

Pfizer COVID-19 Vaccine Trial Whistleblower Case Dismissed by Judge

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Global Research, April 04, 2023

[The Epoch Times](#) 1 April 2023

Region: [USA](#)

Theme: [Law and Justice](#)

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The legal case brought by a whistleblower from Pfizer's COVID-19 vaccine trial has been dismissed by a judge.

Brook Jackson, who worked for Pfizer contractor Ventavia Research Group, didn't prove violations of the False Claims Act, U.S. District Judge Michael Truncale ruled on March 31.

Jackson [sued](#) Ventavia, Pfizer, and another organization involved in the vaccine trial in 2021, alleging that trial violations she uncovered meant that the government was defrauded when it paid for doses of Pfizer's vaccine.

Internal records show Ventavia officials acknowledging that patients were unblinded, adverse events weren't recorded, and vaccine doses were kept unlocked in "disorganized" rooms.

Under the False Claims Act, the government or a party suing on the government's behalf—Jackson in this case—can recover money for false claims made by parties to secure payment for the government. Parties are liable if they knowingly present a false claim for payment or intentionally use a false record or statement material to make a false claim.

While Jackson presented evidence that violations occurred, the government's [prototype agreement](#) with Pfizer only conditioned payment on delivery of a vaccine that had been authorized or approved by the U.S. Food and Drug Administration (FDA), Truncale ruled. The payment section states that "the Government will have no right to withhold payment in respect of any delivered doses, unless the FDA has withdrawn approval or authorization of the vaccine." The FDA, which Jackson alerted to the violations, hasn't withdrawn approval or authorization.

“In sum, Ms. Jackson has failed to plead that the Government conditioned payment on Defendants’ certification of compliance with regulatory provisions or clinical trial protocol,” Truncale said [in the new ruling](#).

While Jackson argued that the false record portion of the False Claims Act (FCA) was violated because of the trial violations, the defendants said false records and statements alone didn’t create liability without a false claim seeking payment from the government.

“The upshot is that there is no liability under the FCA for making or using a false record or statement where the claimant is entitled to the payment,” Truncale said. “Pfizer was entitled to its claims for payment. Therefore, Ms. Jackson has not stated a claim for false record liability.”

The judge quoted a different ruling, which found that the False Claims Act was enacted by Congress “to vindicate fraud on the federal government, not second guess decisions made by those empowered through the democratic process to shape public policy.”

“When the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather, it is concluding that there was no fraud at all,” the ruling reads.

Attorneys for Pfizer offered that argument during [a recent hearing](#) in the case.

“So if the FDA gets it wrong, they just get it wrong, and we live with it?” Truncale asked.

Pfizer attorney Carlton Wessel said, “Exactly.”

“The Government has been aware of Ms. Jackson’s allegations for several years, has granted Emergency Authorization multiple times, and to this day continues to authorize and provide Pfizer’s vaccine at no cost,” the judge said in the new ruling.

He acknowledged the evidence that Jackson offered but said her complaint didn’t “identify any safety risk that was hidden from the FDA in the data from the Ventavia sites, any symptomatic participants who Ventavia did not properly test for COVID-19 infection, or any COVID-19 infections in vaccinated participants that Ventavia falsely reported to have occurred in the placebo group.”

Retaliation Claim

Jackson was hired in September 2020. She reported problems with the trial to Ventavia management shortly after starting at the company. Dissatisfied with the response, she went to the FDA on Sept. 25, 2020. Ventavia fired Jackson that same day.

The False Claims Act protects whistleblowers from harassment, retaliation, and threats. The person must be engaged in protected activity, defined in a previous ruling as “motivated by a concern regarding fraud against the government.” The employer must also know the person was engaged in protected activity, and the punitive action or actions must be because of the activity.

Jackson’s activity doesn’t meet the standard because she hasn’t alleged that she was concerned about potential fraud against the government, according to Truncale.

“Rather, she alleges that she complained about participant safety and regulatory, protocol, and HIPAA violations,” he said, referring to the Health Insurance Portability and Accountability Act. “But that is not protected activity under the FCA’s retaliation provision—internal complaints about patient safety, or protocol and regulatory violations, are not the same thing as complaining about defrauding the Government.”

Even if Jackson was engaged in protected activity, the judge said Jackson didn’t show that Ventavia knew she was involved in such activity.

Truncate dismissed the False Claims Act claims with prejudice, which means they can’t be brought again. The retaliation claim was dismissed without prejudice.

Reaction

Pfizer, Ventavia, and the third defendant, ICON, didn’t respond to requests for comment.

Warner Mendenhall, a lawyer representing Jackson, said an appeal is forthcoming.

“The dismissal of Pfizer’s case is a despicable & heinous betrayal of justice, a slap in the face to vaccine injured and whistleblowers, a blatant example of corruption, incompetence and cowardice, a declaration that the powerful are above the law,” Jackson said in a [statement](#).

“I will never back down, no matter what it costs.”

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Featured image: Brook Jackson speaks outside the courthouse in Beaumont, Texas, on March 1, 2023. (Darlene McCormick Sanchez/The Epoch Times)

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