to market."

Jackson alleged that as a result, millions of Americans received "a misbranded vaccination which is potentially not as effective as represented."

Jackson was a regional director for Ventavia in 2020 before being fired after she filed a complaint with the U.S. Food and Drug Administration (FDA) over indiscretions she said she observed during Pfizer's vaccine trials.

Evidence of fraud and misconduct shared with BMJ

Although the original complaint was sealed, Jackson gave the British Medical Journal (BMJ) a cache of internal company documents, photos and recordings highlighting Ventavia's misconduct in November 2021.

Jackson told the BMJ Ventavia falsified data, unblinded patients, cut corners, improperly diluted the vaccines, employed inadequately trained people to administer vaccines, did not provide informed consent, deviated from the recommended temperature – which is crucial for mRNA vaccines like Pfizer's – and was slow to follow up on and/or did not report adverse events that occurred during the crucial phase 3 clinical trial.

In a recording of a meeting on Sep. 2020 shared with the BMJ by Jackson, a Ventavia executive explained the company wasn't able to quantify the types and number of errors they were finding when examining the trial paperwork for quality control.

"In my mind, it's something new every day," a Ventavia executive says. "We know that it's significant."

In an email sent by ICON, it was revealed Venavia was not keeping up with data entry inquiries. In September 2020, ICON sent Ventavia an email stating the expectation of the study is

that all queries be addressed within 24 hours.

ICON then highlighted over 100 outstanding queries older than three days, including two from individuals for which the subject had "reported with severe symptoms/reactions."

In keeping with protocol, "subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate," the email states.

According to the trial protocol, the participant should have been contacted via phone "to ascertain further details and determine whether a site visit is clinically indicated."

Journalist Matt Taibbi, a journalist, said he listened to a recording where a Ventavia employee referred to its trial data problems as "cleanup on aisle five" and grilled Jackson about whether she had "spilled the beans" to outsiders.

Meanwhile, Facebook censored the BMJ report and warned users not to share it because "Lead Stories," Facebook's questionable fact-checker, claimed the reporting would not "disqualify" the overall Pfizer COVID vaccine trial.

Documents show problems had been going on for weeks. In a list of "action items" sent among Ventavia leaders in early August 2020 – shortly after the trial began and before Jackson's hiring – a Ventavia executive specified three site staff members with whom to "go over e-diary issue/falsifying data, etc."

One of them was "verbally counseled for changing data and not noting late entry," a document indicates.

At numerous times during the September meeting, Jackson and Ventavia executives talked about the chance the FDA could show up for an inspection. "We're going to get some kind of letter of information at least, when the FDA gets here . . . know

it," an executive stated.

Jackson fired for reporting concerns to FDA

According to the complaint, after repeatedly notifying Ventavia of the problems she witnessed, Jackson called the FDA's hotline to report trial protocol violations and patient safety concerns.

Jackson said she received an acknowledgment email from the agency and a follow-up phone call from an FDA inspector, but no further communication. She was fired hours later. Pfizer responded by "expanding its trial to include even more participants."

Jackson then filed a complaint in the U.S. District Court, Eastern District of Texas, Beaumont Division, under the False Claims Act.

The main allegations against Pfizer and Venavia include making or using false records or statements to cause claims to be paid, presenting false and/or fraudulent claims, making or using false records or statements material to false and/or fraudulent claims and retaliation.

The complaint remained under seal until Feb. 10, when Judge Michael Truncale ordered it unsealed after the U.S. Department of Justice declined to intervene.

Although Jackson only witnessed wrongdoing in Texas, "Pfizer and Icon's oversight failures and fraudulent misconduct vis-a-vis Ventavia bring the entire Pfizer-BioNTech clinical trial into question," she claims.

The exhibits posted on Jackson's website, show the FDA was aware of problems with Pfizer's vaccine trials last year, yet claim to have "full confidence" in the data used to support

emergency use authorization of company's vaccine and full approval of its vaccine Comirnaty – which is not even available in the U.S.

Jackson's claims are more than "allegations." They are supported by recordings, photographs, emails and internal documents, including the FDA's formal response to her complaint.