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Judge Unseals 400 Pages of Evidence, Clears Way for Pfizer Whistleblower Lawsuit

A whistleblower lawsuit alleging fraud during Pfizer's COVID vaccine trials is moving forward, after a district court judge unsealed the complaint, including 400 pages of exhibits.

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A whistleblower lawsuit alleging fraud during Pfizer's COVID vaccine trials is moving forward, after a district court judge unsealed the complaint, including 400 pages of exhibits.

Brook Jackson in January 2021 sued Pfizer and two companies the drugmaker contracted with to work on the trials: Ventavia Research Group and ICON PLC.

Jackson worked for Ventavia for a brief period in 2020 before being fired after she filed a complaint with the U.S. Food and Drug Administration (FDA) over alleged improprieties she observed during the vaccine trials.

She also gave The BMJ a cache of internal company documents, photos and recordings highlighting alleged wrongdoing by Ventavia.

Jackson filed the complaint in the U.S. District Court, Eastern District of Texas, Beaumont Division, under the False Claims Act. The lawsuit includes several charges of fraud and retaliation on the part of both Ventavia and Pfizer.

The complaint remained under seal until Feb. 10, when U.S. District Court **Judge Michael Truncale** ordered it unsealed.

Pfizer 'deliberately withheld crucial information' about vaccine's safety

According to Jackson's lawsuit, Pfizer, Ventavia and ICON "deliberately withheld crucial information from the United States that calls the safety and efficacy of their vaccine into question."

The lawsuit states:

> "Defendants concealed violations of both their clinical trial protocol and federal regulations, including falsification of clinical trial documents.
>
> "Due to [the] Defendants' scheme, millions of Americans have received a misbranded vaccination which is potentially not as effective as represented."

The core allegations of Jackson's lawsuit include claims against Ventavia and Pfizer of:

- Making or using false records or statements to cause claims to be paid.
- Presentation of false and/or fraudulent claims.
- Making or using false records or statements material to false and/or fraudulent claims.
- Retaliation.

For instance, Jackson alleges:

> "From 2020 to the present, Defendants [Ventavia and Pfizer] knowingly made, used, or caused to be made or used, false records or statements that were material to false and/or fraudulent claims paid or approved by the United States [Department of Defense, or DoD]. These false records or statements include the clinical trial protocol Pfizer submitted to the United States and the falsified source documents and data behind Defendants' trial results and EUA application.
>
> "By creating and carrying out their fraudulent schemes, Defendants knowingly and repeatedly violated … the False Claims Act. Defendants' false records were material to Pfizer's claims for payment for the vaccine at issue. The United States DoD would not have paid Pfizer if it knew that the clinical trial protocol was not complied with by Defendants, because the protocol violations call the integrity and validity of both the entire clinical trial and Pfizer's EUA into question.
>
> "Defendants' false records also went to the very essence of the bargain the United States contracted for. DoD contracted to purchase vaccines found effective by a valid clinical trial conducted according to the protocol submitted by Pfizer. The integrity of the entire clinical trial was compromised by the trial protocol violations, false source documents, and the false data that resulted, which calls the vaccine's EUA into question. Had the United States DoD known of Defendants' false records, it would not have paid Pfizer.
>
> "Defendants' use, or causation of use, of material false records was a foreseeable factor in the United States DoD's loss and a consequence of Defendants' schemes. By virtue of Defendants' actions, the United States DoD has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false and/or fraudulent claim."

Jackson is requesting damages, including back pay, in addition to reinstatement of her position with Ventavia.

Ventavia, which describes itself as the largest privately owned clinical research company in Texas, operated several sites where clinical trials were taking place on behalf of Pfizer.

Jackson, a regional director for Ventavia, was hired by the company when Pfizer contracted

with it to conduct its phase 3 vaccine trial.

Jackson, who possessed over 15 years' worth of experience working with clinical trials, "repeatedly informed her superiors of poor laboratory management, patient safety concerns and data integrity issues" during the approximately two weeks she was employed by Ventavia.

On Sept. 25, 2020, Jackson emailed the FDA, listing a dozen concerns she said she had witnessed. These included:

- Lack of timely follow-up for patients who experienced adverse events from the trial.
- Protocol deviations that went unreported.
- Retaliation against and targeting of Ventavia employees who reported such problems.
- Trial participants being placed in a hallway after injection and not being monitored by clinical staff.
- Vaccines not being stored at proper temperatures.
- Wrongly labeled laboratory specimens.

Jackson provided documents indicating falsified data, blind trial failures and awareness on the part of at least one Ventavia executive that members of the company's staff were "falsifying data."

Jackson's documents also provided evidence of administrators who had "no training" or medical certifications, or who provided "very little oversight" during the trials.

Several internal company emails would be copied to a Pfizer official, who would respond to some of the correspondence.

The documentation provided by Jackson also demonstrated that she had discussed with Ventavia executives the possibility of the FDA conducting an unannounced inspection. The executives were described as "dreading" such a possibility.

According to Jackson, she received an acknowledgment email from the FDA and a follow-up phone call from an FDA inspector, but no further communication.

Ventavia fired her within hours of her contacting the FDA.

Ventavia executive on Pfizer vaccine trial: 'cleanup on aisle five'

As reported by investigative journalist Matt Taibbi, a recording of a Ventavia executive revealed the individual in question referred to the problems with the vaccine trial as "cleanup on aisle five" and that this same executive pressed Jackson as to whether she had revealed information to outsiders.

This led Jackson to contact The BMJ, which in November 2021 published an article based on the evidence she had provided highlighting Ventavia's repeated failures.

Journalist Paul Thacker, who had previously investigated financial ties between "Big Pharma" and physicians for the U.S. Senate Finance Committee, wrote The BMJ article.

In November 2020, Ventavia appeared to have confirmed its knowledge of problems that occurred with the vaccine trial, and claimed that it would conduct an investigation.

Nevertheless, Pfizer continued its relationship with Ventavia, hiring it as a research subcontractor for at least four other trials, including trialing the COVID vaccine for children, young adults, pregnant women and the safety of a booster dose.

The FDA, despite knowledge of the allegations against Pfizer and Ventavia, went ahead and granted Emergency Use Authorization (EUA) for the Pfizer-BioNTech vaccine, including for children 5 to 11 years old.

The FDA in August 2021 stated that it inspected only nine of the trial's 153 sites. None of Ventavia's sites were included. (A 2007 report by the U.S. Department of Health and Human Services Office of the Inspector General found the FDA inspected only 1% of clinical trial sites).

Ventavia went on the offensive against Jackson, claiming that:

> "Ms. Jackson worked for us for only 18 days and, as a result, did not complete the requisite training for the role for which she was hired. We are confident in our practices and procedures in conducting clinical trials, and, should her case move forward, we will respond to the litigation accordingly."

Ventavia later, in a Feb. 11 statement, modified its claims about Jackson, writing:

> "Although Jackson was hired to oversee certain sites and aspects of clinical trials, she was only employed with Ventavia for 18 days, and, as a result, did not have the longevity with the company to complete the training for the role for which she was hired."

However, according to Thacker, "[s]everal documents show that Jackson worked on Pfizer's clinical trial." These documents include a clinical trial delegation log which lists Jackson as a participant.

Also, according to Thacker, dozens of media organizations also failed to issue retractions of their reports which alleged Jackson had no direct involvement with the vaccine trials.

Jackson threatened to file a separate defamation lawsuit against Ventavia over its characterization of her employment.

The BMJ, in turn, was targeted for publishing the report. Facebook throttled the report and issued warnings to its users not to share it, following a report by one of the company's contracted "fact checkers," Lead Stories, claiming the report would not "disqualify" the overall trial of the Pfizer vaccine.

Lead Stories went so far as to describe The BMJ as a "blog."

The BMJ said that it is "considering all available options" in terms of a potential legal claim against Facebook, which recently admitted in a court of law that its "fact checks" are "pure opinion."

Feds won't intervene in whistleblower case … for now

The documents pertaining to Jackson's lawsuit were released after U.S. Department of Justice (DOJ) attorneys declined to intervene on her behalf in the case.

The DOJ filed a "notice of election to decline intervention," asking the court to get "written consent" in the event the parties to the lawsuit wish to dismiss or settle the case.

The government also reserved the right to intervene at a later date.

Neither the DOJ lawyers nor the FDA offered an explanation for why the DOJ chose not to intervene.

Jackson said that she was not surprised the federal government opted not to intervene, but expressed her "total disappointment," adding that "[w]e're going to pursue the case without the help of the government."

While Jackson has stated her belief that the likelihood of her case succeeding is low, she also said that "[i]t's just a chance I have to take. I just feel like somebody has to be held accountable."

Ventavia also remarked upon the government's refusal to intervene. Lauren Foreman, the company's director of business development and communications, wrote in an email to Just the News, "[w]e are gratified the government has declined the case."

Jackson apparently lost her original Texas-based lawyers in October 2021, but was able to attain new legal representation in December 2021, headed by Los Angeles-based attorney Robert Barnes.

The federal government's refusal to intervene comes in contrast to the FDA welcoming Pfizer's offer to intervene in a Freedom of Information (FOIA) lawsuit filed against the agency.. A federal judge ruled Pfizer must disclose redacted versions of nearly 400,000 pages of documents pertaining to its issuance of an EUA for the Pfizer vaccine.

The FDA claimed it could not release the documents at a fast enough rate to meet the demands of the court or the plaintiffs in the case.

Pfizer then asked the court to intervene, ostensibly to "help" the FDA with the process of releasing the documents.

A federal court rejected Pfizer's bid to intervene.

Pfizer lobbies to limit False Claims Act

Jackson's primary lawsuit against Pfizer, Ventavia and ICON pertains to the False Claims Act — a piece of legislation dating back to the Civil War which rewards whistleblowers who file anti-fraud lawsuits against contractors on behalf of the government.

The law, originally enacted in response to defense contractor fraud during the Civil War, has to date returned $67 billion to the U.S. government.

While the False Claims Act has been in place since the Civil War, it was significantly eroded by a 2016 Supreme Court decision, Universal Health Services v. United States, which found a lawsuit filed under the False Claims Act could be dismissed if the contractor in question

continued to be paid by the government.

This resulted in a series of federal court decisions in which fraud cases were dismissed, while the DOJ, via its 2018 Granston Memo, instructed government attorneys to reject more False Claims Act lawsuits.

In the two years that followed, dismissals of False Claims Act cases indeed increased.

The decision significantly expanded the scope of a legal principle known as "materiality." As interpreted by the court, if the government continued paying a contractor despite the contractor's fraudulent activity, then the fraud was not considered "material" to the contract.

The issue of materiality is a core component of Jackson's lawsuit against Ventavia, Pfizer and ICON.

Proposed legislation, the False Claims Amendments Act of 2021, which was introduced in Congress in July 2021, would again bolster the law, strengthening the original law's anti-retaliation provisions by installing new safeguards against industry-level blacklisting of whistleblowers seeking employment.

The proposed act also would adjust the materiality standard to include instances where government payments have continued despite knowledge of fraud.

This could affect Pfizer, which has contracts with the U.S. government to provide COVID vaccines.

The bill passed through committee by a 15-7 vote and was added to the Senate's legislative calendar on Nov. 16, 2021. However, no action has been taken since.

Perhaps not coincidentally, Pfizer hired a well-connected lobbyist, Hazen Marshall, and the law firm Williams & Jensen to lobby against the False Claims Amendments Act of 2021, as previously reported by The Defender.

Notably, under the terms of a 2009 settlement, Pfizer paid $2.3 billion in fines — the largest healthcare fraud settlement in the history of the U.S. Department of Justice (DOJ) — in a False Claims Act case stemming from allegations of illegal marketing of off-label products not approved by the FDA.

Pharmaceutical companies such as AstraZeneca and Merck have also been forced to pay multimillion-dollar settlements resulting from False Claims Act cases.

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