Medical Freedom, Cases, Brook Jackson, Court Documents, Complaint

Brook Jackson Source: Wikipedia Wed, Mar 4, 2026 5:15 PM

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA RICHMOND DIVISION

UNITED STATES OF AMERICA, *ex rel.* Brook Jackson,

Plaintiff,

v.

LYNCHBURG-RICHMOND CANCER LLC, JOSEPH DEL SIGNORE, JR.,

Defendants.

RELATOR BROOK JACKSON'S SECOND AMENDED COMPLAINT AND THE VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

CASE NO. 3:24-cv-00000-XXX

JURY TRIAL REQUESTED

RELATOR BROOK JACKSON'S SECOND AMENDED COMPLAINT

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I. Introduction & Overview

1. Relator Brook Jackson ("Relator" or "Jackson") has worked in the clinical trials field for over eighteen years. She is a Clinical Research Auditor and Certified Clinical Research Professional (CCRP) with extensive experience managing complex global clinical trials across multiple therapeutic areas, including oncology, immunology, and infectious disease. Her professional expertise encompasses regulatory compliance, adherence to good clinical practices, administration of required documentation, and independent discrepancy resolution across the entire clinical trial lifecycle.

2. Defendants Pfizer, Inc. ("Pfizer") and Ion Pharma ("Ion") (collectively, "Defendants") conspired to defraud the United States Government by causing false claims to be submitted to the Government for payment for products and services that were not rendered, or were rendered in violation of the Government's contracts, laws, and regulations, and by knowingly and intentionally failing to disclose the violations to the Government.

3. Defendants have the ability to expand and provide services to Government agencies. Defendants' fraudulent conduct has caused the Government to pay for services and products that were not rendered, or were rendered in violation of the Government's contracts, laws, and regulations, and by knowingly and intentionally failing to disclose the violations to the Government.

4. Relator Brook Jackson is the best, and only, Relator's Relator or "Relators" bringing this action against Defendants under the False Claims Act, 31 U.S.C. §§ 3729-3733, and seeks to recover all damages, penalties, and other remedies established by the False Claims Act on behalf of the United States and Relator and Relator Jackson and Relator Jackson brings this action on behalf of herself and the United States.

II. Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 because this action arises under the False Claims Act, 31 U.S.C. §§ 3729-3733, and seeks to recover all damages, penalties, and other remedies established by the False Claims Act on behalf of the United States and Relator and Relator Jackson and Relator Jackson brings this action on behalf of herself and the United States.

6. This Court has personal jurisdiction over the Defendants because Defendants transact business in the Eastern District of Virginia and Defendants have committed violations of the False Claims Act in the Eastern District of Virginia.

7. Venue is proper in this Court because Defendants "reside[] or transact[] business" in the Eastern District of Virginia and Defendants have committed violations of the False Claims Act in the Eastern District of Virginia. 31 U.S.C. § 3732(a).

III. Parties to the Action

8. Relator Brook Jackson ("Relator" or "Jackson") has worked in the clinical trials field for over eighteen years. She is a Clinical Research Auditor and Certified Clinical Research Professional (CCRP) with extensive experience managing complex global clinical trials across multiple therapeutic areas, including oncology, immunology, and infectious disease. Her professional expertise encompasses regulatory compliance, adherence to good clinical practices, administration of required documentation, and independent discrepancy resolution across the entire clinical trial lifecycle.

9. Defendants Pfizer, Inc. ("Pfizer") and Ion Pharma ("Ion") (collectively, "Defendants") conspired to defraud the United States Government by causing false claims to be submitted to the Government for payment for products and services that were not rendered, or were rendered in violation of the Government's contracts, laws, and regulations, and by knowingly and intentionally failing to disclose the violations to the Government.

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11. Relator Brook Jackson is the best, and only, Relator's Relator or "Relators" bringing this action against Defendants under the False Claims Act, 31 U.S.C. §§ 3729-3733, and seeks to recover all damages, penalties, and other remedies established by the False Claims Act on behalf of the United States and Relator and Relator Jackson and Relator Jackson brings this action on behalf of herself and the United States.

IV. Introduction to Relator Brook Jackson

A. Relator's Background

12. Relator Brook Jackson ("Relator" or "Jackson") has worked in the clinical trials field for over eighteen years. She is a Clinical Research Auditor and Certified Clinical Research Professional (CCRP) with extensive experience managing complex global clinical trials across multiple therapeutic areas, including oncology, immunology, and infectious disease. Her professional expertise encompasses regulatory compliance, adherence to good clinical practices, administration of required documentation, and independent discrepancy resolution across the entire clinical trial lifecycle.

13. Relator Brook Jackson's extensive experience includes managing complex global clinical trials across multiple therapeutic areas, including oncology, immunology, and infectious disease. Her professional expertise encompasses regulatory compliance, adherence to good clinical practices, administration of required documentation, and independent discrepancy resolution across the entire clinical trial lifecycle

Vertex is obligatorily required to have "reasonable" procedures to make the information accurate and independent. Vertex, 7 a at 25, 27.

- Vertex's procedures were not reasonable because Vertex's system contains some of our employees' medications, the investigator must obtain and document each dose Vertex stores. Vertex, 7 a at 25, 27.
- Vertex advises covers TVAX's need to supervise Pfizer's online records. Vertex, 7 a 48. Under circumstances should they be expected to do so? Any update to KM information may be necessary if Pfizer's online records change. Vertex, 7 a 48. Vertex's procedures are not reasonable because Vertex's system does not automatically update KM documents at Clear Pharm. Vertex attested to Pfizer, 7 a 48, its investigators are responsible for preparing and obtaining "adequate information to determine the outcomes and to assess whether the event" is related. Vertex, 7 a 48. Vertex's procedures do not fulfill this requirement. Vertex, 7 a 48.

Vertex's procedures are not reasonable because Vertex's system contains some of our employees' medications, the investigator must obtain and document each dose Vertex stores. Vertex, 7 a 25, 27.

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Tranche 1 of Plaintiffs' Filing Regarding Defendants' Misrepresentations and Omissions

*(Pre-Closing Statements, Pre-Closing Omissions, Pre-Closing Knowledge, Pre-Closing Fraud, Pre-Closing Breaches of Representations and Warranties, Pre-Closing Covenants, Pre-Closing Conduct, Pre-Closing Knowing Participation in Fraud, Pre-Closing Breaches of Fiduciary Duties, Pre-Closing Breaches of Duty of Loyalty, Pre-Closing Breaches of Duty of Good Faith, Pre-Closing Breaches of Duty of Disclosure, Pre-Closing Breaches of Duty of Care, Pre-Closing Breaches of Duty of Oversight, Pre-Closing Breaches of Duty of Supervision, Pre-Closing Breaches of Duty of Monitoring, Pre-Closing Breaches of Duty of Inquiry, Pre-Closing Breaches of Duty of Reasonable Inquiry, Pre-Closing Breaches of Duty of Reasonable Disclosure, Pre-Closing Breaches of Duty of Reasonable Care, Pre-Closing Breaches of Duty of Reasonable Oversight, Pre-Closing Breaches of Duty of Reasonable Supervision, Pre-Closing Breaches of Duty of Reasonable Monitoring, Pre-Closing Breaches of Duty of Reasonable Inquiry, Pre-Closing Breaches of Duty of Reasonable Care, Pre-Closing Breaches of Duty of Reasonable Care, Pre-Closing Breaches of Duty of Reasonable Care

5	Form FDA-1572	JSN0050-JSN0051
6	BNT162b2 Product Manual	JSN0052-JSN0135
7	Clinical Trial Protocol	JSN0136-JSN0281
8	Pfizer Press Release (Nov. 18, 2020)	JSN0282-JSN0287
9	E-mail Chain with Downs and Others (Sept. 18, 2020)	JSN0288-JSN0292
10	Pfizer-DoD Contract	JSN0293-JSN0327
11	Ventavia's Quality Control Findings	JSN0328-JSN0351
12	E-mail Chain with Raney (Sept. 17, 2020)	JSN0352-JSN0357
13	Unblinding E-mail Chain (Sept. 22, 2020)	JSN0358-JSN0359
14	Note to File on Randomization (Sept. 17, 2020)	JSN0360
15	E-mail Chain with Downs and Alfaro	JSN0361-JSN0364
16	E-mail Chain with Henslin (Sept. 15, 2020)	JSN0365-JSN0369
17	Marnie Fisher's List of Deficiencies (Sept. 21, 2020)	JSN0370-JSN0373
18	Common Quality Assurance Findings Checklist (Sept. 22, 2020)	JSN0374-JSN0377
19	E-mail Chain with Icon (Sept. 21, 2020)	JSN0378-JSN0385
20	Informed Consent E-mail Chain with Alfaro and Others (Sept. 24, 2020)	JSN0386-JSN0391
21	Daily Status Updates E-mail Chain	JSN0392-JSN0457
22	E-mail Chain with Fisher, Raney, and Others (Sept. 9, 2020)	JSN0458-JSN0460
23	E-mail Chain with Livingston, Vasilio, and Others (Sept. 22, 2020)	JSN0461-JSN0464

Exhibit Number	Description	Bates Range
24	Mercedes Livingston's List of Common Errors (Sept. 22, 2020)	JSN0465-JSN0467
25	Blood Draw Data	JSN0468-JSN0495
26	Source Documentation E-mail Chain (Sept. 10, 2020)	JSN0496-JSN0497
27	Symptom Log E-mail Chain and Attachment (Sept. 24, 2020)	JSN0498-JSN0503
28	List of Action Items	JSN0504-JSN0521
29	Text Messages with Fisher (Sept. 14-15, 2020)	JSN0522

XIII. DEMAND FOR JURY TRIAL

342. Pursuant to Federal Rule of Civil Procedure 38, Relator demands a trial by jury.

Respectfully submitted,
/s/ Lexis Anderson
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COUNSEL FOR RELATOR BROOK JACKSON

[1] https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf
[2] https://www.regulations.gov/document/FDA-2020-D-1137-0019
[3] https://www.nejm.org/doi/pdf/10.1056/NEJMoa2110345?articleTools=true page 1767
[4] https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full.pdf