IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA *ex rel.* Brook Jackson Plaintiff, v. VENTAVIA RESEARCH GROUP, LLC; PFIZER INC.; ICON PLC, Defendants.	RELATOR BROOK JACKSON'S SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT CASE NO. 1:21-cv-00008-MJT JURY TRIAL DEMANDED

RELATOR BROOK JACKSON'S SECOND AMENDED COMPLAINT

TABLE OF CONTENTS

I. PRELIMINARY STATEMENT 1

II. INTRODUCTION 4

III. JURISDICTION AND VENUE 9

IV. PARTIES 9

A. Relator Brook Jackson 9

B. Pfizer Inc. 10

C. Icon PLC 10

D. Ventavia Research Group, LLC 10

V. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY 11

VI. STATUTORY AND FACTUAL BACKGROUND 11

A. COVID-19 Vaccine Development 11

B. Congressionally mandated EUA Requirements 13

C. FDA Clinical Trial Regulations 14

1. Clinical Trial Protocol and Manual 17

2. BNT162b2 Product Manual 22

D. Contract at Issue 25

1. FAR Compliance 29

2. FAR Certification 29

VII. FACTUAL ALLEGATIONS 30

A. Pfizer Knew it Could Not Obtain Full Approval nor EUA for its COVID-19 Vaccines because, Based on the Totality of Scientific Evidence, Reasonable Information Indicated Harms Far Outweighed Any Potential Benefit 30

B. To Induce EUA for its modRNA Vaccines, Pfizer Engaged in Fraud in the Design, Conduct, Analysis and Reporting of its Clinical Trials 33

C. Design 33

D. Design/Conduct 35

E. Analysis/Reports 36

F. Pre-requisites 37

G. Pfizer's Clinical Trial Fraud Resulted in Objective Material Falsehoods 38

VIII. EXAMPLE OF PFIZER'S CLINICAL TRIAL FRAUD 39

A. Relator's Background 40

B. Violations of Clinical Trial Protocol 41

1. Inclusion and Exclusion Criteria 41

2. Blinding 44

3. Temperature Control 47

4. Informed Consent 48

5. Dose Preparation 49

6. Administration 50

7. Safety and Patient Monitoring 52

8. Accuracy and Completeness of Data 54

9. Adherence to Protocol 57

10. Privacy Law Compliance 60

C. Violation of FDA Regulations 60

D. Violation of FAR 62

E. Ongoing Monitoring Concerns 62

F. Safety and Ethical Issues 62

IX. RETALIATION AGAINST RELATOR 64

A. Relator photographs violations. 66

B. Relator recommends pausing clinical trial enrollment. 68

C. Ventavia management falsely accuses Relator of violating patient confidentiality. 71

D. Ventavia terminates Relator the next day. 72

X. ACTIONABLE CONDUCT BY DEFENDANTS 73

A. False Claims Act 73

1. Applicable Law 73

2. Defendants' Violations of the False Claims Act 74

XI. CAUSES OF ACTION 83

A. Count I – Fraud in the Inducement 83

B. Count II – Fraudulent Presentment 85

C. Count III – Presentation of False and/or Fraudulent Claims (31 U.S.C. § 3730(a)(1)(A)) 85

D. Count IV – Making or Using False Records or Statements Material to False and/or Fraudulent Claims (31 U.S.C. § 3730(a)(1)(B)) 86

XII. PRAYER FOR RELIEF 87

E. Count V – Retaliation (31 U.S.C. § 3730(h)) 88

F. Count VI - Retaliation (Texas Health and Safety Code § 161.134) 88

XIII. PRAYER FOR RELIEF 88

XIV. INDEX OF EXHIBITS 90

XV. DEMAND FOR JURY TRIAL 91

I. PRELIMINARY STATEMENT

"The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true." - Albert Einstein

1. In early 2020, the United States and the world faced a novel coronavirus called SARS-CoV-2, which caused the contagious illness COVID-19. On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency related thereto.[1] In response to the declaration, in mid-March 2020, President Trump declared a national emergency and guidelines to "flatten the curve" to slow the spread of COVID-19.[2] By April 2020, knowledgeable doctors from around the world, building on early information about the illness, developed promising treatments using repurposed drugs.[3] Thereafter, in May 2020, President Trump sought a streamlined solution: a safe, effective vaccine for the prevention of COVID-19. Pfizer promised it could deliver exactly that, and went about soliciting the contract, soliciting the underlying conditions for that contract, and soliciting funds in exchange for its promised delivery to the American people of a safe, effective vaccine for the prevention of COVID-19. Based partially but substantially on these promises from Pfizer, President Trump announced Operation Warp Speed (OWS) to develop, manufacture, and distribute a proven coronavirus vaccine as fast as possible.[4]
2. What Pfizer knew that the American taxpayers did not was that they could not develop a safe, effective, vaccine for the prevention of COVID-19 at speed and scale, and that alternative treatments already existed for the treatment of COVID-19 that negated the factual basis for emergency use authorization in the first instance. In addition, Pfizer knew it could not submit

[1]https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/
[2]https://www.cnbc.com/2020/03/16/trumps-coronavirus-guidelines-for-next-15-days-to-slow-pandemic.html
[3]https://williambowlesnet.files.wordpress.com/2020/04/evms_critical_care_covid-19_protocol.pdf
[4]https://www.usatoday.com/story/news/health/2020/05/15/coronavirus-operation-warp-speed-could-deliver-vaccine-years-end-trump/5199969002/

honest clinical data to the FDA, had to defame alternative treatments, and silence any whistleblowers. Finally, Pfizer knew it would need to falsify certifications and presentments to obtain payment. At each stage, Pfizer lied, and people died.

3. At the first stage, Pfizer induced the contractual agreement by promising it could deliver a safe, effective, vaccine for the prevention of COVID-19 both at speed and at scale. This induced the Trump administration to solicit the production of a safe, effective, vaccine for the prevention of COVID-19 at speed and scale. At the second stage, Pfizer defamed alternative medications for treatment and falsified data about its own drug to convince the Food & Drug Administration it had produced a safe, effective, vaccine for the prevention of COVID-19 and that was the only available means of treatment. At the third stage, Pfizer fraudulently induced payment from the American taxpayer by claiming it delivered a safe, effective, vaccine for the prevention of COVID-19, certifying and presenting its invoice as contract-compliant in the process. In the process, Pfizer defrauded the American people of billions of taxpayer dollars. The means of the fraud included fraud to induce action, and ultimately payment, but also included express fraudulent certifications, implied fraudulent certifications, and fraudulent presentment. At each stage of the fraud, Pfizer lied, and people died.

4. The bases for the U.S. Secretary of Health to make a declaration for the FDA to issue an EUA include: 1) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved; 2) the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition; 3) there is enough evidence of safety and effectiveness to support the use of the investigational drug or investigational device; 4) the investigational drug or investigational device is under investigation in a controlled clinical trial 5) there is enough evidence of safety and effectiveness to support the treatment of the disease or condition; and 6) in the case of immediately life-threatening diseases, the available scientific

evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury. 21 U.S. Code ("U.S.C.") § 360bbb–3 et seq. When there is data from clinical trials, they must be adequate and well-controlled with a clear statement of objectives, methods for selecting appropriate subjects, methods for assigning subjects to test groups and controlling bias, well-defined and reliable assessment methods of response, statistically valid analysis, informed consent by participants, and IRB review. 21 CFR § 314.126; 21 CFR § 314.126.

5. Due to Pfizer's promises, on June 9, 2020, the Department of Army, US Army Contracting Command issued a request for prototype proposals (RPPs) from the Medical Chemical, Biological, Radiological, and Nuclear Defense Consortium (MCDC), in support of the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND) for COVID-19 Pandemic for a Vaccine Rapid Advanced Research and Development (ARD) to Large Scale Manufacturing prototype project.[5] Pfizer submitted a proposal and, on July 21, 2020, the Army Contracting Command – New Jersey accepted its proposal for a "COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration" issuing a "Technical Direction Letter."[6] Pfizer and its partner BioNTech were already conducting joint clinical trials, without government funding, "towards the demonstration of technical and manufacturing feasibility, including through the initiation of Phase 1/2 studies evaluating the likelihood of safety, tolerability and immunogenicity in the US and in Germany." *Id*, p. 3. Attached to the letter was a Statement of Work (SOW). *Id*. The SOW required Pfizer to obtain Food and Drug Administration (FDA) approval or an Emergency Use Authorization (EUA) to receive payment of up to

[5]https://www.hhs.gov/sites/default/files/request-for-prototype-projects.pdf
[6]https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

$1,950,000,000.00 for its prototype project efforts. *Id*, SOW, p. 8. Critically, the contract required Pfizer comply with all FDA rules and regulations governing clinical trials, noting that the only rules "outside the scope" of the agreement were for items unrelated to the vaccine development itself.

6. On November 20, 2020, Pfizer, on behalf of Pfizer and BioNTech, submitted an Emergency Use Authorization (EUA) request to FDA for an investigational COVID-19 vaccine (BNT162b2) intended to prevent COVID-19 based on the SARS-CoV-2 spike glycoprotein (S) antigen encoded by RNA and formulated in lipid nanoparticles (LNPs). The proposal was for "active immunization" for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.[7]

7. On December 11, 2020, the FDA issued to Pfizer-BioNTech the first COVID-19 EUA for its investigational drug (officially named Pfizer-BioNTech COVID-19 Vaccine). As detailed below, Pfizer knew data it submitted for its successful EUA application was fraudulent because it was not based on "well-controlled trials" with reliable data showing the "known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product […]." 21 U.S.C. § 360bbb–3(c).

8. Since December 11, 2020, Pfizer submitted multiple multi-million-dollar invoices in conformity with the contract certifying "in accordance with the agreement", the work required by the contract had been performed, and the delivery of the product required under the contract. The contract required Pfizer certify the work had been performed according to both FDA and EUA rules, restrictions, and preconditions in the contract. The assurance the product being delivered was "in accordance with the agreement" meant Pfizer certified and presented a claim for payment in exchange for the delivery of a safe, effective vaccine for the prevention of COVID-19. The problem

[7] https://www.fda.gov/media/144416/download

went to the essence of the deal: Pfizer didn't deliver a safe, effective, vaccine for the prevention of COVID-19. Pfizer didn't comply with the FDA and EUA rules, restrictions and regulations required in the contract. Pfizer didn't honestly obtain FDA EUA approval because it fraudulently certified the data and contractual compliance.

9. Pfizer knew it didn't deliver a safe, effective vaccine for the prevention of COVID-19. Pfizer knew alternative treatments existed that negated the need for a vaccine. Pfizer knew it had not complied with the FDA rules, regulations, or restrictions, nor the EUA rules, regulations and restrictions. Yet, Pfizer induced payment by fraudulently claiming compliance with the contract, work "in accordance with the agreement", falsified data, fraudulent certifications of compliance, and fraudulent presentment for payment. This cost the American taxpayer billions. But it was worse. Pfizer lied, and people died.

II. INTRODUCTION

10. Plaintiff/Relator Brook Jackson ("Jackson" or "Relator") sues under the False Claims Act, 31 U.S.C. §§ 3729–3732, and seeks to recover damages, penalties, and other remedies established by the False Claims Act on behalf of the United States of America and on her own behalf. Relator would respectfully show the following:

11. Defendants Pfizer Inc., Icon PLC, and Ventavia Research Group, LLC (collectively, "Defendants") conducted a clinical trial to test a COVID-19 vaccine candidate. In the race to secure billions in federal funding and become first to market, Defendants deliberately withheld crucial information from the United States government that calls the safety and efficacy of their vaccine into question. Defendants concealed violations of clinical trial protocols and federal regulations, including falsification of clinical trial documents. Due to Defendants' scheme, millions of Americans received a government-funded misbranded "vaccination" that did not provide immunity, and which posed the risk of being less effective than represented - a risk that has since become reality. The vaccine's FDA

authorization resulted from a deeply flawed clinical trial that violated FDA regulations. Defendants profited from the COVID-19 pandemic at the expense of the United States and its citizens by abusing the scientific process.

12. BioNTech SE ("BioNTech") and Defendant Pfizer Inc. ("Pfizer") co-developed a nucleoside-modified messenger RNA (modRNA) vaccine against COVID-19. After a reportedly successful Phase 1 clinical trial, Pfizer contracted with the United States Department of Defense ("DOD") to supply 100 million doses of the vaccine for $1.95 billion if it obtained FDA approval or an EUA for the product. To achieve that goal, Pfizer and BioNTech co-sponsored Phase 2 and 3 clinical trials for their vaccine.

13. Pfizer delegated management of the clinical trial to subcontractor Defendant Icon PLC ("Icon"), an Irish clinical research organization. Icon was tasked with oversight of over 160 test sites worldwide, ensuring trial protocol compliance, and ensuring reporting of required information. This includes oversight of Serious Adverse Event ("SAE") reporting, which is required by the trial protocol and federal regulations. Pfizer remained responsible for managing and quality checking all data for the entire clinical trial, per the trial's protocol.

14. Defendant Ventavia Research Group, LLC ("Ventavia") was contracted by Pfizer to provide three Phase 3 test sites for the vaccine trial in Houston, Fort Worth, and Keller, Texas. Ventavia ultimately enrolled about 1,500 clinical trial patients. Ventavia employed Relator Jackson as a Regional Director. Her job was to oversee site management, patient enrollment, quality assurance completion, event reporting, corrective action plan creation, communication with management, and staff training completion at the Keller and Fort Worth sites.

15. Pfizer, aiming for the title of "first successful COVID-19 vaccine," pushed Ventavia to enroll as many patients as possible in the vaccine trial as quickly as possible. Pfizer compensated Ventavia mainly on a per-patient basis—up to a weekly limit—and incentivized Ventavia to enroll as many clinical trial participants as possible per week. Ventavia's race to maximize payment and over-booking

of patients resulted in sloppy and fraudulent documentation practices, poor clinical trial protocol compliance, and little oversight. Pfizer and Icon turned a blind eye to Ventavia's misconduct, despite many warning signs.

16. Ventavia's trial protocol and regulatory violations were so widespread that Relator observed them daily. For example, Relator observed:

- fabrication and falsification of blood draw information, vital signs, signatures and other essential clinical trial data;
- enrollment and injection of ineligible clinical trial participants, including Ventavia employees' family members;
- failure to timely remove ineligible patients' data from the trial;
- failure to maintain temperature control for the vaccine;
- failure to assess patients for acute reactions after injection as required by the trial protocol;
- principal investigator oversight failures;
- use of unqualified and untrained staff as vaccinators and laboratory personnel;
- failure to maintain the "blind" as required, which is essential to the credibility and validity of the observer-blinded clinical trial;
- ethical violations, such as failure to secure informed consent and giving patients unapproved compensation;
- medication dosing errors (*i.e.*, either by over-diluting or under-diluting vaccine concentrate or using the wrong needle size);
- failure to make sure trial site staff were properly trained as required by good clinical practices;
- safety and confidentiality issues, including HIPAA violations;
- Unexpectedly high adverse events in trial participants in the control arm;
- failure to test symptomatic trial participants for COVID-19; and,
- other violations of the clinical trial protocol, FDA regulations, and Federal Acquisition Regulations and their DOD supplements.

17. Ventavia failed to report most of its clinical trial protocol and regulatory violations to Pfizer or the external Institutional Review Board (IRB). Issues were improperly documented or hidden in "notes to the file" and not corrected.

18. Icon and Pfizer communicated with each trial site to monitor compliance, but failed to follow up on missing information, ignored "red flags" of trial protocol violations and false data, and failed to exclude ineligible participants from the trial data. Thus, Pfizer withheld material information from the United States, and submitted false data and records in its clinical trial results.

19. Relator reported the violations she saw to Ventavia management, who allowed most violations to continue unabated. Defendant Ventavia harassed Relator and terminated her in retaliation for her reports of and efforts to stop fraud against the United States DOD. Relator also reported her concerns to Pfizer after termination, yet Pfizer pressed on, expanding its trial to include more participants.

20. Although Relator's direct experience with test sites is limited to Texas, this example of Pfizer and Icon's oversight failures and fraudulent misconduct brings the entire Pfizer-BioNTech clinical trial into question. Relator knows of similar fraud at other Pfizer clinical trial sites.

21. The FDA issued additional EUAs for the Pfizer-BioNTech vaccine for different age cohorts: the first on December 11, 2020 for individuals 16 years of age and older; the second on May 10, 2021 for individuals 12 years of age and older; the third on October 29, 2021, for children 5 through 11 years of age. Oddly, on August 23, 2021, the FDA concurrently granted a biologic license for Pfizer's COMIRNATY vaccine with a same marketing start and end date and reissued EUAs for the Pfizer-BioNTech product.[8] These authorizations and approvals are based on Defendants' falsified clinical trial results and concealment of key efficacy and safety information. As a result, DOD bought misbranded vaccines from Pfizer, relying on Defendants' fraudulent misrepresentations that the vaccine trial was properly conducted, and Defendant's falsified data, false certifications of compliance with the contract, and false presentment for payment claiming delivery of a safe, effective, vaccine for the prevention of COVID-19. What Pfizer delivered wasn't safe, wasn't effective, wasn't even a vaccine, and didn't prevent COVID-19. Had American taxpayers known of Defendants' fraud, they wouldn't have issued a single check to Pfizer. But worse, Pfizer lied, and people died.

[8] https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=595377

III. JURISDICTION AND VENUE

22. Jurisdiction and venue are proper in the Eastern District of Texas pursuant to 31 U.S.C. § 3732(a) because Relator's claims seek remedies on behalf of the United States for multiple violations of 31 U.S.C. §§ 3729–3732 in Texas by Defendants that damaged the United States government.

23. Defendants Pfizer, Inc. and Ventavia do business in Texas and are registered with the Texas Secretary of State.

24. Defendant Icon PLC conducts continuous and systematic business in Texas. It maintains corporate offices in San Antonio and Sugar Land, Texas, and employs hundreds of Texans statewide, including in this District. Icon PLC also oversees and manages clinical trial sites in Texas and in this District.

25. Defendants are therefore subject to general and specific personal jurisdiction under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1367.

IV. PARTIES

A. Relator Brook Jackson

26. Relator Brook Jackson ("Relator" or "Jackson") worked supporting clinical trials for over eighteen years as she spent a lifetime supporting safe, effective medicines. She is a Clinical Research Auditor and Certified Clinical Research Professional. Before working for Defendant Ventavia Research Group, LLC ("Ventavia"), Jackson served as the Director of Operations for a multi-state clinical trial company. Second only to the CEO, she oversaw legal and regulatory compliance, adherence to good clinical practices, submission of required documentation, and business development across the company.

27. Relator has direct and independent knowledge of the information on which she bases her allegations. If any allegations or transactions herein have been publicly disclosed, Relator has independent knowledge that materially adds to any publicly disclosed allegations or transactions and

has informed the United States and DOD before filing a complaint by serving a voluntary pre-filing disclosure statement. Relator submitted an original disclosure statement and the material evidence and information she had, to the Attorney General of the United States, Department of Justice, and United States Attorney for the Eastern District of Texas upon filing the Original Complaint.

B. Pfizer Inc.

28. Pfizer Inc. ("Pfizer") is a Delaware corporation headquartered at 235 East 42nd Street, New York, New York 10017-5703. It maintains an office in this District at 1301 Solana Boulevard, Westlake, Texas 76262. Pfizer and BioNTech developed the vaccine and co-sponsored the clinical trial.

29. Pfizer is publicly traded on the New York Stock Exchange under the ticker symbol "PFE."

C. Icon PLC

30. Icon PLC ("Icon") is an Irish company headquartered in Dublin. Icon conducts extensive business in the United States and Texas, including at its offices in Sugar Land and San Antonio, Texas. Icon has hundreds of employees in Texas, including in this District, and oversees and manages clinical trials statewide.

31. Icon is publicly traded on the NASDAQ stock exchange under the ticker symbol "ICLR."

32. Defendant Pfizer subcontracted Icon to manage the clinical trial. Icon oversaw over 160 test sites worldwide and was tasked with ensuring clinical trial protocol compliance and required information reporting.

D. Ventavia Research Group, LLC

33. Ventavia Research Group, LLC ("Ventavia") is a Texas limited liability company headquartered at 1307 Eighth Avenue, Suite 202, Fort Worth, Texas 76104. Ventavia operates ten test sites in Texas, some of which are in this District. Three of Ventavia's test sites—in Keller, Fort Worth, and Houston—participated in the Pfizer clinical trial.

34. Ventavia secured its contract to operate three test sites for the Pfizer-BioNTech vaccine trial through its contracting agent Platinum Research Network, LLC, and was paid directly by Defendant Pfizer for that work. Pfizer compensated Ventavia mainly on a per-patient basis, with more paid per Serious Adverse Event reported and for activities like training.

35. Ventavia recorded all key participant and clinical trial information in "source documents" provided to Pfizer and Icon after entry or upload.

V. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

36. The acts alleged to have been committed by Defendants were committed by officers, directors, employees, representatives, or agents, acting for Defendants and within the course and scope of their employment, or by corporate predecessors to whom successive liability applies.

VI. STATUTORY AND FACTUAL BACKGROUND

A. COVID-19 Vaccine Development

37. On May 15, 2020, the White House announced Operation Warp Speed ("OWS"), a partnership between the United States Department of Health and Human Services ("HHS") and the United States Department of Defense ("DOD").

38. OWS aimed to begin delivery of 300 million doses of FDA-authorized COVID-19 vaccines by January of 2021. HHS, Fact Sheet: Explaining Operation Warp Speed (Nov. 30, 2020).[9] OWS coordinates with and expands existing HHS programs, including the National Institutes of Health's Accelerating COVID-19 Therapeutic Interventions and Vaccines ("ACTIV") partnership. *Id.*

39. OWS's main initiative was to contract with pharmaceutical companies to fund clinical trials and buy promising COVID-19 vaccine candidates. Purchases would occur only after vaccine

[9]https://public3.pagefreezer.com/content/HHS.gov/15-11-2020T07:52/https://www.hhs.gov/sites/default/files/fact-sheet-operation-warp-speed.pdf

candidates secured approval or Emergency Use Authorization from the United States Food and Drug Administration ("FDA"). The Pfizer-BioNTech product is part of one such contract, explained further *infra*.

40. The definition of this entire project was "Large Scale Vaccine Manufacturing Demonstration". The Statement of Work listed the work to be performed in any certification and presentment of payment by the contractor. The Statement of work became the "Project Agreement" Pfizer's work must certify it performed "in accordance with" as precondition of payment.

41. Pfizer promised to deliver a vaccine "capable of providing protection against" COVID-19"and related coronaviruses" subject to its "technical, clinical, and regulatory success." The purpose of the project is "bringing a Covid-19 vaccine to market to address this urgent medical need while preserving high quality and safety standards." As the Statement of Work and Project Agreement repeatedly requires a product "preventing Covid-19 infection."

42. The "deliverables" required in the contract include clinical trial data, any filings with the FDA, manufacturing data, delivery of 100 million doses of a safe, effective, vaccine for the prevention of COVID-19.

43. The contract incorporates the FDA requirements noting "given that these clinical trials are regulated by the FDA and HHS, there is no need for separate regulation by the U.S. Army Medical Research and Material Command." The Statement of Work repeatedly reiterated the importance of Pfizer compliance with FDA rules and regulations incorporated into the contract, noting it could only seek FDA approval or authorization "assuming the clinical data supports such application for approval or authorization."

44. The Statement of Work also highlights the purpose of the clinical trials, the reasoning for disclosure of the data independently to the DOD as well as the FDA, and the essence of the bargain:

"the primary objective of the study is to describe the safety and tolerability" of the 'vaccine" and "the immune response" to assess efficacy.

45. The Statement of Work and Project Agreement highlighted "a randomized, placebo-controlled, observer-blind, dose-finding and vaccine candidate-selection study in healthy adults" for "evaluating the safety, tolerability, and immunogenicity of the Covid-19 mRna vaccine candidates."

46. The Statement of Work and Project Agreement noted the importance of the "pivotal efficacy study" and only "upon gathering adequate safety and efficacy data in a sufficient number of subjects" could the drug be administered.

47. To obtain payment, Pfizer "shall establish the effectiveness of a technology capable of proving immediate and long-term solutions to coronavirus infections" that conform to "pre-clinical, clinical, and chemistry/manufacturing/controls" through manufacturing and distributing a safe, effective vaccine for the prevention of COVID-19.

48. The only requirements considered "out of scope" for this project are those that do not relate to the COVID-19 vaccine project, described throughout as "the large-scale manufacturing demonstration" in the title, description, and throughout the agreement.

49. Pfizer promised in the Project Agreement and Statement of Work "to manufacture and deliver" 100 million doses of the "vaccine" that Pfizer developed, designed, and manufactured "in a manner compliant with applicable laws and regulations" governing clinical trials, best manufacturing processes, and EUA authorization in order to produce "the necessary quantity of safe and effective doses for vaccination of the U.S. population." This is the listed Objective of the Agreement.

B. Congressionally mandated EUA Requirements

50. Congressional requirements for an EUA are at 21 U.S. Code § 360bbb–3(c) – Authorization for medical products for use in emergencies as follows:

(1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;
(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—
(A) the product may be effective in diagnosing, treating, or preventing—
(i) such disease or condition; or
(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and
(B)the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

C. FDA Clinical Trial Regulations

51. The FDA promulgates regulations applicable to all clinical trials of new drugs. *See* 21 C.F.R. §§ 312.1 *et seq.* These regulations applied to COVID-19 vaccine trials, despite their accelerated nature and the pandemic emergency. *See* 42 U.S.C. § 247d-6d(c)(5)(C)(i).

52. Clinical trial sponsors like Pfizer must submit an Investigational New Drug Application ("IND") before beginning the trial. *See* 21 C.F.R. § 312.23(a). An example IND (Form FDA-1571) is attached as Exhibit 4. In the IND, the sponsor commits to conduct the trial "in accordance with all [] applicable regulatory requirements." 21 C.F.R. § 312.23(a)(v); Ex. 4, Form FDA-1571, at 2. The IND form warns clinical trial sponsors that making a "willfully false statement is a criminal offense." Ex. 4, at 2.

53. Clinical trial sponsors must use an Institutional Review Board ("IRB") for initial and continuing review and approval of the clinical trial. *See* 21 C.F.R. § 312.23(a)(iv). The sponsor must report "all changes in the research activity" to the IRB, along with "all unanticipated problems involving risk to human subjects or others." 21 C.F.R. § 312.66. The sponsor must assure that it "will not make any changes to research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects." *Id.* (emphasis added).

54. The sponsor must promptly investigate "all safety information it receives" and follow up on any adverse reactions. 21 C.F.R. § 312.32(d)(1). The sponsor must also review all safety and effectiveness information reported by contract investigators (*i.e.*, clinical trial sites). The sponsor must notify the FDA of potential serious risks and adverse reactions. *See* 21 C.F.R. § 312.32(c).

55. If a study sponsor uses contract investigators for its clinical trial (like Pfizer contracted with Icon and Ventavia), it must make sure the investigator is qualified, provide the investigator with the information needed to properly conduct a clinical trial, ensure proper monitoring of the trial, make sure the trial follows the IND and clinical trial protocol, and ensure "that FDA and all participating investigators are promptly informed of significant new adverse effects or risks" regarding the drug under investigation. 21 C.F.R. § 312.50.

56. The sponsor must obtain a signed Form FDA-1572 from each contract investigator. 21 C.F.R. § 312.53(c). In Form FDA-1572, each investigator certifies it:

> (a) Will conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, the rights, or welfare of subjects;
>
> (b) Will comply with all requirements regarding the obligations of clinical investigators and all other pertinent requirements in [21 C.F.R. part 312];
>
> (c) Will personally conduct or supervise the described investigation(s);
>
> (d) Will inform any potential subjects that the drugs are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent (21 CFR part 50) and institutional review board review and approval (21 CFR part 56) are met;
>
> (e) Will report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with § 312.64; . . . [and]
>
> (f) Will ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments. 21 C.F.R. § 312.53(c)(vi); *see also* Ex. 5, Form FDA-1572.

57. Each contract investigator also commits in Form FDA-1572 to promptly report to the IRB "all changes in the research activity and all unanticipated problems involving risks to human subjects or others[.]" 21 C.F.R. § 312.53(c)(vii). The contract investigators further commit to not making any

research changes without IRB approval "except where necessary to eliminate apparent immediate hazards to the human subjects." *Id.* The Form warns contract investigators that a "willfully false statement is a criminal offense." Ex. 5, at 2.

58. The sponsor must monitor its contract investigators' progress and compliance with the clinical trial protocol, IND, and all applicable regulations. *See* 21 C.F.R. §§ 312.50, 312.56. "A sponsor who discovers an investigator not complying" with those requirements "shall promptly either secure compliance or discontinue shipments of the investigational new drug to the investigator and end the investigator's participation in the [clinical trial]." 21 C.F.R. § 312.56(b). Contract investigators are bound by the same regulations as the sponsor, to the same degree, regarding any obligation the sponsor delegates to them. *See* 21 C.F.R. § 312.52.

59. Thus, in the clinical trial here, all Defendants are bound by FDA regulations and "subject to the same regulatory action . . . for failure to comply[.]" 21 C.F.R. § 312.52(b). Failure to comply with FDA regulations or submission of false information to the trial sponsor or FDA can disqualify a company from conducting future clinical trials. *See* 21 C.F.R. § 312.70(b).

60. Contract investigators are required to "furnish all reports to the sponsor." 21 C.F.R. § 312.64(a). The sponsor "is responsible for collecting and evaluating the results obtained." *Id.*

61. Contract investigators must maintain adequate records of drug dispensation, "including dates, quantity, and use by subjects." 21 C.F.R. § 312.62(a). They must also keep "adequate and accurate case histories" for all study participants which "record all observations and other data pertinent to the investigation[.]" 21 C.F.R. § 312.62(b).

62. Informed consent must be obtained and documented for every participant in the clinical trial. *See* 21 C.F.R. §§ 50.27(a), 312.60, 312.62(b). The investigator must document "that informed consent was obtained **prior to** participation in the study." 21 C.F.R. § 312.62(b) (emphasis added).

63. The clinical trial drug (here, the vaccine) shall be given only to subjects under an investigator or sub-investigator's personal supervision. *See* 21 C.F.R. § 312.61. It shall not be given to any person not authorized to receive it. *Id.*

64. Contract investigators must immediately report any Serious Adverse Event ("SAE") to the sponsor, "whether or not considered drug related, . . . and must include an assessment of whether there is a reasonable possibility that the drug caused the event." 21 C.F.R. § 312.64(b). Nonserious adverse events must also be reported to the sponsor. *Id.*

65. SAEs have the potential to pause clinical trials if sufficiently serious. *See* 21 C.F.R. § 312.44. In fact, two of Pfizer's competitors in the COVID-19 vaccine race—Astra Zeneca and Johnson & Johnson—had to pause clinical trials when participants developed unexplained illnesses.

1. Clinical Trial Protocol and Manual

66. Pfizer has publicized its clinical trial protocol on the Internet, and it is attached as Exhibit 7. The protocol portions most relevant to this matter are summarized below.

a. Inclusion and Exclusion Criteria

67. The trial at issue here was supposed to be randomized, placebo-controlled, and observer-blinded. *See* Ex. 7, Clinical Trial Protocol, at 1. By the end of Phase 3, the trial included healthy individuals, aged twelve to eighty-five, at risk of acquiring COVID-19, capable of informed consent and willing and able to comply with scheduled visits, vaccination plan, laboratory tests, and study procedures. *See* Ex. 7, at 40–41. Individuals with certain pre-existing conditions or history are excluded, including pregnant and breastfeeding women and people with a history of severe vaccine reactions. *See* Ex. 7, at 41–43.

68. The study also excludes "[i]nvestigator site staff or Pfizer/BioNTech employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members." Ex. 7, at 43.

69. Participants who have begun the study must be withdrawn if they deviate from the protocol, lose their eligibility, or take certain medications. *See* Ex. 7, at 50–53. Participants who become pregnant after receiving the first dose of the vaccine, for example, must withdraw from the study. *See* Ex. 7, at 65.

70. All participants' eligibility screening evaluations must be reviewed "to confirm that potential participants meet all eligibility criteria." Ex. 7, at 55. Ventavia was required to "maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable." *Id.*

71. Each participant's full date of birth must be collected to facilitate evaluation of immune response and safety by age. Ex. 7, at 54.

b. Blinding

72. The study is observer blinded. Ex. 7, at 1. The physical appearance of the vaccine and placebo differ, so blinding the person administering the vaccine is not possible. *See* Ex. 7, at The patient receiving the vaccine, study coordinator, and other site staff are blinded. *See* Ex. 7, at 36, 48–49.

73. At the test site level, the only people who should be unblinded are those administering the injection. *See* Ex. 7, at 36, 48–49. Nobody involved in "evaluation of any study participants" should be unblinded. Ex. 7, at 49.

c. Temperature Control

74. The investigator must confirm that vaccine doses received have been transported and stored under "appropriate temperature conditions[,]" and that "any discrepancies are reported and resolved before use of the study intervention." Ex. 7, at 47.

75. The vaccines must be stored in "a secure, environmentally controlled, and monitored" area in accordance with the product manual, as described further *infra*. *Id.* Daily maximum and minimum temperatures must be recorded for all storage locations and those records must be provided upon request. *See id.*

76. Deviations from recommended temperature, called "temperature excursions," must be reported to Pfizer upon discovery, "along with any actions taken." Ex. 7, at 47. The vaccines subject to the excursion must be quarantined from others and not used unless Pfizer subsequently provides permission. *See id.*

d. Informed Consent

77. As with all clinical drug trials, the participant must provide informed consent. The protocol for the trial at issue requires obtaining signed and dated informed consent documentation before performing *any* study-specific procedures, including administration of the vaccine. *See* Ex. 7, at 54, 117.

e. Administration

78. Before administration of the vaccine, study participants receive a clinical assessment "to establish a baseline." Ex. 7, at 58. The participant's medical history and observations from any physical examination must be documented and submitted to Pfizer. *See id.*

79. Women of childbearing potential must undergo a pregnancy test before receiving the vaccine or placebo. *See* Ex. 7, at 23, 65.

80. Only participants enrolled in the study may receive the vaccine, and only authorized site staff may administer it under medical supervision. Ex. 7, at 47, 50.

81. The date and time of injection must be recorded. *Id,* 50.

82. Participants must receive their second injection nineteen to twenty-three days after the first. *See* Ex. 7, at 23, 88.

f. Safety and Monitoring

83. All adverse events in the first thirty minutes after injection must be documented in an Adverse Event Case Report Form. *See* Ex. 7, at 58, 86, 89.

84. Participants use an electronic diary ("e-diary") application to record any adverse events and use of any antipyretic (fever-reducing) medication. *See* Ex. 7, at 58–59. E-diary data is periodically transmitted directly to Pfizer and Icon. *See* Ex. 7, at 59.

85. After participants report any ongoing local reactions, systemic events, or use of antipyretic medication, the investigator must obtain and document end dates for those events. *See* Ex. 7, at 59–60.

86. Serious adverse events ("SAEs") must be reported to Pfizer within twenty-four hours. Ex. 7, at 66. Under no circumstances should they be reported later. *Id.* Any update to SAE information must be reported to Pfizer within twenty-four hours of it becoming available. *Id.* Any non-serious adverse events must be reported and documented on Case Report Forms submitted to Pfizer. *See id.* Site investigators are responsible for pursuing and obtaining "adequate information both to determine the outcome and to assess whether the event" is serious "or caused the participant to discontinue the study intervention." Ex. 7, at 65.

87. Follow-up on adverse events must continue until the event resolves or stabilizes at a level acceptable to the investigator and concurred with by Pfizer. *Id.* Follow-up information must include

enough detail to allow for complete medical assessment and independent determination of possible causality. Ex. 7, at 67.

88. If any participant is confirmed to have been injected while pregnant or breastfeeding, Pfizer must be notified within twenty-four hours. *See* Ex. 7, at 67–68. The same applies to pregnancy in partners of clinical trial participants. *Id.* The investigator must conduct follow-up on the pregnancy and its outcome and keep Pfizer updated. *See* Ex. 7, at 68–69.

g. Legal and Regulatory Compliance

89. The protocol emphasizes that investigators must notify Pfizer of SAEs "so that legal obligations and ethical responsibilities towards the safety of participants and the safety of [the vaccine] under clinical investigation are met." Ex. 7, at 67. The protocol notes that Pfizer "has a legal responsibility to notify" the government about the safety of the vaccine under investigation, and "will comply with country-specific regulatory requirements relating to safety reporting to the appropriate regulatory authority . . . and investigators." *Id.*

90. The protocol also states that the study will be conducted in accordance with all applicable laws and regulations, including privacy laws. Ex. 7, at 116.

91. Ventavia is responsible for oversight of the study at their sites and adherence to FDA regulations found in Title 21 of the Code of Federal Regulations. *See id.*

h. Adherence to Protocol

92. Adherence to the trial protocol "is essential and required for study conduct." Ex. 7, at 54. "Protocol waivers or exemptions are not allowed." *Id.* Thus, as noted previously, participants who deviate from the protocol must be excluded.

93. The protocol also requires that the clinical trial adhere to "ICH GCP"—Good Clinical Practices established by the International Council for Harmonization. *See* Ex. 7, at 116, 138–39.

94. Any failure to provide a test or procedure required by the protocol must be documented, alongside any corrective or preventive actions taken by the administrator, and Pfizer's safety team must be informed. *See* Ex. 7, at 55.

95. Site investigators must inform Pfizer immediately if they know of any new information which might influence the evaluation of the benefits and risks of the vaccine at issue. Ex. 7, at 116. They must also immediately inform Pfizer of any serious breaches of the study protocol or ICH GCP. *Id.*

96. Pfizer may close a study site early for any reason, including when the site investigator violates the study protocol. *See* Ex. 7, at 121.

i. Accuracy of Data

97. Site investigators must maintain accurate source documentation supporting all information entered into electronic Case Report Forms submitted to Pfizer. *See* Ex. 7, at 119–21. If source documents differ from any information in the Case Report Form, the discrepancy must be explained. Ex. 7, at 120.

98. Site investigators must verify that data entries are accurate and correct by signing the Case Report Forms transmitted to Pfizer. Ex. 7, at 119.

99. Pfizer or Icon is responsible for data management of the study, "including quality checking of the data." Ex. 7, at 120.

2. BNT162b2 Product Manual

100. The product manual for BNT162b2—attached as Exhibit 6—provides specifics as to how the vaccine and placebo should be stored and administered. These specifics supersede storage conditions set out in the clinical trial protocol and provide more guidance for temperature excursions and use. *See* Ex. 7, Clinical Trial Protocol, at 47–48, 52, 80, 86, 88. Thus, noncompliance with the product manual equals noncompliance with BNT162b2's clinical trial protocol.

a. Additional Blinding Precautions

101. The patient, study coordinator, and other test site staff are blinded, as previously noted. The vaccinator is not. "Blinded personnel should not have access to the container IDs" for the vaccine. Ex. 6, Product Manual, at 23. "Only the site staff who will be dispensing, preparing, and administering the [vaccine] are unblinded and can have this access." *Id.*

102. Occluding labels are applied to the syringe barrel to mask its contents and preserve blinding. *See* Ex. 6, at 49–50. Patients are also instructed to look away during injection. *See* Ex. 6, at 50.

103. Each prepared BNT162b2 syringe expires six hours after preparation. Ex. 6, at 49. To preserve the blind, both the vaccine and placebo are given the same expiration date and time. *Id.*

104. Sites must have a process to maintain the study blind, including making sure vials, dilution material, and dosing syringes "are shielded from the view of BLINDED study staff and the participant during dose preparation, dispensing, transportation, administration, and disposal." Ex. 6, at 49. The site should "ensure that the study blind was maintained and that the [BNT162b2] cartons, preparation records, syringes, and disposal of used supplies were carefully handled prior to and after administration." *Id.* The site must document for each participant whether the blind was maintained. *See* Ex. 6, at 50.

105. Pfizer must be notified of any potential unblinding, and further enrollment and injection must stop immediately:

> if the study drug is not stored, handled, or administered according to the protocol and/or relevant site documentation to adequately maintain the blind. The site must provide details of the incident or any protocol deviations and [] assist in resolving the issue and/or determining corrective actions to take. If the blind is broken or potentially broken, unblinded staff must contact [Pfizer] immediately. Do not administer or dispense the study drug to any participant and do not randomize a new participant until the Sponsor provides further instructions. Ex. 6, at 43.

b. Temperature Excursions

106. BNT162b2 must be protected from light and stored at -112°F to -76°F in its original packaging before use in dose preparation. *See* Ex. 6, at 36, 40.

107. BNT162b2 is shipped in a specialized container with dry ice (solid carbon dioxide). Ex. 6, at 36. The shipping containers used in the clinical trial included a monitoring device that triggered an alarm if the acceptable temperature range for the product was exceeded. *See* Ex. 6, at 36, 38.

108. If any deviation in temperature for BNT162b2 shipments outside of the accepted range occurs, the product must be segregated and the excursion reported to Pfizer. *See id.*; Ex. 7, Clinical Trial Protocol, at 47. Pfizer then notifies the site if the product is acceptable for use despite the excursion. *See* Ex. 6, at 38.

109. The same process must be followed if there is any lapse in temperature monitoring or even when the site is not sure if there has been a temperature excursion. *See* Ex. 6, at 40.

c. Dose Preparation

110. BNT162b2 is shipped as a frozen concentrate, which is thawed for about 30 minutes and diluted with sodium chloride (saline) solution before injection. Ex. 6, at 47. "Only clinical site personnel who are appropriately trained on the procedures" in the product manual may prepare and administer BNT162b2. Ex. 6, at 46.

111. The doses must be allowed to reach room temperature before administration. Ex. 6, at 48. Preparation time is standardized at thirty minutes or more to avoid unblinding, since the placebo has no thaw time. *See* Ex. 6, at 47–49, 53, 56, 60, 72, 76; Ex. 9, E-mail Chain with Downs and Others (Sept. 18, 2020), at 2.

d. Injection

112. Participants are injected using a 1" or 1.5" needle, depending on their body weight.

Ex. 6, at 51. A 5/8" needle may also be used for participants weighing less than 130 pounds if the skin is stretched tightly. *Id.* The 1" needle size is appropriate for all participants except males over 260 pounds and females over 200 pounds, for whom a 1.5" needle is required. *See id.*

113. Only "an appropriately qualified and experienced member of the study staff" may prepare and administer the vaccine or placebo. Ex. 6, at 44, 72, 75, 78. The product manual specifies that this must be a "nurse, physician's assistant, nurse practitioner, pharmacy assistant/technician, or pharmacist[,] as allowed by local, state, and institutional guidance." *Id.*

114. The vaccine is injected into the deltoid muscle of the participant's non-dominant arm. Ex. 6, at 44.

115. Any error in dispensing the vaccine that may cause or lead to patient harm while in the site's control must be reported to Pfizer and Icon immediately. Ex. 6, at 62.

e. Monitoring

116. "Blinded site staff must observe" clinical trial participants after injection "for at least 30 minutes" to monitor "for any acute reactions." Ex. 6, at 44; *see also* Ex. 6, at 61. Reactions must be recorded in source documents, on an adverse event reporting form and as an SAE if necessary. Ex. 6, at 44.

D. Contract at Issue

117. On July 21, 2020, the United States DOD entered into the contract, referred to as the OTA Base Agreement ("OTA") with Defendant Pfizer, through Advanced Technology International ("ATI"). *See* Ex. 10, Pfizer-DOD Contract, at 1.

118. DOD likely used ATI as its intermediary to simplify the contracting process and avoid possible delay resulting from typical procurement processes. Despite the use of an intermediary, the United

States clearly stated the contract was between itself and Pfizer. *See* Ex. 10, Pfizer-DOD Contract, at 1, 2; Press Release, HHS, U.S. Government Engages Pfizer to Produce Millions of Doses of COVID-19 Vaccine (July 22, 2020).[10]

119. Under the contract, DOD bought 100 million doses of the vaccine, with the option to buy up to 500 million more doses later. *See* Ex. 10, at 11–12, 17. DOD contracted to pay Pfizer $1.95 billion for the vaccines ($19.50 per dose) after FDA approval or Emergency Use Authorization ("EUA"). *See* Ex. 10, at 1, 17.

120. The clinical trial at issue, which was privately funded, aimed to secure FDA approval or EUA of the vaccine by the end of 2020, as a prerequisite for DOD's purchase of the vaccine and payment to Pfizer under the contract. *See* Ex. 10, at 5, 6.

121. The OTA Base Agreement cited by Pfizer did not discard FDA rules, but reinstated and reinforced them.

122. Section 21.06 of the OTA states, "Deployment and production of medical products and processes fall under the purview of the Food and Drug Administration (FDA) and research on these products involving animal or human studies is regulated by other laws, directives and regulations.... Efforts conducted under this OTA shall be done ethically and in accordance with all applicable laws, directives, and regulations." Indeed, Pfizer was required to share all FDA information with the DOD, including listening to conferences, sharing all documents, exchanging all communications, allowing government attendance at all visits and audits.

123. Section 21.12 of the OTA further requires that Pfizer comply "with current Good Manufacturing Processes as defined by FDA guidance", including "clinical trials", and any "failure to

[10]https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19- vaccine.html.

comply" that had any "material adverse effect on the safety" of the product would be a "material failure."

124. The Statement of Work ("SOW") further incorporated the terms of the OTA, as 1.1 of the SOW states the agreement is entered into "pursuant to" it.

125. The SOW further provides that the agreement is "for provision to the Government, a state of the art candidate vaccine...providing protection against the SARS-Cov-2 threat and related coronaviruses, subject to technical, clinical and regulatory success." The government was led to believe Pfizer could do "unprecedented phase" clinical trial design and its modRNA technologies would "abolish the risk of anti-vector immunity." Indeed, Pfizer promised they could scale fast "while preserving high quality and safety standards." Pfizer promised its product would be "for the prevention of Covid-19." The agreement required "regulatory approval" after "conducting clinical trials." The agreement only provided for funding "if clinical trials are successful and the FDA grants" EUA and BLA licensure.

126. In the event this burden was not apparent enough, the SOW is crystal clear: "Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials." They can only seek FDA approval or authorization if "the clinical data supports such application for approval or authorization." Indeed, the only reason no separate regulation was required by the Army was because "these clinical trials are regulated by the FDA and HHS." The SOW even goes into detail on the kind of study necessary to "evaluating the safety" of the vaccine -- "a randomized, placebo-controlled, observer-blind, dose-finding, and vaccine candidate-selection study in healthy adults." The SOW describes the clinical trials as "pivotal efficacy study design." Only upon "adequate safety and efficacy data" could it be approved. The words "FDA approval or authorization" repeat throughout. The SOW even expressly incorporated the EUA preconditions for approval with express document incorporation.

Pfizer's promise was that "doses shall establish the effectiveness of a technology capable of potentially providing immediate and long-term solutions to coronavirus infections."

127. The SOW repeated throughout that Pfizer must comply "in a manner compliant with applicable laws and regulations" and expressly referenced the Good Manufacturing Practices regulation (21 CFR 210 & 21 CFR 211). The payment was only for "safe and effective doses required for vaccination" and Pfizer was being paid to "deliver those doses" at scale and speed. Any additional production required "particularly favorable" results. Over and over again, the SOW required Pfizer's drug be an "FDA-approved or authorized vaccine." Again and again, the DOD required any approval was "subject to FDA-approval or authorization" and "subject to FDA-approval or authorization." There would be no approval if "clinical" or "regulatory" failure occurred. Pfizer had to provide the DOD all "data updates from clinical studies." Additionally, Pfizer had to "notify the Government of any event, risk, formal or informal FDA communication, or other issue" that could impact the project. All payments were "subject to change" based on "clinical trials and the validation of the product." Just as no payment could be made until successful clinical trials and FDA authorization or approval, the Government could stop payment whenever the FDA withdrew approval or authorization. That is why Pfizer had to provide all the "data updates" from the clinical trials as well as "any and all inspection and compliance notices, observations and responses" of those clinical trials.

128. Pfizer delegated some management of the clinical trial at issue to Defendants Icon and Ventavia, as previously explained.

129. Under the contract, Pfizer sends monthly invoices to DOD at $19.50 per dose for each delivery of vaccines, which are paid within thirty days. *See* Ex. 10, at 17.

130. In late December of 2020, DOD exercised a contractual option to buy 100 million more doses of the vaccine for $1.95 billion. Thus, the contract's total value is now $3.9 billion.

1. FAR Compliance

131. To perform under the contract, Pfizer must comply with Federal Acquisition Regulations ("FAR"), including but not limited to the provisions discussed below. *See* 42 C.F.R. §§ 3.1004(a), 52-203.13; Ex. 4, Form FDA-1571, at 2; Ex. 7, Clinical Trial Protocol, at 116.

132. FAR 52.203-13 contains the Contractor Code of Business Ethics and Conduct. That regulation requires Pfizer to maintain a code of ethics and conduct, exercise due diligence to prevent criminal conduct, and disclose any credible evidence that a subcontractor (including Icon and Ventavia) has committed a False Claims Act violation. 48 C.F.R. § 52.203-13(b). This regulation also requires Pfizer maintain an "internal control system" with procedures in place to detect fraud and improper conduct "in connection with Government contracts." 48 C.F.R. § 52-203.13(c)(2). Pfizer must include the Contractor Code of Business Ethics and Conduct in any subcontract with a performance period of over 120 days. 48 C.F.R. § 52- 203(13)(d)(1).

133. FAR 42.202(e)(2) requires Pfizer to manage all of its subcontracts. *See* 48 C.F.R. § 42-202(e)(2). Pfizer therefore had to monitor Ventavia and Icon's performance and make sure they followed the clinical trial protocol. *Id.*

2. FAR Certification

134. Federal Acquisition Regulation 52.232-32 requires Pfizer to certify the following in any request for payment under the contract:

> I certify to the best of my knowledge and belief that-
>
> (1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared from the books and records of the Contractor, in accordance with the contract and the instructions of the Contracting Officer[.] 48 C.F.R. § 52.232-32(m).

VII. FACTUAL ALLEGATIONS

A. Pfizer Knew it Could Not Obtain Full Approval nor EUA for its COVID-19 Vaccines because, Based on the Totality of Scientific Evidence, Reasonable Information Indicated Harms Far Outweighed Any Potential Benefit

135. Pfizer knew the premise of its modRNA vaccine was flawed. Blood-borne antibody responses provide little or no protection or immunity from respiratory diseases. Worse, real time clinical and epidemiological data show Pfizer's vaccines have a negative efficacy: the more shots people received of the COVID 19 vaccine, the more likely they would contract COVID-19. For example, a Harvard study looking at 68 countries and 2,947 counties in the United States showed no decrease of infection rates in areas with higher injection rates. Instead, the trend suggested "positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people."[11] Similarly, a study by the Cleveland Clinic, Shrestha, et al. shows a correlation between the cumulative incidents of COVID-19 cases and the number of COVID-19 injections.[12]

136. Several factors explain this negative efficacy. Experts have long understood that mass vaccination with a "leaky vaccine" – one unable to neutralize the infection – can lead to a more severe health crisis called "Antibody Dependent Enhancement," or ADE. As more people get vaccinated with a leaky vaccine, infection rates increase because viruses are not blocked from entering the cells by the injection-induced antibodies. Medical evidence and respected medical opinions indicate that the injection-induced antibodies themselves can assist SARS-CoV-2's entry into the cells, by bridging between the virus and the cell receptors. Moreover, studies have confirmed a long-feared process of immune tolerance caused by a class switch towards non-inflammatory IgG4 antibodies, which rose in

[11] S. V. Subramanian, 36 Eur. J. Epidemiol. 1237-1240 (2021

[12] https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v5.full.pdf

one study, on average, from 0.04% shortly after the second injection to 19.27% late after the third injection. This class switch was associated with a reduced capacity of the antibodies to mediate antibody dependent cellular phagocytosis and complement deposition. These and other studies show modRNA injections can cause long term T-cell and B-Cell dysfunction, which can lead to "Vaccine Acquired Immune Deficiency Syndrome" or VAIDS resulting in more infections with COVID-19 and other illnesses, including malignancies.

137. On the other side of the equation, the much harm is caused by Pfizer's COVID-19 vaccines. Adverse events, in only the first 90 days following the public rollout of Pfizer's COVID 19 modRNA gene therapy product, were staggering. Between December 1, 2020 and February 28, 2021, 42,086 subjects or patients with 93,473 Adverse Events (AEs) or Adverse Events of Special Interest (AESIs) were reported. Findings include, but are not limited to:

a. 275 patients, with 300 events reports, were within the stroke data set. 61 events (22% of patients) were fatal.

b. 1.07% of the total patient post marketing population, or 449 total people, experienced facial paralysis and facial paresis diagnoses. 399 (88%) of cases were classified as serious.

c. 542 neurological events, 95% of which were series, occurred in 501 patients. 16 patients died. 376 seizures reported, 12 of which were status epilepticus, a rare condition of prolonged seizure or series of seizures that is life threatening; 38 cases of multiple sclerosis; 11 cases of transverse myelitis, a destructive inflammation of the spinal cord; 10 cases of optic neuritis, inflammation of the optic nerve threatening blindness,; 24 cases of Guillain Barre syndrome, three cases of meningitis, and seven cases of encephalopathy.

d. Out of 42,086 total trial participants with identified adverse events, 2.2% (932 individuals) experienced blood system related events. There were 34 deaths and 17 cases of permanent damage.

e. 34 vasculitis adverse events were reported among 32 patients one fatal. Since BNT162b2 was introduced, there have been alarming rates of spike-protein diseases, and individuals who receive the injections suffer statistically significant higher rates of heart and blood disorders (including myocarditis, pericarditis, pleural effusion and congestive heart failure), autoimmune diseases (including rheumatoid arthritis, vasculitis, encephalitis, neuropathy and demyelination), prion like diseases (such as Creutzfeldt Jakob Disease and Alzheimer's Disease) other neurological diseases (such as strokes, seizures, multiple sclerosis, neuritis, Guillain Barre syndrome, meningitis), immune dysfunction and cancers (including IgG4 induced tolerance), and fertility, pregnancy and menstrual disorders (including spontaneous abortions, premature birth with neonatal death, fetal demises, abnormal uterine bleeding, vaginal hemorrhaging and post-menopausal bleeding, breast pain and swelling, genital pain and dysfunction, and low sperm counts and mobility).

138. A recent study concluded that 1 out of every 35 people injected with the vaccines develops myocarditis. Nine months after the rollout of the COVID 19 injection, substantial birth rate drops were seen in 13 European countries, including England, Wales, Australia, and Taiwan. Indeed, pregnant women are more likely to experience a miscarriage if they receive a COVID-19 vaccine compared to any other vaccine. According to VAERS, from 1990 through March 2022, miscarriages were reported 4,693 times by women vaccinated for all diseases through March 2022. Out of the women who reported losing her babies to miscarriage after receiving a single vaccine, 76% received only the COVID-19 vaccine. So, 76% of all the vaccinations that resulted in a baby dying in miscarriage in the past 30

years occurred when pregnant women started receiving COVID-19 vaccines. More data arrive daily showing the vast harm caused by Pfizer's modRNA injection.

B. To Induce EUA for its modRNA Vaccines, Pfizer Engaged in Fraud in the Design, Conduct, Analysis and Reporting of its Clinical Trials

139. Development of new medicine, on average, takes 10 years and costs $2.6 billion dollars.[13] Only one out of every 10,000 scientific discoveries make it to market.[14] Pfizer knew that it could never gain either approval or an EUA based on truthful clinical data. Instead, Pfizer sought an EUA by engaging in fraudulent conduct in the design, conduct, analysis and reporting of its clinical trials, and by making false statements and material omissions in its applications, forms, reports, and data submissions to FDA.

C. Design

140. **Designed not to measure immunity or transmission.** Despite agreeing to produce an immunizing vaccine, Pfizer knew its product would not confer immunity, i.e., it would not prevent infection or transmission. So, Pfizer purposefully designed its clinical trials to avoid measurement of the extent to which immunity was conferred. This was done specifically to avoid admission of a fundamental failure of the vaccine to accomplish its stated purpose: stop or at least reduce infection. The lack of protection against infection means there was not enough public health benefit to justify authorization under the standards imposed by Congress. Truthful data showing the lack of reduction of infection in vaccinated subjects would have undermined Pfizer's request for EUA, and so it designed the clinical trials to omit those data.

---

[13] https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html

[14] https://www.boehringer-ingelheim.com/human-pharma/human-pharma/drug-discovery-boehringer-ingelheim

141. **Assumed and used a faulty PCR test.** Pfizer knew that the PCR test could not objectively measure the diagnosis of illness from SARS Cov 2. It also knew that the PCR test results could be manipulated by adjusting the cycle threshold used to amplify small amounts of genetic material to a measurable level. Despite this knowledge, Pfizer designed clinical trials to measure an outcome using the flawed PCR test. Pfizer then increased the cycle threshold for symptomatic control subjects (finding COVID-19 in subjects who were not infected) and lower the cycle threshold for symptomatic treatment subjects (finding no COVID-19 in subjects sick from the virus).

142. **Cut the study short to avoid showing negative efficacy.** Pfizer knew that the injections would confer negative efficacy in the study group, and that such negative immunity would be revealed in the data as it continued to conduct the trials. To avoid demonstration of the negative efficacy, Pfizer designed the study to end after only 2 months (8 weeks).

143. **Cut the study short to avoid showing severe spike protein diseases caused by injections.** Pfizer knew vaccine injuries would appear in the treatment subjects in the months and years after injection, including harm to the lungs, heart, brain and nervous system, reproductive systems and many other vital organs. To suppress evidence of harm caused by its product from coming out in the clinical trials, Pfizer designed the study to end after 2 months. In so doing, Pfizer knowingly made false representations that adverse events attributable to biologic occurred within 6 weeks. Moreover, after two months, Pfizer unblinded the subjects in the control group offering them the injection. By injecting the control group, Pfizer obscured the relatively poor health of the treated group over the control group in the short, medium and long term. In fact, deaths in trials occurred after the data cutoff. There were 38 subject deaths in the 6-month interim report, and 14 of 38 deaths – well over one third – resulted from cardiovascular events. This is a 3.7-fold increase in deaths due to cardiovascular events in the treatment arm of the clinical trial.

144. **Lied about non durability of the modified RNA material.** Pfizer knowingly lied when it represented and/or assumed that the biologic would not circulate in the blood or leave the injection site in the arm. This was one of the false representations it used to justify its flawed short-term design. It knew from its own studies that the LNP would circulate throughout the body and penetrate membranes, including the blood brain barrier. It also knew that modRNA was bio engineered to persist for a long time.

145. **Excluded pregnant women to avoid reporting harms.** Pfizer knew that the vaccines would cause injuries to pregnant women and their fetuses, and it did not want this revealed in clinical data. Therefore, Pfizer designed the study to exclude pregnant women hiding the harm caused to them. When presenting this information for EUA, Pfizer knowingly omitted the consequence of this design: that the clinical trials could thus not provide evidence that the benefits outweighed the harm for pregnant women.

D. Design/Conduct

146. **False manipulation of inclusion/exclusion.** Pfizer did not use random allocation in its clinical trial. Instead, it considered personal health facts about the subjects, and manipulated the inclusions and exclusions from the control group and the treatment group to exaggerate the benefit/reduce the harm in the treatment group and maximize the harm to the control group.

147. **Failed to design and conduct blindness.** Pfizer failed to design and control for blindness in the clinical trials, letting investigators know who was in the treatment group and who was in the control group. Such violations alone render the data unusable.

148. **Product degradation**. Pfizer knew that the active ingredients likely to cause injury would degrade if the refrigeration was not maintained. To avoid reporting the level of injury to the treatment group, Pfizer failed to design controls and failed to conduct the study to maintain temperature control,

allowing for degradation, and therefore reduction of the number in the treatment group who suffered adverse events.

149. **Failure to report Contaminated Control Group.** Pfizer knew the control group in the clinical trials were contaminated inflating adverse events above what it otherwise would have reported in that arm of the study. Some of these adverse events may have been caused by a failure to check cross-registration by trial subjects enrolling in other Pfizer clinical trial sites or even clinical trials conducted by other COVID-19 vaccine manufacturers. Elevated adverse events in the control group could have resulted from the other sources of contamination. Pfizer knew the control groups were reporting unexpected excess adverse events, but failed to institute proper controls against contamination, investigate, or disclose the anomaly.

E. Analysis/Reports

150. **Did not Report Adverse Events.** In the conduct, analysis and reporting of the clinical trial data, Pfizer did not monitor, report, or acknowledge adverse events in the treatment group, and it lied about those true data. For example, Maddie de Garay, a trial subject at Cincinnati Children's Hospital Medical Center, was listed as having psychological problems despite obvious vaccine injury. The Principal Investigator at her site, Robert W. Frenck, Jr., M.D., published a report denying any vaccine related serious adverse events among his adolescent test subjects. Augusto Roux was a test subject in the Argentine clinical trial run by Fernando Pollack, M.D. There is a telling mismatch between his medical record and the clinical trial records. His medical record shows vaccine induced pericarditis. Mr. Roux's injury is not in Pfizer's final submissions to FDA.

151. **Lied that adverse events more than 6 weeks out were not related.** Pfizer knew injuries appeared months or years after the injection, including when the vaccinated individuals are exposed to the wild virus. To FDA, however, it made knowing false material statement: that adverse events over 6 weeks after the injections were not related.

152. **Pfizer used relative risk reduction instead of absolute risk reduction to describe efficacy.** The FDA provides guidance on communicating risks and benefits. Absolute risk reduction is the recommended manner to communicate risks and benefits. Pfizer could not measure potential benefit on the individual basis, looking only at those individuals who became sick from an infection to determine efficacy. Out of about 44,000 trial subjects the end data points came from a mere 170 people--8 in the vaccine arm and 162 in the control arm that contracted COVID-19 which was the basis for a claimed 95% percent efficacy. But Pfizer's data, before exclusions, showed that among 3410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group.

153. Congressionally mandated standards require better efficacy than this.

154. **Falsely counted vaccinated as unvaccinated.** Pfizer knew that treatment group subjects would get COVID-19 within a few days of getting the injection, and that they often would suffer adverse events caused by the injections. To fraudulently under-report the number of treatment group subjects who got sick and/or suffered adverse events, Pfizer classified those individuals as "unvaccinated" until 14 days after the second shot. This allowed Pfizer to manipulate the analysis and falsely report vaccinated individuals as unvaccinated. Pfizer knew the real data, which showed the lack of efficacy and presence of severe adverse events. In this fashion, Pfizer constructed an efficacy rate by pure manipulation of the statistics.

F. Pre-requisites

155. **Suppressed alternative existing remedies.** Pfizer knew that alternative effective treatments existed in repurposed remedies, such as Ivermectin ("IVM") and Hydroxychloroquine ("HCQ"). Although these medications were not approved by FDA to treat COVID-19 patients, that is expected with a novel disease. Doctors and scientists quickly discovered other treatments, already determined

safe, were effective in treating COVID-19. Pfizer falsely represented to FDA that such treatments were still investigational, and not yet shown effective, when it knew otherwise. Moreover, Pfizer funded research groups to conduct flawed studies showing otherwise.

156. **Departure from scientific protocol.** Scientific protocols and requirements they followed are written into the requirements for clinical trials. Departure from the protocols renders the data useless. Pfizer knew that it did not follow protocols, and that the data therefore could not support its analysis and reports, but it submitted the data anyway to win EUA.

157. **Departure from ethics.** FDA regulations require that clinical trials used to win EUA and approval follow strict guidelines for the conduct of human experimentation. Failure to follow these guidelines renders the data unusable in clinical trials. Here, Pfizer knowingly violated rules and regulations about informed consent, including failing to provide information regarding potential harms, and failing to shut down the trials when the data showed the harm outweighed the benefits.

G. Pfizer's Clinical Trial Fraud Resulted in Objective Material Falsehoods

158. Pfizer's clinical trial fraud, as alleged here, resulted in objective falsehoods material to the EUA determination. This materiality is determined by the statute, which requires that FDA's decision to issue an EUA would be based on the totality of scientific evidence showing reason to believe that the known and potential benefits outweighed the known and potential harm. As contemplated in the statute, FDA relied on the statements and reports of the clinical trials in determining to grant EUAs.

159. The FDA was unaware of the fraudulent conduct and materially false representations made by Pfizer. Even when FDA was aware of, or approved, the clinical trial protocols, it was unaware of the fraudulent nature of the design, and/or the information known to Pfizer. Even after Relator and others raised issues over Pfizer's clinical trials, FDA regulators did not believe Pfizer had engaged in the fraud it had. Had Pfizer not engaged in the clinical trial fraud as alleged herein, it would not have obtained an EUA based on the totality of the scientific evidence and the objective facts showing that

the harm far outweighed any potential benefit. Had the United States learned that Pfizer had engaged in this misconduct, it would not have issued the EUAs and/or it would have withdrawn them sooner than it did. As stated by Principal Deputy Assistant Attorney General Ethan P. Davis in June 26, 2020: "We will vigorously pursue claims against companies and executives that knowingly create or relay false or manipulated data in connection with clinical trials."

VIII. EXAMPLE OF PFIZER'S CLINICAL TRIAL FRAUD

160. Pfizer's fraud was systemic. Ms. Jackson was correctly alleged Pfizer knew, but did not care, that its vaccines were ineffective and unsafe, and that these violations were not only occurring at Ventavia but were systemic.

161. Defendants' conduct in the clinical trial violated their own stated protocols, FDA regulations, and FAR, as described further below. Defendants fraudulently misrepresented their regulatory and protocol compliance to the United States which resulted in unreliable data submitted to the FDA. At the outset OWS the FDA stated that even under the lower standards of an EUA it would require data "from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner."[15]

162. On September 10, 1991, the FDA published its Application Integrity Policy (AIP) formally titled, "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy" (Federal Register, 56 FR 46191). The AIP described the Agency's approach regarding the review of applications that may be affected by wrongful acts that raise significant questions regarding data

[15]https://www.fda.gov/news-events/fda-brief/fda-brief-fda-issues-guidance-emergency-use-authorization-covid-19-vaccines.)

reliability. The AIP provides principles that define wrongful acts as those "that raise significant questions regarding data reliability."[16]

163. Because Ventavia only enrolled about 3%—approximately 1,500 of nearly 44,000—of the total clinical trial participants. One might think this contractor would not affect data integrity. However, with a data endpoint of 170 people, Ventavia's errors, plus demonstrated reckless monitoring by ICON and Pfizer of clinical trial sites, easily push the number of endpoints below statistical significance.

A. Relator's Background

164. Relator Brook Jackson ("Relator" or "Jackson") has worked in clinical trials for over eighteen years. She is a Clinical Research Auditor and Certified Clinical Research Professional. Before working for Defendant Ventavia Research Group, LLC ("Ventavia"), Jackson served as the Director of Operations for a multi-state clinical trial company. Second only to the CEO, she oversaw legal and regulatory compliance, adherence to good clinical practices, submission of required documentation, and business development across the company.

165. Because Relator's prior position required a great deal of travel, she decided to leave that company and begin working for Ventavia on September 8, 2020 as a Regional Director.

166. As Regional Director, Relator oversaw site managers, patient recruitment success, training completion, quality assurance completion, enforcement of communication paths, and growth plans at her assigned test sites. These duties included ensuring that Serious Adverse Event ("SAE") reports were timely submitted, and that her assigned sites created corrective action plans to address protocol deviations. Relator's job duties also included daily and weekly communication with the site operations managers of her assigned test sites and Ventavia's leadership team. Relator was responsible for the

[16]FDA APPLICATION INTEGRITY POLICY. 1998 Mar 5. at https://www.fda.gov/media/71236/download

duties above at two of Ventavia's three test sites for the clinical trial at issue, located in Fort Worth and Keller, Texas.

167. Relator's direct supervisor during her employment with Ventavia was Director of Operations Marnie Fisher ("Fisher"). Her other superiors were Ventavia's Executive Directors Olivia Ray ("Ray") and Kristie Raney ("Raney") and the Chief Operating Officer, Mercedes Livingston ("Livingston").

168. Ventavia retaliated against Relator in response to her reports of, and efforts to stop, fraud against the United States DoD resulting from the Pfizer-BioNTech COVID-19 vaccine trial.

B. Violations of Clinical Trial Protocol

169. Relator observed noncompliance with virtually every provision of the clinical trial protocol, as explained further below.

170. The cumulative violations of the clinical trial protocols resulted in a False Claims Act violation by causing the clinical trial to be neither "adequate" nor "well-controlled" resulting in data too unreliable to assess whether "the known and potential benefits of the product, when used to … treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable." 21 U.S. Code § 360bbb–3(c)(2)(B).

171. Without an EUA, the DoD would not have paid for the vaccines.

172. Furthermore, Defendants represented to the United States in FDA forms 1571 and 1572 that they would abide by the protocol. *See* Ex. 4, Form FDA-1571; Ex. 5, Form FDA-1572. Defendants' regulatory noncompliance also rendered Pfizer's later claims for payment fraudulent.

1. Inclusion and Exclusion Criteria

173. Ventavia enrolled and injected ineligible clinical trial participants.

174. Pregnant women are ineligible, and the trial protocol has multiple layers of safeguards to prevent administration of the vaccine or placebo to them. *See* Ex. 7, Clinical Trial Protocol, at 42, 44, 52, 65, 73, 86, 88, 132–35. Women of childbearing potential ("WOCBPs") and their partners must provide information about and use certain methods of contraception. *See* Ex. 7, at 44, 73, 86, 88, 132–35. WOCBPs also undergo a pregnancy test at every vaccination appointment during the trial, as previously noted.

175. Due to Ventavia's carelessness and rush to enroll and inject as many patients as possible, however, pregnant women appear to have been enrolled in the clinical trial and injected with the vaccine or placebo. *See* Ex. 12, E-mail Chain with Raney (Sept. 17, 2020), at 3, 5–6 (describing injection of pregnant patient after a positive pregnancy test). Ventavia did not report all clinical trial participants' pregnancies to Pfizer and Icon as required. *See* Ex. 7, at 67–68, 128 (required reporting protocol).

176. Women who have undergone a tubal ligation may still become pregnant.

The clinical trial protocol does not list tubal ligation as an accepted contraception method. *See* Ex. 7, at 134. Ventavia had to ensure that these women provided other contraception information and that pregnancy tests were administered before injection with BNT162b2 or placebo. Ventavia instead treated these women as non-WOCBPs, violating the clinical trial protocol. *See* Ex. 11, Ventavia's Quality Control Findings, at 3 (Subject 1018, seen at Keller site, had tubal ligation, but pregnancy test was not given). Ventavia's violations would be obvious from the source documents. Pfizer and Icon ignored these red flags and kept the ineligible participants' data in the clinical trial.

177. Ventavia's recklessness also resulted in other ineligible participants being enrolled and injected. The errors were not timely "caught" or corrected, due to Ventavia's recklessness and long-delayed "quality control" of source documents.

178. For example, Subject 11281302 was enrolled and injected before routine laboratory work and a nasal swab COVID-19 test. The subject did not give informed consent until after injection. If this subject was COVID-19 positive, that would have rendered him or her ineligible and the failure to obtain informed consent is itself a protocol, regulatory, and ethical violation. When "quality checking" this subject's documents, Ventavia edited a question about why injection preceded informed consent, transforming it into a comment that the informed consent time was incorrect:

VENTAVIA RESEARCH GROUP

Quality Assurance Checklist – Source Documents

Protocol: C4591001 Subject #: 11281302 Subject Initials: S-B

Visit	Page #	Finding	QCd by: (Init/Date)	Responsible Staff	Corrected by: (Init/Date)
		Random pg in chart	GL		
V1	3	Initial/Date note for Exc. #22	GL	TS	
V1	12	Ptuxs held for over 2 hours after dose?	GL	AS	
V1	9	Labs/Nasal collected after pt dosed?	GL	TS	
V1	9	Labs/nasal weren't collected until after dose but checked off prior to dosing	GL	NM	
V1	10	~~Why dose time prior to ICF?~~	GL		
V1	1	ICF time recorded incorrectly	GL	TS	

Ventavia subsequently would have "corrected" this patient's records to hide the informed consent and ineligibility violations, creating false source documents.

179. Relator also observed that Ventavia employees and their family members were enrolled in the clinical trial, in direct breach of the protocol, creating a serious conflict of interest.

2. Blinding

180. The clinical trial was to be observer-blinded. At each study site, only those administering the vaccine and placebo are unblinded. *See* Ex. 7, at 47–49. Thus, the only unblinded people at Ventavia's study sites should have been those vaccinating patients: Kandy Downs, Nadia Martinez, Jailyn Reyes, and Cordy Henslin. However, Ventavia's recklessness in product and document handling led to others becoming unblinded—including Relator, Fisher, and Fort Worth Site Operations Manager Jennifer "Jen" Vasilio. More people were likely unblinded since the conduct described below had the potential to unblind patients and anyone working at Ventavia's Fort Worth and Keller locations.

181. On September 16, 2020, Relator photographed BNT162b2 vaccine boxes left out in the open at Ventavia's Fort Worth location, and later sent her photos to management. These boxes were marked as such and bore numbers that allow determination of whether a patient received a placebo or the Pfizer-BioNTech vaccine. This type of unblinding incident had occurred before at least once. *See* Ex. 13, Unblinding E-mail Chain (Sept. 22, 2020), at 1 (describing a similar incident witnessed one month before by Downs). Neither unblinding was ever reported to Pfizer. Instead, Fisher directed Relator and others to discipline the responsible employees. *Id.*

182. On or around September 14, 2020, Ventavia discovered that randomization confirmation pages had improperly been placed in every patient's chart. These pages unblind the reader by revealing whether the patient received a placebo and had been in place since the beginning of Ventavia's involvement in the Pfizer-BioNTech trial. About 1,200 patients' charts were affected, compromising

the integrity of the trial. Ventavia subsequently removed or "lined through" (crossed out) this information, but it had been visible and accessible to all employees and patients for over two months. Ventavia did not report this issue to Pfizer or Icon, instead placing Notes to File ("NTFs") in patients' charts, dated September 17, 2020, and stating:

> This Note to File serves as notification that confirmation printouts of research participant drug assignments will not be placed within participant charts for study C4591001. Inclusion of the drug assignment confirmation will disclose drug dosage information contraindicated for study blinding. It is for this purpose that the confirmation of drug assignment is located in Complion within the unblinded binder. This note to file addresses IMPALA drug assignment confirmation requested in study source document versions 1 through 5.
> An update [to] the source document removing this requirement has been created in follow-up to this Note to File. Ex. 14, NTF on Randomization, at 1.

183. The NTFs are not viewable by Pfizer or Icon until the end of the clinical trial. The NTF on randomization does not show that patients and staff could have been unblinded; it simply states that randomization documents should not be in patients' charts. *See id.* However, Pfizer was alerted to the issue via a "red flag" e-mail chain from September 14–18, 2020, sent to Dr. Arturo Alfaro of Pfizer. Downs asked Alfaro to confirm that randomization forms should not be given to blinded staff, and Alfaro concurred. *See* Ex. 15, E-mail Chain with Downs and Alfaro, at 1–2. Pfizer should have realized that Downs' inquiry could indicate that the unblinding had occurred. To Relator's knowledge, Pfizer never followed up on the issue or removed affected patients' data from the clinical trial, resulting in fraud on the United States DoD.

184. Ventavia's unblinded vaccinators also carelessly forwarded and shared communications marked "UNBLINDING"—intended only for unblinded staff—to staff who should have been blinded. For example, on September 15, 2020, Recruitment Specialist Cordy Henslin forwarded such an e-mail to Relator. Ex. 16, E-mail Chain with Henslin, at 1. The e-mail was originally sent by Icon to Henslin, and had subject numbers, placebo dosing information, and other data that unblinded Relator. *See* Ex. 16, at 1–4.

185. During her employment, Relator observed that the Pfizer-BioNTech vaccine containers were stored in a way that could unblind Ventavia staff and patients. Specifically, the vaccines for all vaccine trials at Ventavia were stored together, and the vaccines for this trial were labeled with each patient's subject identification number after randomization. The vaccines are often left outside of cabinets while thawing, exposing that unblinding information to all in the vicinity. The vaccine preparation area is accessible by any staff member and even visible by patients—especially when patients were placed in hallways for "observation" after injection. To provide an illustration, if an employee was blinded for the trial at issue, but unblinded on another trial, she could see patients' IDs and drug assignment for the trial at issue every time she went to the vaccine preparation area—becoming unblinded.

186. When Relator joined Ventavia, she was given lists of action items that predated her employment. Based on that documentation, inadvertent unblinding was also an issue at Ventavia's Keller location.

187. The above conduct constituted reportable violations of the clinical trial protocol which compromised the integrity of the entire study and should have been reported to Pfizer and Icon, per the protocol. *See* Ex. 7, at 54–55, 116. However, when Relator reported unblinding concerns to Ventavia management, for example, she was instructed to "write up" Fort Worth's vaccinators for discipline. Management seemed more concerned with punishing employees than investigating the extent of the unblinding. Unblinding incidents were never reported to Pfizer during Relator's employment and were documented only in NTFs.

188. Maintaining blinding in clinical trials is critical for data integrity due to the observer effect. So Ventavia had to inform Pfizer when any potential unblinding could have occurred.

189. Instead of reporting potential unblinding of incidents, Ventavia used NTF to conceal them, including the massive unblinding event that affected about 1200 patient charts.

190. This unblinding was in place from the beginning of Ventavia's clinical trial and lasted 2 months, allowing anyone who looked at the patient's chart to be unblinded by the randomization confirmation pages placed in their charts. This information would have been accessible by all employees and patients from the start, rendering all subsequent data from those participants invalid.

191. Although the NTF were not accessible to Pfizer or Icon until the end of the clinical trial which was at least two years out, Pfizer should have been aware of this unblinding event from the "red flag" email between Downs and Alfaro.

192. Furthermore, Ventavia used NTF to conceal that they were not properly tracking when clinical trial participants developed symptoms of COVID-19 from the start of the trial until September 24th. This corresponds to the same time frame that anyone looking into a patient's chart would see the randomization confirmation pages inserted in their charts. This led to a situation where both employees and patients could be unblinded with poor symptom tracking and under-reporting of COVID-19 symptoms, particularly in individuals who were given BNT162b2.

3. Temperature Control

193. Ventavia, in violation of temperature control requirements in the clinical trial protocol and product manual, did not report all temperature excursions to Pfizer and did not always properly segregate vaccines affected by excursions.

194. For example, around September 11, 2020, a freezer at Ventavia's Keller location was unplugged and moved, resulting in a temperature excursion. The excursion was reported to Pfizer late, in violation of the protocol's requirement that excursions be reported as soon as discovered. The Fort Worth site also had unreported temperature excursions.

4. Informed Consent

195. Ventavia performed screening and injected clinical trial patients before obtaining informed consent, in direct violation of the clinical trial protocol. *See* Ex. 7, at 54, 117.

196. For example, on July 30, 2020, Ventavia recorded the same informed consent and vital sign collection times for Subject 1001 at Keller—an impossibility. Ex. 11, Ventavia's Quality Control Findings, at 1 ("[informed consent form] time same as [vital signs] Rest"). Relator observed this often was due to vital signs being taken during or before the informed consent process. She also observed that the issue was often corrected during "quality control" by falsifying the time of vital signs to several minutes after informed consent. This is likely what was done to "correct" Subject 11281001's source documents. Similar issues were observed for the following clinical trial participants, and were likely corrected via falsification:

Subject Number	Site	Visit Type	Date of Visit	Reflected in
1004	Keller	Eligibility Screening	July 30, 2020	Ex. 11, at 1
1007	Keller	Eligibility Screening	July 30, 2020	Ex. 11, at 2
1010	Keller	Unspecified	July 30, 2020	Ex. 11, at 2
1011	Keller	Unspecified	July 30, 2020	Ex. 11, at 2
1013	Keller	Unspecified	July 30, 2020	Ex. 11, at 2
1083	Keller	Unspecified	Aug. 11, 2020	Ex. 11, at 5
1087	Keller	Unspecified	Aug. 11, 2020	Ex. 11, at 5
1088	Keller	Unspecified	Aug. 12, 2020	Ex. 11, at 5
1090	Keller	Unspecified	Aug. 12, 2020	Ex. 11, at 5
11281007	Fort Worth	First Injection	July 31, 2020	Ex. 11, at 12
11281010	Fort Worth	First Injection	July 31, 2020	Ex. 11, at 13
11281011	Fort Worth	First Injection	July 31, 2020	Ex. 11, at 13
11281012	Fort Worth	First Injection	July 31, 2020	Ex. 11, at 14

197. This issue was also observed as a recurring problem by Fisher on September 21, 2020. *See* Ex. 17, Fisher's List of Deficiencies, at 2–3 (describing ongoing informed consent timing errors and need for correction).

198. To give another example, on August 5, 2020, Subject 11281035's progress notes were written before execution of informed consent. *See* Ex. 11, Ventavia's Quality Control Findings, at 3.

199. A Ventavia-internal quality assurance checklist circulated by Livingston on September 22, 2020 documenting common documentation errors at Ventavia noted that the incorrect version of the informed consent form was often used, informed consent forms sometimes had "obvious mismatch[es]" in signatures (indicating possible forgery of patient signatures), and other problems. Ex. 18, Common Quality Assurance Findings Checklist, at 1.

200. Ventavia likely falsified informed consent times to hide these protocol deviations from Pfizer and Icon. However, Pfizer and Icon had access to the original source documents in many cases, imparting constructive knowledge of informed consent time discrepancies. *See* Ex. 19, E-mail Chain with Icon (Sept. 21, 2020), at 1, 3, 4–5 (noting informed consent date errors). Pfizer also received e-mails from Ventavia indicating past informed consent protocol violations. *See* Ex. 20, Informed Consent E-mail Chain with Alfaro and Others (Sept. 24, 2020). Had Pfizer reviewed data as required, it would have noticed this issue and removed these patients' data from the clinical trial, but it did not. Ventavia never reported its informed consent violations to the IRB overseeing the clinical trial.

5. Dose Preparation

201. Ventavia routinely rushed preparation of BNT162b2 frozen concentrate, in violation of the clinical trial protocol and resulting in potential unblinding of clinical trial participants. Livingston directed employees to hold the frozen concentrate in their hand to thaw it faster than the mandated thirty minutes. *See* Ex. 6, Product Manual, at 47, 53, 56, 72, 76; Ex. 9, E-mail Chain with Downs and Others, at 1–2, 4; Ex. 21, Daily Status Updates E-mail Chain, at 51–53. Ventavia did this to maximize the number of patients injected per day and their per-patient payments from Pfizer.

202. Ventavia also used an outdated product manual that set a thaw time of twenty, rather than thirty minutes. *See* Ex. 9, at 4. Pfizer notified Ventavia of this in August of 2020, and was placed on notice that Ventavia was likely deviating from thaw time protocols. *See id.* The issue persisted, however. On September 21, 2020, Fisher listed injection wait times of less than thirty minutes as a consistent issue, finally suggesting protocol deviation reporting and resolution with an NTF. *See* Ex. 17, Fisher's List of Deficiencies, at 2. However, to Relator's knowledge, Pfizer never removed the affected patients' data from the clinical trial.

6. Administration

203. Ventavia, in violation of the clinical trial protocol, used improperly trained vaccinators. Cordelia "Cordy" Henslin ("Henslin"), a medical assistant, was qualified to vaccinate but was trained over the telephone instead of in-person. And, that training did not occur until after Henslin had already started giving BNT162b2 to patients in the Pfizer-BioNTech trial.

204. Issues with Henslin were discussed via e-mail. Ray noted on August 28 that she was uncomfortable with Henslin being "the only unblinded vaccinator for this trial" at her site and asked for a more experienced person to give training. Ex. 21, Daily Status Updates E-mail Chain, at 29. Raney replied: "I actually feel like this was brought up a few weeks ago…that [Henslin] had no training and has very little oversight [because] she is the unblinded." Ex. 21, at 28. Raney expressed concern that "something bad is going to happen with" Henslin unless she was trained. Ex. 21, at 29. On August 31, 2020, Downs acknowledged via e-mail that Henslin had finally been trained but over the telephone, and only later "rechecked when onsite." Ex. 21, at 27.

205. Additionally, other vaccinators were unqualified to administer BNT162b2. Nadia Martinez, an office assistant at the Fort Worth site, who had no medical certifications or background, acted as an unblinded vaccinator in the Pfizer-BioNTech trial. *See* Ex. 22, E-mail Chain with Fisher, Raney, and

Others (Sept. 9, 2020), at 2. Ventavia was seeing so many patients that the qualified vaccinator at that site, Jailyn Reyes, could not perform all vaccinations. *See id.*; Ex. 23, E-mail Chain with Livingston, Vasilio, and Others, at 2 ("Nadia is now doing all the vaccines for the COVID trial, to eliminate this from Jailyn's plate, occasionally if Nadia is behind or not in office, then Jailyn will jump in to vaccinate").

206. Many clinical trial participants were given their second injection outside of the protocol-mandated nineteen to twenty-three day window. Relator and others reported this to Ventavia staff multiple times. *See, e.g.*, Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 1 (noting injection "OOW", meaning out of window); Ex. 2, E-mail Chain with Ray and Others (Sept. 23, 2020), at 1 (noting "visits that are out of window"); Ex. 18, Common Quality Assurance Findings Checklist, at 1. Ventavia never reported this violation to Pfizer or Icon, but it would have been obvious from the source documents. However, Pfizer and Icon, to Relator's knowledge, never removed these patients from the clinical trial data.

207. Multiple clinical trial participants were injected with the wrong needle size for their body weight and sex, in violation of the clinical trial protocol. For example, on August 7, 2020, Subject 11281072 was injected with the wrong size needle at Ventavia's Fort Worth site. *See* Ex. 11, Ventavia's Quality Control Findings, at 24. The same issue recurred for Subjects 11281054, 11281050, 11281047, 11281040, 11281039 at the Fort Worth site. *See* Ex. 11, at 21–24. Ventavia also did not record needle size for multiple participants, meaning that more patients could also have been injected with the wrong needle size. *See* Ex. 11, at 17, 19, 20, 24. If this issue was not concealed via needle size falsification by Ventavia, then Pfizer and Icon had constructive notice of it via the source documents and violated regulations by not removing these patients from the clinical trial data.

208. Ventavia also improperly diluted the concentrated BNT162b2 vaccine and did not document that failure. At least four times, Ventavia employees used too much sodium chloride solution for dilution (1.7 mL versus 1.2 mL). Defendant Icon noticed the issue and informed Ventavia. Ventavia falsely told Icon that the discrepancy was due to a transcription error. See Ex. 16, E-mail Chain with Henslin (Sept. 15, 2020), at 2.

7. Safety and Patient Monitoring

209. In violation of the clinical trial protocol, clinical trial participants were not monitored under medical supervision for thirty minutes after injection. *See* Ex. 6, Product Manual, at 44, 61; Ex. 7, Clinical Trial Protocol, at 50. Ventavia's Fort Worth site, for example, had only five examination rooms. To see as many patients as possible per day, patients were instructed to wait in a hallway for thirty minutes after injection. A Ventavia receptionist or non-medically qualified employee periodically "checked on" the patients and asked if they were "OK." This does not rise to the level of thirty minutes of "medical supervision" required by the protocol. Ex. 7, Clinical Trial Protocol, at 50; *see also* Ex. 6, at 44. Furthermore, the period of supervision was often less than thirty minutes. *See* Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 1.

210. Ventavia's lack of patient monitoring was reported to management by Relator and by multiple employees and acknowledged as a recurring issue. *See, e.g.*, Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 1; Ex. 24, Mercedes Livingston's List of Common Errors (Sept. 22, 2020), at 2. Pfizer was put on notice of Ventavia's patient monitoring violations by Relator in an anonymous post-termination telephone call to Dr. Arturo Alfaro.

211. In a September 22, 2020 list of common errors in documentation and protocol compliance, Director of Operations Mercedes Livingston acknowledged that "Patients['] location during 30 minute

waiting period" after injection was an issue, and that she would train employees accordingly. Ex. 24, at 2. Livingston instructed employees:

- Be in the waiting area where **the receptionist** can see the patients
- If in the hallway, a staff member needs to be in the hallway with a work station
- Patients need to be brought back into a room for 30-minute post observation period.

Ex. 24, at 2 (emphasis added). Relator observed that Ventavia's monitoring practices did not change despite Livingston's stated plan, and that non-medical staff were still performing "observation."

212. Ventavia management perceived its patient monitoring practices as sufficient and questioned whether patient safety was really at risk. As Jones and Fisher told Relator at a September 24, 2020 meeting:

> BROOK JACKSON: **Okay, if we're gonna talk about just the safety, the safety of the patient component, they know that they don't have the rooms to manage the number of patients** [for] their recruitment goals that they're putting for these sites.
>
> MARNIE [FISHER]: That's –
>
> WILLIAM JONES: So what would be your recommendation? As the expert?
> BROOK JACKSON: As the expert – you just –
> MARNIE [FISHER]: Hold that thought. And, **what are you seeing that has led to that's a safety issue –** . . . That you've seen, that's gonna be a [FDA] warning letter? That's what I mean. That detail. So we can target –
>
> **BROOK JACKSON:** But nobody would ever know if we were putting patients in the hallway and they weren't being monitored. **But –**
>
> MARNIE: **But they are, they are being checked on.** See that's what I mean, like, they are.
>
> BROOK JACKSON: **Marnie, no, they're not.**
>
> MARNIE: **They are! Because I see them out there. When I'm coming and going, I'm seeing people out there all the time.** They are but, now, do we have it documented? That's where I would say, "Okay…" That's what I mean by go find – okay, that's a concern. Are we documenting it? Is it clear? So we can speak to that.

Ex. 3, Transcript of September 24, 2020 Meeting Recording, at 27–28 (emphasis added).

213. Ventavia also failed to report all adverse events and Serious Adverse Events ("SAEs") to Pfizer and Icon in the clinical trial at issue.

214. On September 17, for example, Raney e-mailed Relator, Ray, Downs, Fisher, and Livingston about issues with not reporting SAEs to Pfizer and Icon. *See* Ex. 12, E-mail Chain with Raney, at 1–2. Ventavia was actually paid by Pfizer per SAE reported, making the failure puzzling. *See* Ex. 12, at 1.

215. In a September 21, 2020 e-mail to Livingston, Downs, Relator, and Jones documenting ongoing issues, Fisher noted that adverse events "are not being reported correctly **or at all**[.]" Ex. 17, Fisher's List of Deficiencies, at 1 (emphasis added). Fisher claimed that the problem was due to conflicting information from Pfizer but emphasized that Ventavia "should follow the protocol as to how we read it and record any [adverse events] ASAP[.]" Ex. 17, at 1.

216. Pfizer and Icon had constructive notice because they had access to clinical trial participants' "electronic diary" entries, which recorded any symptoms experienced after vaccination. Pfizer and Icon could have seen that Ventavia was not reporting all these diary entries as adverse events, as required.

8. Accuracy and Completeness of Data

217. Ventavia maintained careless and sloppy documentation practices during the Pfizer-BioNTech trial, violating the clinical trial protocol's requirement that sites maintain accurate source documents supporting all information submitted to Pfizer, and verify the accuracy of all data entry. *See* Ex. 7, Clinical Trial Protocol, at 119–21. Ventavia even falsified some patient data to cover protocol violations or missing data. Pfizer and Icon, despite obvious warning signs of documentation failures in the source documents and its communications with Ventavia, turned a blind eye to the fraud and, to Relator's knowledge, did not remove affected patients' data from the clinical trial. By doing so, Pfizer

and Icon violated their responsibility to quality check all study data. *See* Ex. 7, Clinical Trial Protocol, at 120.

218. Ventavia's over-enrollment of patients and rush to see as many as possible per week took its toll on documentation. Data was often missing, and as previously mentioned, ineligible patients were sometimes enrolled and injected. *See, e.g.*, Ex. 2, E-mail Chain with Ray and Others (Sept. 23, 2020), at 1 (reporting "missing charts" to Ventavia management).

219. Ventavia's most egregious data and documentation failure relates to blood samples. Patients' blood is used to establish a baseline before injection with the vaccine or placebo. Any failure in timely processing or recording data from the first sample affects the baseline, which could hide subsequent changes (and possible side effects) of the vaccine that could be slow to develop. For example, white blood cell counts are a key metric and a defective baseline would affect future readings. Furthermore, blood is used to measure immune response, in other words, whether the vaccine actually works against COVID-19. Any errors in blood draw data or processing go to the heart of the clinical trial—effectiveness of BNT162b2.

220. An example blood draw log from Ventavia's Fort Worth location is attached as Exhibit 25. The document shows egregious data falsification and blood processing failures that call into question the validity of all Ventavia patients' data for the clinical trial. The document reveals:

- The time that plasma samples were frozen was changed to hide delayed freezing. *See* Ex. 25, Blood Draw Data, at 1. Freeze times are completely missing for some subjects. *See* Ex. 25, at 5, 10, 18.
- The time of centrifuge insertion was changed to disguise noncompliance with required clotting times (at least thirty minutes), required centrifuge times (at least fifteen minutes), or processing delays. *See* Ex. 25, at 4, 7, 18.
- One patient's blood did not clot, but a clot time was recorded anyway. *See* Ex. 25, at 4.
- No clot time or centrifuge insertion time was recorded for some patients. *See* Ex. 25, at 7, 8, 18.
- Blood draw times are missing for some patients. *See* Ex. 25, at 15, 18, 19, 20.
- A clot time of 309 minutes is listed for Subject 11281013 at a post-injection monitoring visit (visit 3). Ex. 25, at 1. Per Relator, the responsible employee left the lab and the blood sample sat unattended, resulting in a very long clot time being recorded. The

patient should have been brought back to Ventavia for a re-draw, but that was never done.

- Clot times of exactly thirty minutes are recorded for "strings" of over twenty patients in a row—a strong indicator of falsified data. *See* Ex. 25, at 13–18, 24–28

221. The above violations are so obvious from the source documents that Pfizer and Icon had constructive notice of Ventavia's fraud. Icon also directly questioned missing blood collection and processing times on September 21, 2020 in an e-mail to Fisher, Downs, Relator, and others. *See* Ex. 19, E-mail Chain with Icon, at 1. Yet, to Relator's knowledge, Pfizer and Icon never removed affected patients from the clinical trial data.

222. Ventavia "quality checked" patients' source documents after seeing each patient, to make sure information was consistent with protocol, was not omitted, and matched up with electronically entered information. However, due to Ventavia's push to maximize enrollment and consequent revenue, "quality control" quickly fell behind its scheduled twenty-four-hour window.

223. Ventavia eventually brought in employees' friends and family members on weekends to help "catch up" on quality control. These temporary employees were not listed on delegation logs. Some of the temporary employees were also clinical trial participants—a serious conflict of interest.

224. Relator observed that quality control staff were not fixing deficiencies in documentation. She personally saw employees change data during "quality checking." For example, in late September of 2020, she saw employee Thea Sonnier ("Sonnier") change blood pressure readings in source documents, apparently fabricating new numbers. Sonnier was one of the lead employees for "quality checking" and her practices would have been followed by other employees at Ventavia.

225. Ventavia management was aware of serious documentation issues—including falsification of data—as far back as August 13, 2020. On that day, Fisher sent a company-wide e- mail emphasizing the importance of filling out source documents "real-time." Ex. 26, Source Documentation E-mail Chain, at 1. Fisher noted that if data was completed after-the-fact:

> the time has passed so data or assessments have been forgotten, source may already have been scanned in, signatures were missed[,] and now the investigator is not available to sign. **This results in deviations, queries, and overall will jeopardize the integrity of the data** and ultimately our reputation and future access to studies and thus revenue coming in.

Ex. 26, at 2 (emphasis added). Still, falsification of data and incomplete documentation persisted at Ventavia, and was never completely remedied. One month later, Fisher forwarded her August 13 e-mail to Downs and Relator, noting that sites were still falling behind on documentation. *See* Ex. 26, at 1.

226. Ventavia also failed to document improper dilution of the frozen BNT162b2 vaccine concentrate. Defendant Icon noticed the issue and informed Ventavia. Ventavia falsely told Icon that the discrepancy was due to a transcription error. See Ex. 16, E-mail Chain with Henslin (Sept. 15, 2020), at 2.

227. For months, Ventavia sites did not properly track when clinical trial participants developed symptoms of COVID-19. Ventavia created a symptom log in August, but no sites used it until Downs circulated the log on September 24, 2020. *See* Ex. 27, Symptom Log E-mail Chain and Attachment (Sept. 24, 2020), at 1. The issue was documented in an NTF but Pfizer and Icon were not notified. Still, Pfizer knew of this failure via the NTF, and should have excluded affected patients from its trial data.

9. Adherence to Protocol

228. Defendants had to adhere to Pfizer's clinical trial protocol but did not. In addition to the protocol violations listed *supra*, Defendants also violated the clinical trial protocol in many ways.

229. Ventavia did not consistently use up-to-date versions of the clinical trial protocol or BNT162b2 product manual as they were required to. *See* Ex. 9, E-mail Chain with Downs and Others, at 4; Ex. 17, Marnie Fisher's List of Deficiencies (Sept. 21, 2020), at 1.

230. Clinical trial participants were, per the protocol, to be examined/enrolled one at a time. Ventavia, however, cancelled single patients' appointments in favor of married couples or groups of friends who sought to participate in the trial. *See* Ex. 28, List of Action Items, at 14. In Ventavia's view, groups could be scheduled and seen at the same time, maximizing the number of patients (and Ventavia's payments) per day. However, seeing groups could unblind patients, could violate privacy laws, and violated the clinical trial's 1:1 randomization protocol. This practice would be apparent to Pfizer and Icon from overlapping times in the source documents. Pfizer and Icon thus ignored obvious red flags of noncompliance.

231. Ventavia also did not maintain adequate principal investigator oversight. Dr. Mark Koch, the principal investigator at Ventavia's Fort Worth location, signed records for patients he did not personally or adequately examine. Sub-investigator physicians or other medical staff examined patients instead, and Dr. Koch "signed off" on the records. This issue was noted, for example, during a "quality check" of Subject 11281278's first injection visit at Ventavia's Fort Worth site, but never reported to Pfizer or Icon:

V1	13	Why did PI sign	JR		
		when Dr. E saw the			
		pt?			

The document signed by Dr. Koch is a false record because he did not actually examine the patient. The same issue affected Subject 11281378's first injection visit as well:

V1	14	Why did PI sign	JR	LBL	
		when Dr. E saw pt?			

232. To provide another example, no principal investigator signed records of Subject 1031's screening visit on August 5, 2020. *See* Ex. 11, Ventavia's Quality Control Findings, at 3. Per Relator, this indicates there was no principal investigator oversight for that subject's visit.

233. This issue occurred because Ventavia was seeing too many clinical trial participants per day. Principal investigator and sub-investigator physicians had their own medical practices to oversee and could not stay at Ventavia test sites all day. Some investigator physicians even went back and forth from their own offices to Ventavia multiple times per day.

234. The Houston site's principal investigator, Dr. Van Tran, wanted to close his medical practice during certain times, effectively setting aside scheduled "blocks" to examine clinical trial participants at Ventavia. On August 15, 2020, Raney told Downs, Ray, Fisher, Livingston, and another employee that Dr. Tran's plan was not acceptable because the Houston site could not "hit" its cap of forty patients per week, maximizing its payments from Pfizer. *See* Ex. 21, Daily Status Updates E-mail Chain, at 55–56. Raney wrote:

> I understand that [Dr.] Tran had a different plan due to his patients and practice, but we can't allow that kind of stuff to impact a high-enrolling study. I know you brought this up on our call last week, but I didn't fully grasp the impact. In the future, if you need to detour off of my recruitment guidance, I need you to seek approval first before you agree or put anything into action. You brought the detour up really quickly on our call and it was already in place when you told me about it, so it was a little too late for me to say no (though I now realize I should have). The direction was to see the 40 patients within the first 2.5 days...so that when Pfizer did increase their [weekly] cap, we'd be the first ones approved for additional drug[s] (and I did clearly explain my strategy and the rationale behind it when I gave my direction). And now, Pfizer is planning to increase their drug and [Houston] didn't hit their 40 in the first week. Honestly, that's unacceptable. I need you to figure out how 9 patients will be randomized on Monday.Ex. 21, at 56.

Raney's directive exemplifies the focus on quick enrollment over protocol compliance and could have resulted in inadequate oversight by Dr. Tran at the Houston site.

235. Ventavia also did not report many clinical trial protocol deviations to Pfizer and Icon. The issues, as noted, were often buried in "notes to the file" if they were reported at all. Fisher

acknowledged this as an ongoing issue on September 21, 2020, noting that she was "not sure" if deviation reports were "getting completed or not[.]" Ex. 17, Fisher's List of Deficiencies, at 3.

10. Privacy Law Compliance

236. Defendant Ventavia's Fort Worth location mishandled clinical trial participants' protected health information, in violation of the Health Insurance Portability and Accountability Act ("HIPAA") and clinical trial protocol.

237. For example, on September 16, 2020, Relator observed that a wall calendar posted near a reception area visible to all staff and patients had patients' names, phone numbers, and health information (as a method of reminding staff to follow up with patients). Both medical and non-medical staff could see this information. That same day, Relator also observed that patient files had been left out unattended in an area where they were visible to non-medical staff.

238. On September 21, Fisher documented common findings during document "quality checking" and noted that Ventavia's test sites were inconsistent in safeguarding patients' protected health information, describing, for example, "patient folders out on counters in the clinic and face[] up with names visible[.]" Ex. 17, Fisher's List of Deficiencies (Sept. 21, 2020), at 1.

239. Ventavia employees at all three test sites regularly used the smartphone and computer application "Slack" for communication, including patients' names and identification numbers. Slack is not secure or HIPAA-compliant. Ventavia's HIPAA violations violate the clinical trial protocol, which requires compliance with all "applicable privacy laws." Ex. 7, at 116.

C. Violation of FDA Regulations

240. Defendants' clinical trial also violated FDA regulations, as explained further below.

As noted previously, Icon and Ventavia are bound by FDA regulations to the same extent and degree as Pfizer. *See* 21 C.F.R. §§ 312.50, 312.52, 312.56; Ex. 7, at 116.

241. Defendants violated FDA regulations regarding IRB oversight and reporting when they failed to report additional clinical trial participant compensation, failure to follow clinical trial protocols, and informed consent violations to the clinical trial's IRB. *See* 21 C.F.R. §§ 312.66, 312.53(c).

242. Defendants violated FDA regulations when they failed to investigate and report all adverse event information received in the clinical trial, and failed to notify the FDA of all potential serious risks and adverse reactions. *See* 21 C.F.R. §§ 312.32, 312.50. Defendants Ventavia and Icon violated 21 C.F.R. § 312.64(b) when they failed to immediately report all adverse events to Pfizer.

243. Defendant Pfizer violated 21 C.F.R. § 312.50 and 21 C.F.R. § 312.56 when it failed to properly oversee Defendants Ventavia and Icon and failed to ensure that they followed the clinical trial protocol.

244. Defendants Pfizer and Icon also violated FDA regulations when they learned of Defendant Ventavia's regulatory and protocol violations and elected not to "promptly . . . secure compliance" or "discontinue shipments of [BNT162b2] and end [Ventavia's] participation" in the clinical trial. 21 C.F.R. § 312.56(b).

245. Ventavia and Icon violated 21 C.F.R. § 312.64 by failing to furnish all required reports to Pfizer, including but not limited to reports of adverse events, temperature excursions, and clinical trial protocol deviations.

246. Defendant Ventavia violated 21 C.F.R. § 312.62 by failing to maintain adequate and accurate records of BNT162b2 dispensation and clinical trial participants' case histories.

247. Defendants violated FDA regulations by failing to obtain and document informed consent for every patient before clinical trial participation. *See* 21 C.F.R. §§ 50.27(a), 312.60, 312.62(b).

248. Defendant Ventavia violated FDA regulations by giving BNT162b2 to subjects not under the personal supervision of the principal investigators or sub-investigators at its clinical trial sites. *See* 21 C.F.R. § 312.61.

249. Defendant Ventavia violated 21 C.F.R. § 312.61 by administering BNT162b2 to ineligible clinical trial participants and to Ventavia employees and their family members.

250. Defendants' violations of FDA regulations violate the clinical trial protocol as well. *See* Ex. 7, Clinical Trial Protocol, at 116 (requiring compliance with all applicable laws and regulations).

251. Defendants' violations of FDA regulations rendered their certifications and representations of compliance in Pfizer's claims for payment, the clinical trial protocol, Form FDA-1571, and Form FDA-1572 false.

D. Violation of FAR

252. As previously noted, Defendant Pfizer must comply with FAR. Defendant Pfizer did not maintain due diligence to detect and did not disclose Defendants' violations of the False Claims Act to DoD. Defendant Pfizer has breached its contract with DoD and violated federal regulations. *See* 48 C.F.R. § 52.023-13.

253. Additionally, Pfizer did not monitor its subcontractors, Icon and Ventavia, as it had to do under FAR 42-202(e)(2). *See* 48 C.F.R. § 42-202(e)(2).

E. Ongoing Monitoring Concerns

254. Enrollment in the trial has closed and only required ongoing patient monitoring is still taking place. The fraud alleged also affects this ongoing monitoring. Due to Defendants' aforementioned fraudulent practices, data from ongoing monitoring (including possible new adverse events) may be falsified or concealed, preventing material information about BNT162b2 from reaching the United States.

F. Safety and Ethical Issues

255. Relator observed fundamental safety risks to study participants and Ventavia employees, over and above those which violate the clinical trial protocol. She also saw breaches of ethical standards required in clinical trials.

256. On September 16, Relator observed used needles placed in biohazard bags instead of sharps containers. The bags are not puncture-proof, so Ventavia employees were directly put at risk of injury or infection during bag handling and disposal.

257. Ventavia internally requires every patient's chart to have dosage ranges for epinephrine based on weight, age, and other factors. Epinephrine is used to counter anaphylaxis if a patient reacts allergically to a vaccine. Relator observed and reported to Ventavia management that the protocol was not being followed. The deficiency could lead staff to incorrectly guess the correct epinephrine dosage in an emergency, putting patients' safety and lives at risk. Relator reported this issue to Ventavia supervisors verbally and via e-mail, including on September 23 and 24, 2020. The issue was not remedied, to Relator's knowledge.

258. To adhere to industry-standard "Good Clinical Practices," Ventavia trial site employees had to undergo training in biologics handling, occupational safety and health, and other areas. Relator strove to make sure all employees underwent and reported their training, but was terminated before this task was complete. To Relator's knowledge, Ventavia never provided all employees with all required training.

259. Ventavia and other trial sites for the Pfizer-BioNTech trial must get IRB approval for all compensation paid to clinical trial participants. Ventavia, however, routinely gave participants gift cards as a "customer service" initiative, to apologize for long patient wait times. For example, on August 17, 2020, Ray directed Fisher and Downs as follows:

> Let your [Site Operations Managers] know that sometimes we need to use kindness to deal with difficult patients (purchase lunch, a coffee, small gift card, apologize, etc.) Make it right when they are in the office, **don't wait until they leave upset and go write reviews or report us to the IRB, FDA.** Customer service is everything. Ex. 28, List of Action Items, at 13 (emphasis added).

Providing gift cards to clinical trial participants is additional patient compensation not approved by the IRB and breaches ethical obligations.

260. Ventavia reported none of the above misconduct to the IRB or Pfizer.

IX. RETALIATION AGAINST RELATOR

261. Defendant Ventavia Research Group, LLC ("Ventavia") retaliated against Relator in response to her reports of, and efforts to stop, Defendants' fraud against the United States DoD.

262. Relator began working at Ventavia on September 8, 2020 as a Regional Director.

263. Relator was responsible for the duties above at two of Ventavia's three test sites for the clinical trial at issue, in Fort Worth and Keller, Texas. The third site, in Houston, was overseen by another Regional Director and managed by Lovica "Kandy" Downs. The Fort Worth site was managed by Jennifer Vasilio and the Keller site was managed by Katie Benitez.

264. The principal investigators for the three sites are medical doctors: Mark Koch, M.D. ("Dr. Koch") in Fort Worth, Gregory Fuller, M.D. in Keller, and Van Tran, M.D. in Houston. The doctors are not employees of Ventavia; they serve as principal investigators in addition to practicing medicine elsewhere. Ventavia and the principal investigators were paid by Pfizer for supervision of the study on a per-patient basis, with more funds paid per SAE reported and for activities such as training.

265. Relator's direct supervisor during her employment with Ventavia was Director of Operations Marnie Fisher ("Fisher"). Her other superiors were Ventavia's Executive Directors Olivia Ray ("Ray") and Kristie Raney ("Raney") and the Chief Operating Officer, Mercedes Livingston ("Livingston").

Relator begins her efforts to stop fraud on the United States Department of Defense.

266. Beginning on September 8, 2020, Relator reported on a near-daily basis to Fisher and Livingston that patient safety and the integrity of the Pfizer-BioNTech vaccine trial was at risk, via telephone, conversation, and e-mail. Relator discussed virtually all of the clinical trial protocol and FDA regulatory violations she witnessed with Livingston, Raney, and Fisher, including, but not limited to: (1) enrollment and injection of ineligible trial participants; (2) falsification of data, poor recordkeeping, and the deficiency of Ventavia's documentation "quality control"; (3) deficiencies in

and failure to obtain informed consent from trial participants; (4) adverse event and SAE capture and reporting; (5) failure to preserve blinding; (6) vaccine dilution errors; (7) failure to list all staff on delegation logs; (8) principal investigator oversight; (9) reporting temperature excursions; (10) patient safety issues, such as not keeping epinephrine dose information in patient charts; (11) failure to secure and record staff training required by clinical research standards; (12) use of unqualified staff as vaccinators; (13) use of biohazard bags for needle disposal; and (14) failure to properly monitor patients post-injection.

267. Every time that Relator raised concerns about safety or Ventavia's clinical trial protocol compliance with Fisher, she was told to e-mail Fisher about the issue or make a list of affected patients. Many of the identified issues were systemic, and Relator did not have access to information required to make the lists Fisher requested. Relator did as Fisher requested to the extent that she was able, but the identified problems were never addressed. *See* Ex. 3, Transcript of Sept. 24 Meeting (discussing, in part, Relator's prior reports of protocol violations).

268. Relator also reported some clinical trial protocol violations to the Fort Worth Principal Investigator, Dr. Koch. In particular, Relator discussed Ventavia's practice of "quality checking" patient source documents long after the fact and issues of missing documentation. Dr. Koch acknowledged that Ventavia needed to "clean up" the problems before starting any new clinical trials.

269. Ventavia was required to scan or enter all data from clinical trial participants' source documents into the "Complion" Clinical Trial Management System Database, so that it could be passed on to Icon and Pfizer. Ventavia "quality checked" all source documents before scanning or uploading them. In Ventavia's scramble to enroll as many participants as possible per week and maximize revenue, quality checking and uploading fell behind schedule. Relator observed that the "back log" of documents to be quality checked often lacked key information, such as patient or doctor signatures and blood draw times. Relator also observed that Ventavia's quality checking process was performed by unqualified

staff not listed on delegation logs, and often involved falsification of missing data. Relator reported her concerns to Ventavia management, who seemed more concerned with "catching up" on quality checking than preventing fraud.

270. On September 15, 2020, Relator reported to Fisher that some patient charts had never been sent to Pfizer, were needed "urgently," and had not been quality checked. *See* Ex. 29, Text Messages with Fisher, at 1.

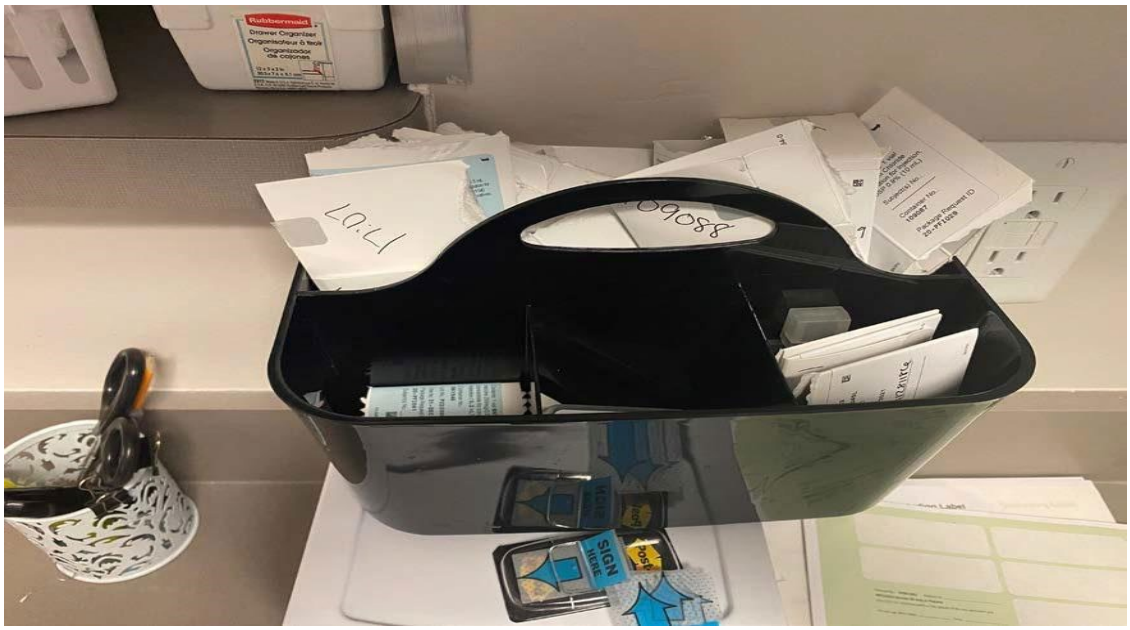
271. Relator called Ventavia's contact at Pfizer for the trial, Dr. Arturo Alfaro ("Dr. Alfaro") on September 14 and 16 to discuss protocol violations but could not reach him.

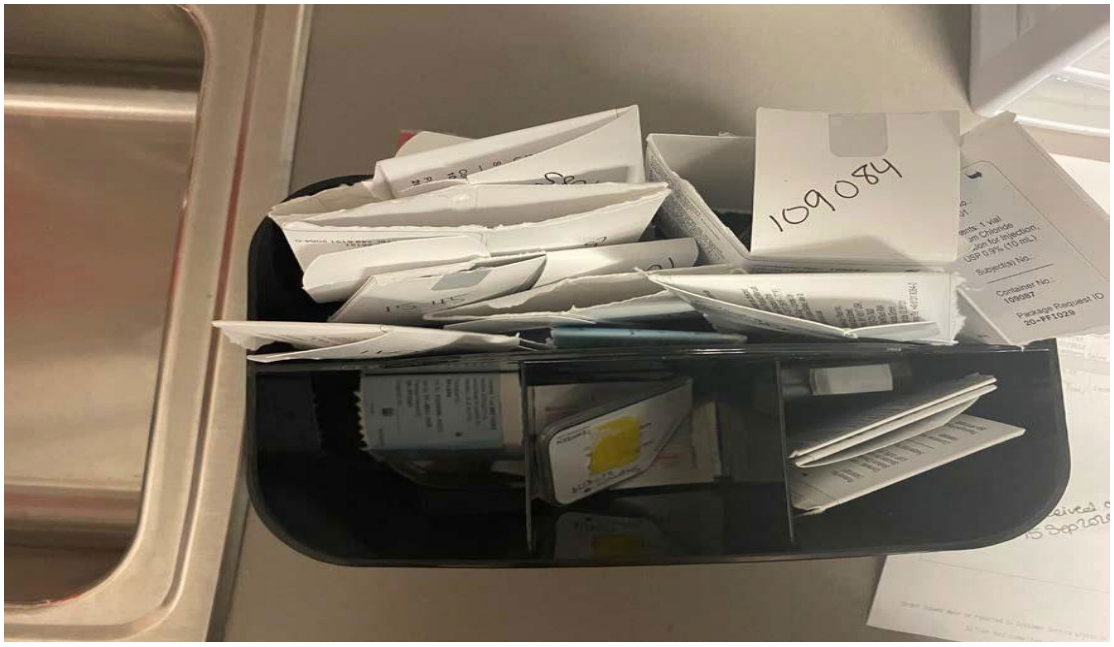
A. Relator photographs violations.

272. On September 16, 2020, Relator examined some of the biohazard disposal bags at Ventavia's Fort Worth site. She had been asked to monitor this issue because Ventavia was charged by weight for disposal of the bags, and non-biohazard items were sometimes improperly placed there. Relator discovered that used needles had been disposed of in the bags:

See also Ex. 3, Transcript of September 24 Meeting Recording, at 1–2. Biohazard bags are not puncture-proof, so this presented a serious risk to employees' safety.

273. That same night, Relator photographed ongoing HIPAA violations. Ventavia kept a calendar of patients to follow up with in public view in a reception area. The calendar had patients' names and information. Similarly, patient records were left out in public view. Relator also documented that product cartons and patient randomization numbers from the BioNTech- Pfizer vaccine trial had been left in public view in a preparation area, potentially unblinding all Ventavia staff at the site and some patients as well:





274. Relator shared her photographs from September 16 with Livingston and Fisher via text message or e-mail. The following day, she reported an identical biohazard bag issue at the Keller site to the same people.

B. Relator recommends pausing clinical trial enrollment.

275. On September 17, 2020, Relator spoke to Downs and Ventavia's Quality Control Director William Jones ("Jones") via telephone. Relator asked both for their opinion about what would happen if the FDA audited Ventavia. Both Downs and Jones responded the same way— afraid that Ventavia would receive warning letters or be asked to stop trial enrollment.

276. Later that day, in her daily phone call with Ray, Raney, Fisher, Downs, and Livingston, Relator brought up virtually all of the protocol and regulatory violations she had seen to date and Ventavia's HIPAA violations. Relator explained that the FDA would likely issue warning letters against Ventavia if it visited or audited the trial sites. She recommended that Ventavia immediately stop enrollment in the Pfizer-BioNTech clinical trial.

277. Ray directed Relator and others to conduct FDA trainings, to prepare for a possible future site visit or audit by the FDA. *See* Ex. 28, List of Action Items, at 1; Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 1. Ventavia also paused enrollment to catch up on "quality checking" source documents. *Id.*

278. Later, on September 17, Relator responded to a group text message including Ray, Downs, Raney, Livingston, and Fisher. *See* Ex. 1, at 2. First, Relator passed on the concerns of Fort Worth Site Operations Manager Jennifer Vasilio regarding documentation and patient observation protocol violations, patients being injected outside of the nineteen to twenty-three day "window," and HIPAA violations. Ex. 1, at 1. Second, Relator complained about Ventavia's "quality checking" (QC):

> I would like us to create a solid monitoring plan . . .
>
> I don't think it is as simple as pulling a chart and looking for missing check boxes or missing initial in a header/footer which I have been seeing a lot of when I have QC'd the QC'er.
> We need to be able to reconcile time of [vaccine] prep and admin[istration], for example. This cannot be done by everyone who is QC'ing to ensure we do maintain the blind. This is one reason I think we need to carefully consider what we are looking at especially if we are approaching this from the perspective of an FDA auditor, which I 100% think we should be. . . .
>
> I would have liked the opportunity to discuss this with [the principal investigators, Drs. Fuller and Koch] individually and I still would.

Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 2. The "reconcil[ing]" Relator discussed showed that vaccine preparation and administration times were not compliant with the clinical trial protocol. *Id.*

279. Ventavia shortly thereafter decided to pause enrollment in order to catch up on "quality checking" source documents. Ventavia was not up-front with Pfizer and Icon about the reasons for the enrollment pause (sloppy documentation that violated the clinical trial protocol). In a text message conversation on September 17, Raney instructed Ventavia employees how to respond to questions from Pfizer about the pause. She told them to "make it like it's no big deal" and that the pause resulted from Ventavia was "being responsible by considering we have a certain bandwidth and these visits on top [of] each other has hit our bandwidth." Ex. 1, at 10. Raney also directed employees to falsely tell patients that Ventavia was not enrolling because "we met our company capacity[.]" Ex. 1, at 6. Ventavia was also not up-front with its Houston principal investigator, Dr. Van Tran, regarding the reason for the pause. Downs was directed to convey to Dr. Tran that the pause was due to Ventavia being "at capacity" and not wanting "to overd[o] it." Ex. 1, at 9.

280. Ventavia ultimately elected to schedule patients for several weeks later rather than truly pause enrollment. *See* Ex. 1, at 6, 9–10. Raney directed employees not to cancel any patients already "on

their way" to test sites because "that might piss them off and they can call the news, etc[.]" Ex. 1, at 11. Livingston responded, "if [patients] were scheduled far enough out[,] cancel[,] but if they are there then see them." *Id.* Downs responded that she would not cancel patients in Houston. *See id.*

281. During the enrollment pause, Ventavia's "quality checking" not only failed to correct documentation violations but also involved falsification of missing or inconsistent data. Ventavia hired employees' friends and family members on a temporary basis to perform quality checking who were not adequately trained. Relator even personally observed employees falsifying source document data (*i.e.*, by changing blood pressure readings). Relator also noticed that information was often completely obscured when changed, rather than "lining through" (which preserves legibility of the original text). In short, Ventavia's "quality checking" failed to prevent or stop fraud on the United States DoD.

282. On September 23, 2020, Relator e-mailed Ray, Fisher, Raney, Downs, Jones, Livingston, and Director of Quality Control William Jones ("Jones") to report ongoing serious issues with Ventavia's "quality checking." *See* Ex. 2, E-mail Chain with Ray and Others (Sept. 23, 2020). Relator noted, among other issues:

- There were 100 outstanding queries from Icon about missing or inconsistent data which were up to twenty-eight days old. *See* Ex. 2, at 1.
- Scheduling errors resulted in multiple patients receiving their second injection outside of the required nineteen to twenty-three day window. Ventavia was not truthfully recording the vaccine delay for these patients, and due to the oversight, Pfizer and Icon could not discover that these patients were vaccinated outside of the permissible window. *Id.*
- Quality checking caused large delays. Relator found a twenty-one-day-old patient chart that had not been entered into the Electronic Data Capture system to send to Icon and Pfizer. That information should have been entered within twenty-four hours. *Id.*
- Some patient charts and laboratory specimens were missing. *Id.*

Due to the seriousness of these violations, Relator noted that she "might be in a little bit of shock." Ex. 2, at 1.

283. On September 23, 2020, Relator e-mailed Livingston to report that Ventavia's emergency response protocol for allergic reactions was not being followed. Ventavia internally required every

patient's chart to contain appropriate dosage ranges (based on age, weight, etc.) for epinephrine in the event of anaphylaxis. The patients' charts did not contain this information. No action was taken to correct this during Relator's employment.

C. Ventavia management falsely accuses Relator of violating patient confidentiality.

284. On the evening of September 24, 2020, Relator met with Fisher and Jones. *See* Ex. 3, Transcript of September 24, 2020 Meeting Recording. The meeting was arranged to discuss Relator's photographic documentation of safety issues, HIPAA violations, and unblinding from September 16. The meeting quickly escalated into harassment. Fisher questioned repeatedly why Relator took the photographs and falsely accused Relator of removing patient source documents from another Ventavia location. *Id.*

285. Fisher reiterated her instructions to provide specific patient names which, as noted previously, was not always possible. *See* Ex. 3, at 4, 18, 20, 22. Fisher and Jones gave contradictory instructions, telling Relator to fix violations once identified but also noting that Ventavia cannot correct all violations, and has to pick and choose what to address. *See, e.g.*, Ex. 3, at 12, 15, 27. Jones stated that Ventavia had not "even finished quantifying the number of errors" because "it's something new every day." Ex. 3, at 12. He acknowledged that the problems were "not just in one site" either, and stated "we're gonna get some kind of letter of information at least, when the FDA gets here. Know it." *Id.*

286. When Relator discussed her unblinding documentation, Fisher seemed more concerned with punishing the employees responsible for the unblinding incident than preventing the issue in the future. *See* Ex. 3, at 2, 3; *see also* Ex. 13, Unblinding E-mail Chain (Sept. 22, 2020), at 1 (instructing employees to discipline those responsible for unblinding incident).

287. Relator specifically referenced FDA regulatory violations in her September 24 conversation with Fisher and Jones. *See* Ex. 3, Transcript of September 24, 2020 Meeting Recording, at 14. She told

Fisher and Jones that if they did not see what she saw when quality checking patients' source documents, then they needed to "get on Google" and search for FDA warning letters. Ex. 3, at 14.

288. Relator also reported to Fisher and Jones that Raney and Ray had acknowledged that Ventavia did not have the staff or patient room capacity to handle the number of clinical trial participants being seen every day. Ex. 3, at 15. Relator questioned whether Raney and Ray truly prioritized patient safety. *See id.* Fisher questioned whether placing patients in the hallway for "monitoring" after injection was actually a safety risk. *Id.*

289. Relator also discussed with Jones and Fisher that Downs had previously reported many of the same violations and safety risks that Relator had. *See* Ex. 3, at 21, 23–24. Fisher claimed that Ventavia addressed Downs' concerns, but clearly the same issues had recurred, or else Relator would not have spotted them. *See* Ex. 3, at 24.

D. Ventavia terminates Relator the next day.

290. The following morning, Relator called the FDA's hotline to report the clinical trial protocol violations and patient safety concerns she witnessed.

291. Relator was terminated from her position at Ventavia that same day—September 25, 2020 – under the pretext that she was "not a good fit." Relator was never formally disciplined or reported for any failure regarding her job performance until the day that she was terminated.Relator was harassed and terminated by Defendant Ventavia as a direct consequence of her reports of and efforts to stop fraud against the United States DoD.

292. After Relator was terminated, she called Ventavia's contact at Pfizer, Dr. Alfaro, and generally summarized her concerns about unblinding, principal investigator oversight, and patient safety in the Pfizer-BioNTech vaccine trial. She also informed Dr. Alfaro she had contacted the FDA. Relator did not identify herself or discuss any specific trial sites, concerned that doing so might adversely affect a future retaliation action.

293. Soon after her termination, the FDA contacted Relator and spoke to her for several hours regarding the violations she saw at Ventavia.

294. Right after Relator was terminated (the next business day), Ventavia lifted the enrollment "pause" and resumed the push to enroll as many clinical trial participants per week as possible. Given the amount of "quality control" left to be performed when Relator was terminated, Relator estimates that Ventavia had neither completed quality checking nor remedied its ongoing violations by the time it resumed enrollment.

295. Relator's termination is but one example of a pattern and practice of retaliatory terminations by Defendant Ventavia. Ventavia's prior Fort Worth Site Operations Manager Michelle Gaines was terminated in August of 2020 for reporting and trying to stop protocol noncompliance and regulatory violations in other clinical trials.

X. ACTIONABLE CONDUCT BY DEFENDANTS

A. False Claims Act

1. Applicable Law

301. This is an action to recover damages and civil penalties on behalf of the United States and Relator Jackson arising from the false and/or fraudulent statements, claims, and acts that Defendants made in violation of the False Claims Act, 31 U.S.C. §§ 3729–3732.

302. For conduct on or after May 20, 2009, the FCA provides, in relevant part, that any person who:

> (A) knowingly presents, or causes to be presented, a false and/or fraudulent claim for payment or approval; [or]
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false and/or fraudulent claim[,]

31 U.S.C. § 3729(a)(1), is liable to the United States for a civil penalty of not less than $11,665 and not more than the applicable regulatory maximum for each such claim, plus three times the amount of

damages sustained by the Government because of the false and/or fraudulent claim. *See* 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5.

303. The FCA defines "claim" as:

> (A) mean[ing] any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that--
>
> (i) is presented to an officer, employee, or agent of the United States; or
>
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--
>
> (I) provides or has provided any portion of the money or property requested or demanded; or will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded. . . .
>
> 31 U.S.C. §3729(b)(2).

304. The FCA allows any person knowing of a false and/or fraudulent claim against the Government to sue in federal district court for himself and for the United States, and to share in any recovery, as allowed by 31 U.S.C. § 3730.

305. Based on these provisions, Relator Jackson seeks damages and civil penalties arising from Defendants' violations of the False Claims Act.

2. Defendants' Violations of the False Claims Act

a. Fraud In The Inducement

306. Pfizer induced the contract by promising a particular deliverable: a safe, effective, vaccine, for the prevention of COVID-19 at speed and scale. When Pfizer made that promise, it never intended to, and knew it could not, deliver because the data it used to get the EUA was unreliable.

307. In October 2020, FDA issued guidance regarding the data and information needed to support issuance of an Emergency Use Authorization (EUA) for COVID-19 vaccines. The guidance explained that FDA may issue an EUA after FDA has determined the following

key criteria are met:

- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the vaccine may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.
- The known and potential benefits of the vaccine, when used to diagnose, prevent, or treat the disease or condition that can be caused by SARS-CoV-2, outweigh the known and potential risks of the vaccine.[17]

308. The means of measurement of the safety, efficacy, immunization capacity and preventive capability of their product were clinical trials conducted in accord with the FDA rules. Pfizer lied by claiming no alternative effective treatments existed, but hid information from the government about it.

309. Pfizer induced the issuance of the EUA to Pfizer by breaking the clinical trial rules, covering it up when exposed, refusing to remedy violations when detailed, submitting unreliable and false data to the government. In short, the clinical trials were not adequate nor well controlled and the totality of the scientific evidence was not available to the FDA.

310. Indeed, Pfizer's EUA was based on fewer than 0.4% of clinical trial participants. In many cases, the regulatory violations and clinical trial violations were disqualifying protocol deviations that should have invalidated trial participants to an extent that the data used to grant the EUA was wholly inadequate and insufficient.

[17] https://www.regulations.gov/document/FDA-2020-D-1137-0019

311. The hidden evidence is revealed in the released trial data and real-world data: 1) all-cause mortality was greater in the "vaccine" arm versus the placebo arm[18]; 2) men and women's fertility is damaged; and 3) individuals become more susceptible to COVID-19 the more shots they take.[19]

b. Fraudulent Presentment

312. Pfizer's invoices sought payment to deliver a safe, effective, vaccine to prevent COVID-19.

313. Pfizer had to expressly guarantee this in their invoice, which expressly incorporated the contract-compliant language as a precondition of payment. This is the essence of the bargain. Pfizer didn't. Pfizer knew they didn't. The lie worked.

314. Pfizer lied by claiming no alternative effective treatments existed, but hid information from the government about it. Worse, what Pfizer delivered was a historically dangerous, ineffective, gene therapy that didn't prevent COVID-19, but would cause death and disability of millions of people, and they knew it.

c. Fraud By Express False Certification

315. Pfizer certified their product complied with all the regulatory requirements explicitly included in the contract, when they used the contractually required language that required a contractually compliant product in the certification in the invoice. Pfizer lied. Pfizer's contract required they comply with all clinical testing safeguards and safety metrics required to assure their product was the required deliverable: a safe, effective, vaccine to prevent COVID-19.

316. Pfizer lied by claiming no alternative effective treatments existed, but hid information from the government about it. Pfizer didn't comply with the clinical trial safeguards and safety metrics because they knew compliance would expose their product as a historically dangerous, ineffective,

[18] https://www.nejm.org/doi/pdf/10.1056/NEJMoa2110345?articleTools=true page 1767
[19] https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full.pdf

gene therapy that didn't prevent COVID-19, but would cause the death and disability for millions of people, and they knew it.

d. Fraud By Implied False Certification

317. Pfizer certified their product complied with all the regulatory requirements explicitly included in the contract, when they used the contractually required language that required a contractually compliant product in the certification in the invoice. Pfizer lied.

318. Pfizer's contract required they comply with all clinical testing safeguards and safety metrics required to assure their product was the required deliverable: a safe, effective, vaccine to prevent COVID-19.

319. Pfizer lied by claiming no alternative effective treatments existed, but hid information from the government about it. Pfizer didn't comply with the clinical trial safeguards and safety metrics because they knew compliance would expose their product as a historically dangerous, ineffective, gene therapy that didn't prevent COVID-19, but would cause death and disability for millions of people, and they knew it.

e. Presentation of False Claims (31 U.S.C. § 3729(a)(1)(A))

320. From 2020 to the present, Defendants knowingly presented, or caused the presentment of, false and/or fraudulent claims for payment or approval to the United States. Pfizer’s claims for payment to DOD were rendered false and/or fraudulent by express and implied false certifications.

321. First, when Defendant Pfizer submitted its clinical trial protocol to the United States in connection with its contract, it represented that the clinical trial would comply with all applicable laws and regulations. Defendants violated FAR and multiple FDA regulations when conducting the clinical trial, rendering this certification false.

322. Second, Defendant Pfizer's IND for the vaccine and clinical trial warned that making a "willfully false statement is a criminal offense." Ex. 4, Form FDA-1571, at 2. Defendants rendered Pfizer's acknowledgement of this warning false by submitting false data to the FDA.

323. Third, Defendants Ventavia and Icon certified in Form FDA-1572, submitted to Pfizer and the United States, that they would: (1) conduct the trial under the protocol and FDA regulations; (2) obey informed consent and IRB reporting requirements; (3) report adverse events; (4) make sure all "associates, colleagues, and employees assisting in" the trial were "informed about their obligations"; and (5) make no changes to the trial without IRB approval. B, Form FDA-1572; 21 C.F.R. § 312.53(c)(vi). Ventavia and Icon acknowledged when submitting Form FDA-1572 that making willfully false statements is a crime. *See* Ex. 5, at 2. This acknowledgement and certification was rendered false by Ventavia and Icon's violations of the clinical trial protocol, FDA regulations, and fraudulent conduct described *supra*.

324. Fourth, Defendant Pfizer certified in its claims for payment that they were true and correct, prepared from Pfizer's books and records, and in accordance with the Pfizer-DoD contract. *See* 48 C.F.R. § 52.232-32(m). This certification was rendered false by Defendants' submission of false data and violation of FDA regulations and FAR, and by the other fraudulent conduct described *supra*.

325. Defendants' fraudulent schemes transform these certifications into false certifications, rendering Defendant Pfizer's claims for payment to DoD false and/or fraudulent.

326. As part of the fraud, Pfizer falsified records, falsified data, falsified statements, and falsified certifications. Pfizer did so to hide their fraud in inducing the contract in the first instance, to mask their fraudulent invoices, and to deceive the government about their fraudulent certifications to the government about what they were delivering to the government and how the product came to be developed contrary to contractual compliance, regulatory requirement, and ethical stricture, as well as the very essence of the bargain.

327. By creating and carrying out their fraudulent schemes, Defendants knowingly and repeatedly violated Section 3729(a)(1)(A) of the False Claims Act.

328. Defendants' knowing submission, or causation of submission, of false and/or fraudulent claims had the potential to influence the government's payment decision and was material to the government's decision to pay the claims.

329. Defendants' violations of the applicable statutes and regulations, and misrepresentations regarding their compliance, were material, because they went to the very essence of the bargain for which the United States DOD contracted. Had the United States DOD known of Defendants' fraudulent non-compliance, which resulted in the submission of ineligible false and/or fraudulent claims for reimbursement, it would not have paid the claims.

330. Defendants' presentment, or causation of presentment, of false and/or fraudulent claims to the United States DOD was a foreseeable factor in DOD's loss and a result of Defendants' schemes. Because 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.

f. Making or Using False Records or Statements to Cause Claims to be Paid (31 U.S.C. § 3729(a)(1)(B))

331. From 2020 to the present, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false and/or fraudulent claims paid or approved by the United States 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.

332. By creating and carrying out their fraudulent schemes, Defendants knowingly and repeatedly violated Section 3729(a)(1)(B) of the False Claims Act.

333. Defendants' false records were material to Pfizer's claims for payment for the vaccine. The United States DOD would not have paid Pfizer if it knew that the clinical trial protocol was not followed by Defendants, because the protocol violations call the integrity and validity of both the entire clinical trial and Pfizer's EUA into question.

334. Pfizer fooled both the Defense Department and the FDA. Neither the Defense Department nor the FDA knew Pfizer lied. Though later aware of allegations of fraud, both the DOD and FDA believed Pfizer's lies, and did not believe the fraud allegations against Pfizer. Pfizer lied by claiming no alternative effective treatments existed, but hid information from the government concerning it. Pfizer continued to lie to this day, including hiding adverse events reporting occuring to this very day. Indeed, Pfizer, to this day, often delivers a different chemical compound than the one ordered, altering or adulterating their delivered product.

335. 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.

336. Defendants' use, or causation of use, of materially false records was a foreseeable factor in the United States DOD's loss and a consequence of Defendants' schemes. Because 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.

g. Retaliation (31 U.S.C. § 3730(h))

337. Defendants' use, or causation of use, of materially false records was a foreseeable factor in the United States DOD's loss and a result of Defendants' schemes. Because 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.

338. Section 3730(h) of Title 31 of the United States Code defines whistleblower protection under the False Claims Act as follows:

> (1) Any employee, contractor, or agent shall have the right to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others to further an action under [the False Claims Act] or other efforts to stop 1 or more violations of [the False Claims Act].
> (2) Relief . . . shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained because of the discrimination, including litigation costs and reasonable attorneys' fees. 31 U.S.C. § 3730(h).

339. As discussed *supra*, in violation of 31 U.S.C. § 3730, Defendant Ventavia retaliated against Relator because of Relator's efforts to stop Defendants from committing False Claims Act violations. Defendant Ventavia punished Relator for her lawful and statutorily protected activity with harassment and termination.

340. Relator has suffered both economic loss and emotional harm because of Defendant Ventavia's retaliatory actions.

h. Retaliation (Texas Health and Safety Code § 161.134)

341. Texas Health and Safety Code § 161.134 prohibits retaliation against employees of any hospital, mental health facility, or treatment facility, which "may not suspend or terminate the

employment of or discipline or otherwise discriminate against any employee for reporting to the employer's supervisor, an administrator of the facility, a state regulatory agency, or a law enforcement agency a violation of law, including a violation of this chapter, a rule adopted under this chapter, or a rule of another agency."

342. An employee who is discriminated against in violation of this provision has a private right of action for damages, including actual damages, exemplary damages, and reasonable attorney's fees.

343. The statute expressly confers protection on any employee who reports on a "violation of this chapter," or any agency rule. Here, Jackson reported major protocol deviations in violation of Federal Acquisition Regulations. Moreover, as shown in the first subchapter of Chapter 161 – § 161.0001 – Texas requires every "health care provider who administers a vaccine is required to record in a medical record under 42 U.S.C. Section 300aa-25, as amended, including: . . . "any adverse or unexpected events for a vaccine."

344. As discussed *supra*, in violation of Texas Health and Safety Code § 161.134, Defendant Ventavia retaliated against Relator because of Relator's efforts to stop Defendants from committing violations of Texas law.

345. Defendant Ventavia punished Relator for her lawful and statutorily protected activity with harassment and termination.

346. Relator has suffered both economic loss and emotional harm because of Defendant Ventavia's retaliatory actions.

XI. CAUSES OF ACTION

A. Count I – Fraud in the Inducement

347. Relator realleges and hereby incorporates by reference each and every allegation contained in all paragraphs of this Second Amended Complaint.

348. As alleged herein, Defendants knowingly engaged in fraudulent conduct in the design, conduct, analysis and reporting of the clinical trials, and it made false representations and omissions of material facts to the FDA in the applications, forms, reports, and data submissions to induce the issuance of the EUA. Defendants abused clinical trial protocols and produced false, unreliable clinical trial data. Defendants provided false data and statements regarding the safety and efficacy of the vaccine to FDA in support of its vaccine authorization. Such false and fraudulent clinical trials were material to the issuance and extensions of the EUA, as determined by the standards set by Congress. Had Pfizer designed, conducted, analyzed and reported the truth of its clinical trials, it would not have been granted EUA under those standards.

349. Defendants' false statements were material to the FDA authorization and approval process, and FDA relied on the integrity of the clinical trial data in granting emergency use authorization. A reasonable agency would have found this data to be material. FDA was induced to grant the authorization of Pfizer's vaccine because of Defendants' false statements and fraudulent clinical trial data. FDA was unaware of the fraudulent conduct and false statements at the time of the authorizations, and to the extent that FDA had learned of flaws in the clinical trials, FDA officials were unaware and/or disbelieving in the fraudulent actions by defendants.

350. As alleged herein, Pfizer's contracts with the United States required Pfizer to obtain EUA as a necessary condition for payment. Obtaining the EUA was a material pre-condition for obtaining payment.

351. Because of Pfizer's knowing false statements and omissions, and its fraudulent conduct as alleged herein, every claim for payment by Pfizer on its contracts with the United States was a violation of the False Claims Act. Under the Act, the United States is entitled to treble damages for all amounts paid to Pfizer on the contract, and statutory penalties for each violation of the Act.

352. In addition, Pfizer engaged in fraudulent conduct, and it made false statements and omissions, as alleged herein, promising a particular deliverable: a safe, effective, vaccine, for the prevention of COVID-19 at speed and scale. These promises induced the United States to enter into the contracts in the first instance. When Pfizer made those promises, it never intended to, and knew it could not, deliver.

353. Pfizer induced the contract by fraud in the inducement, as Pfizer broke the rules for clinical trials, covered it up when exposed, refused to remedy when detailed, falsify the data reported to the government, and cause Relator's termination after blowing the whistle of her employer's fraud upon the government.

354. Defendants knowingly presented or caused the presentment of false and/or fraudulent claims that fraudulently induced the authorization of Pfizer's COVID-19 vaccine, rendering Pfizer ineligible for subsequent payment on the contract.

355. Because of the fraudulent report of material clinical data, Defendants were not eligible for subsequent payments by the Government, which were conditional upon the authorization or approval of the vaccine by the FDA. A reasonable watchdog agency would not have allowed payments to Defendants had it known that the authorization was based on false data.

356. By creating and carrying out their fraudulent scheme, Defendants knowingly and repeatedly violated the False Claims Act. See 31 U.S.C. § 3729(a)(1)(A).

357. Defendants' presentment or causation of presentment of false and/or fraudulent claims was a foreseeable factor in the United States' loss and a result of Defendants' fraudulent scheme. Because of

Defendants' actions, the United States has suffered damages and is entitled to recover treble damages plus a civil monetary penalty for each false and/or fraudulent claim.

B. Count II – Fraudulent Presentment

358. Relator realleges and incorporates by reference each and every allegation contained in all paragraphs of this Second Amended Complaint.

359. Pfizer's invoices sought payment for delivering a safe, effective, vaccine to prevent COVID-19.

360. Pfizer had to expressly guarantee this in their invoice, which expressly incorporated the contract-compliant language as a precondition of payment. This is the essence of the bargain. Pfizer didn't. Pfizer knew they didn't. The lie worked.

361. Pfizer lied by claiming no alternative effective treatments existed, but hid information from the government about it. Worse, what Pfizer delivered was a historically dangerous, ineffective, gene therapy that didn't prevent COVID-19, but would cause the deaths and disabilities of millions, and they knew it.

362. Pfizer won billions of taxpayer money, and then their product caused the deaths and disabilities of millions. Pfizer lied and people died.

C. Count III – Presentation of False and/or Fraudulent Claims (31 U.S.C. § 3730(a)(1)(A))

363. Relator realleges and incorporates by reference every allegation in all paragraphs of the Second Amended Complaint.

364. Since December of 2020, Defendants have knowingly presented or caused to be presented false and/or fraudulent claims to the United States for payment or approval. Defendant Pfizer's claims for payment to DOD were rendered false or fraudulent by Defendants' implied and express false

certifications of legal and regulatory compliance, accuracy of data, and clinical trial protocol compliance.

365. By creating and carrying out their fraudulent scheme, Defendants knowingly and repeatedly violated the False Claims Act. *See* 31 U.S.C. § 3729(a)(1)(A).

366. Defendants' knowing submission, or causation of submission, of false and/or fraudulent claims had the potential to influence the United States' payment decision and was material to the United States' decision to pay the claims.

367. The United States paid the false and/or fraudulent claims.

368. Defendants' presentment or causation of presentment of false and/or fraudulent claims was a foreseeable factor in the United States' loss and a consequence of Defendants' fraudulent scheme. Because of Defendants' actions, the United States has suffered damages and is entitled to recover treble damages plus a civil monetary penalty for each false and/or fraudulent claim.

D. Count IV – Making or Using False Records or Statements Material to False and/or Fraudulent Claims (31 U.S.C. § 3730(a)(1)(B))

369. Relator realleges and incorporates by reference every allegation in all paragraphs of the Second Amended Complaint.

370. From 2020 to the present, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false and/or fraudulent claims paid or approved by the United States. These false records or statements include the clinical trial protocol that Defendant Pfizer submitted to the United States and the falsified source documents and data behind Defendants' clinical trial results and Emergency Use Authorization application.

371. By creating and carrying out their fraudulent scheme, Defendants knowingly and repeatedly violated 31 U.S.C. § 3729(a)(1)(B)

372. Defendants' false records or statements, or causation thereof, had the potential to influence the United States' payment decision and were material to the United States' decision to pay the claims.

373. Defendants' false records or statements, or causation thereof, were material because they went to the very essence of the bargain for which the United States contracted. Had the United States known of Defendants' fraudulent misrepresentations regarding the clinical trial at issue, which resulted in the submission of ineligible false/fraudulent claims for reimbursement, then the United States would not have paid those claims.

374. The United States paid the false and/or fraudulent claims

375. Defendants' false records or statements, or causation thereof, was a foreseeable factor in the United States' loss and a result of Defendants' scheme. Because of Defendants' actions, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false and/or fraudulent claim.

XII. PRAYER FOR RELIEF

WHEREFORE, Relator prays this Court enter judgment against Defendants and award:

(1) Damages for three (3) times the actual damages suffered by the United States as a result of Defendants' conduct;

(2) Civil penalties against Defendants up to the maximum allowed by law for each violation of 31 U.S.C. § 3729;

(3) The maximum award Relator may recover under 31 U.S.C. § 3730(d);

(4) All costs and expense of the litigation, including attorneys' fees and costs of court; and

(5) All other relief on behalf of Relator or United States that the Court deems just and proper.

E. Count V – Retaliation (31 U.S.C. § 3730(h))

376. Relator realleges and incorporates by reference every allegation in all paragraphs of this Complaint.

377. In violation of 31 U.S.C. § 3730(h), Defendant Ventavia Research Group, LLC ("Ventavia") retaliated against Relator Jackson because of her efforts to stop Defendants from committing violations of the False Claims Act.

378. Ventavia punished Relator for her lawful and statutorily protected activity with harassment, termination, and slander.

379. Relator has suffered economic loss and emotional harm because of her termination by Ventavia.

F. Count VI - Retaliation (Texas Health and Safety Code § 161.134)

380. Relator realleges and incorporates by reference every allegation in all paragraphs of this Complaint.

381. In violation of **Texas Health and Safety Code § 161.134**, Defendant Ventavia Research Group, LLC ("Ventavia") retaliated against Relator Jackson because of her efforts to stop Defendants from committing violations of Federal Acquisition Regulations and Texas state law, Chapter 161.

382. Ventavia punished Relator for her lawful and statutorily protected activity with harassment, termination, and slander.

383. Relator has suffered economic loss and emotional harm because of her termination by Ventavia.

PRAYER FOR RELIEF

384. WHEREFORE, Relator prays this Court enter judgment against Defendant Ventavia Research Group, LLC for the following:

(1) Reinstatement with the same seniority status;

(2) Two times the amount of Relator's back pay;

(3) Interest on Relator's back pay;

(4) Compensation for special damages sustained by Relator because of Defendants' actions, including but not limited to compensatory damages for emotional pain, suffering, inconvenience, mental anguish, loss of enjoyment of life, loss to reputation, and other pecuniary and nonpecuniary losses;

(5) Punitive damages;

(6) Litigation costs and attorneys' fees;

(7) Prejudgment interest at the highest rate allowed by law; and

(8) Any other relief that the Court deems just and proper to make Relator whole.

XIII. INDEX OF EXHIBITS

385. The exhibits referenced are:

Exhibit Number	Description	Bates Range
1	Text Messages with Ray and Others (Sept. 17, 2020)	JSN0001-JSN0011
2	E-mail Chain with Ray and Others (Sept. 23, 2020)	JSN0012-JSN0014
3	Transcript of September 24, 2020 Meeting	JSN0015-JSN0046
4	Form FDA-1571	JSN0047-JSN0049
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
30	OTA Base Agreement	JSN0523-JSN0577

XIV. DEMAND FOR JURY TRIAL

386. Under Federal Rule of Civil Procedure 38, Relator demands a trial by jury.

Respectfully submitted,
/s/ Warner Mendenhall
Warner Mendenhall, OH Bar No. 70165
MENDENHALL LAW GROUP
190 North Union Street, Suite 201
Akron, OH 44304
Tel: (330) 535-9160; Fax: (330) 762-9743
Email: warner@warnermendenhall.com

Robert E. Barnes, Esq., *Admitted Pro Hac Vice*
Lexis Anderson, Esq. Member Eastern District of Texas, TX State Bar No. 24127016
BARNES LAW
700 South Flower Street, Suite 1000
Los Angeles, California 90017
Tel: (310) 510-6211; Fax: (310) 510-6225
Email: robertbarnes@barneslawllp.com
Email: lexisanderson@barneslawllp.com

Jeremy L. Friedman, CA Bar No. 142659
LAW OFFICE OF JEREMY L. FRIEDMAN
2801 Sylhowe Road.
Oakland, Ca. 94610
Tel: (510) 530-9060
Fax: (510) 530-9087
Email: jlfried@comcast.net

Counsel for Relator Brook Jackson