EXHIBIT E

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HIGHLY CONFIDENTIAL

Mr. Gregory Shilling
Assistant Special Agent in Charge
South West Region
Defense Criminal Investigative Service
Via e-mail: Gregory.shilling@dodig.mil

Re: New *qui tam* action against Pfizer, Inc., Icon PLC, and Ventavia Research Group, LLC

Dear Mr. Shilling:

I am writing regarding a new *qui tam* action under the federal False Claims Act that we plan to file against Pfizer, Inc. ("Pfizer"), Icon PLC, and Ventavia Research Group, LLC ("Ventavia") in early January of 2021.

The United States Department of Defense[1] contracted with Pfizer to purchase 100 million doses of Pfizer's COVID-19 vaccine, BNT162b2, for $1.95 billion, pending Emergency Use Authorization ("EUA"). The U.S. Food and Drug Administration ("FDA") granted EUA for the vaccine on December 11, 2020, and the United States began to pay Pfizer, acquiring the vaccines. Icon PLC and Ventavia were subcontractors of Pfizer who respectively oversaw and operated clinical trial sites.

The *qui tam* case we plan to file alleges that Pfizer, in concert with its subcontractors Icon PLC and Ventavia: (1) concealed or withheld violations of FDA and federal acquisition regulations, vaccine clinical trial protocol violations, adverse events, and other information material to the United States' purchase of the vaccines, resulting in implied and express false certifications; and (2) used false clinical trial records and supporting data that were material to Pfizer's claims for payment to the United States. Had the United States known of the concealed and falsified information, it would not have purchased the vaccines under the contract at issue.

The EUA Pfizer obtained is based on a deeply flawed clinical trial that violated FDA regulations and the clinical trial protocol Pfizer submitted to the United States. This means that the vaccine is misbranded. The alleged fraudulent scheme has caused the United States to pay over $1.9 billion that it would not have paid had it known that the safety and efficacy of the vaccine at issue was not accurately represented or properly proven. This means that, at worst, the vaccine could be far less effective than represented, and the United States has paid billions for something that will not protect the public from COVID-19. At best, the vaccine is effective, but Pfizer will

[1] The United States contracted through an intermediary, Advanced Technology International ("ATI"). The United States likely used ATI as its intermediary in order to simplify the contracting process and avoid possible delay resulting from typical procurement processes. Despite the use of an intermediary, however, the United States has clearly stated that the contract is between HHS, DoD, and Pfizer.

still have profited from the pandemic by lying to the United States, violating federal regulations, and failing to uphold the integrity of the scientific process.

Background

Pfizer, in conjunction with German company BioNTech SE ("BioNTech"), developed a vaccine candidate to combat the novel Coronavirus ("COVID-19") which is based on messenger RNA technology. After allegedly promising Phase I clinical trial results, Pfizer and BioNTech decided to proceed to Phase II and III trials for the most successful dosage of the vaccine candidate, referred to as "BNT162b2." Around that time, the U.S. Department of Defense contracted with Pfizer to purchase 100 million doses of BNT162b2, contingent on FDA approval or EUA.

Pfizer subcontracted with Irish company Icon PLC ("Icon") for clinical trial management. Icon oversaw more than 160 test sites worldwide, and was tasked with ensuring trial protocol compliance and required information reporting. This included oversight of Serious Adverse Event ("SAE") reporting, which is required both by the clinical trial protocol and federal regulations.

Pfizer subcontracted Ventavia to operate 3 Phase III test sites for the BNT162b2 clinical trial in Keller, Houston, and Fort Worth, Texas. Approximately 1,500 of the 43,998 total BNT162b2 trial participants were injected and monitored at Ventavia's three sites. Pfizer paid Ventavia mainly on a per-patient basis, up to an allotted maximum enrollment number per week.[2] Ventavia recorded all key participant and trial information in "source documents" that were made available to Pfizer and Icon after entry. Ventavia recruited clinical trial participants via advertising, contact with local businesses and organizations, and features in local news media. Trial participants are compensated monetarily in amounts approved by an external Institutional Review Board ("IRB").

Pfizer remains responsible for "data management" of the clinical trial under Section 10.1.5 of its clinical trial protocol, "including quality checking of the data."

The BNT162b2 trial was, per its protocol, randomized, placebo-controlled, and observer-blinded. It was open to healthy individuals aged 12 to 85 who were at risk of acquiring COVID-19, capable of giving informed consent, and willing and able to comply with scheduled visits, a vaccination plan, laboratory tests, and clinical trial procedures. The trial protocol excluded individuals with certain pre-existing conditions or histories, including pregnant individuals. The trial also excluded investigator site staff and their family members from being participants.

BNT162b2 must be transported and stored in medical-grade freezers or in specialized dry ice coolers at negative 112 to negative 76 degrees Fahrenheit. It can also be kept in a conventional refrigerator for up to 5 days, or in its specialized cooler (if opened for no more than 1 minute every 5 days, and if dry ice is replenished every 15 days). The clinical trial protocol requires monitoring and reporting of any temperature "excursions" (deviations from the temperature requirements) to Pfizer, as well as segregation of the affected product.

Trial enrollment is now complete, and only ongoing monitoring is still occurring.

[2] Ventavia was also paid for each SAE reported and on other bases as well.

Relator Brook Jackson

Relator Brook Jackson ("Relator" or "Jackson") has worked in the clinical trials field for over thirteen years. She is a certified Clinical Research Auditor and Clinical Research Professional. Relator worked for Ventavia Research Group as a Regional Director from September 8 to September 25, 2020. 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 in Fort Worth and Keller, Texas. 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.

Ventavia's violations of the clinical trial protocol, Federal Acquisition Regulations and their Department of Defense supplements ("FAR"), and FDA regulations were so widespread and blatant that Relator witnessed them on a daily basis, even during her brief employment period. As discussed further *infra*, Ventavia retaliated against Relator for her reports of and efforts to stop fraud against the United States.

Key Allegations

During her employment at Ventavia, Relator observed that Ventavia was rushing to enroll, inject, and monitor as many clinical trial participants as possible in order to maximize per-patient payments from Pfizer. Pfizer also exerted pressure on Ventavia to enroll as many patients as possible, in pursuit of finishing the clinical trial and the coveted accolade of "first successful COVID-19 vaccine." Ventavia's rush to get paid and over-booking of patients resulted in sloppy documentation practices, poor clinical trial protocol compliance, and little oversight. Pfizer and Icon turned a blind eye to Ventavia's misconduct, despite numerous "red flags."

Relator observed violations of the BNT162b2 clinical trial protocol and FDA regulations on a near-daily basis during her tenure at Ventavia. For example, Relator observed:

- Ventavia did not submit clinical trial documentation (i.e., of participants' health records, time of injection, etc.) in a timely manner to Pfizer and Icon. Ventavia performed "quality control" on missing documentation by fabricating much of the required data. For example, clotting times and collection times for blood draws were often fabricated after the fact to disguise missing data as well as noncompliance with blood collection protocols. This is vital and material because the blood draws were used to assess whether a trial participant had developed an immune response to COVID-19—in other words, **whether the vaccine was effective**.
- Ventavia employees recruited friends and family members to help perform "quality control" on the weekends, but those family members were not listed on delegation logs that Ventavia was required to keep and report to Pfizer and Icon. "Quality control" documents were internal-only and never seen by Pfizer or Icon. They reveal that many acknowledged issues in documentation were never corrected.

- Relator personally observed quality control personnel change data in patient files, such as altering blood pressure numbers.
- Clinical trial participants who should have been excluded at their first pre-injection visit due to underlying conditions like pregnancy were not removed from the trial until later. There are multiple safeguards in the clinical trial protocol to prevent pregnant women from being trial participants, but due to Ventavia's recklessness, it happened anyway. Ventavia must report any injection of a pregnant individual to Pfizer under the protocol (and monitor any resulting birth), and did not always do so.
- Clinical trial information and vaccine storage carelessness and mishandling caused potential and actual unblinding of trial participants and Ventavia site staff, compromising the integrity of the entire trial. This unblinding was never reported to Pfizer or Icon.
- BNT162b2 is given as a two-injection series. The second injection must be given 19 to 23 days after the first. Clinical trial participants were frequently injected past the 23-day window. Relator personally observed that this issue affected at least ten patients.
- Clinical trial participants were not monitored for 30 minutes after injection as required by the protocol. They were instead instructed to sit in a hallway and cursorily "checked on" by a non-medical professional who would ask them if they were "OK." The Fort Worth location only had 5 exam rooms, so this hallway monitoring was used to let Ventavia see more patients per day.
- On several occasions, the BNT162b2 vaccines were not stored at the proper temperatures, resulting in temperature "excursions." Not all excursions were reported to Pfizer, and the affected vaccines were not properly segregated.
- Untrained or unqualified medical assistants performed blood draws and laboratory work at some Ventavia test sites.
- The trial protocol requires that injections be performed by qualified and trained medical professionals. Ventavia used untrained medical assistants as vaccinators (which is not acceptable under the protocol). And, one of Ventavia's qualified vaccinators was not trained properly—she was given instructions over the telephone.
- Ineligible participants were enrolled in the clinical trial, including, for example, Ventavia employees' family members. Ventavia did not report the breaches of protocol to Pfizer as required. Some of these participants' data were not removed from the clinical trial. Some of these participants also performed work for Ventavia, like assisting with "quality control."
- Clinical trial participants did not always give informed consent in the manner required by the clinical trial protocol for each visit. For example, sometimes informed consent forms were missing or unsigned. Ventavia staff fabricated signature dates (and sometimes patient signatures, too) to conceal the discrepancy. Additionally, in Ventavia's rush to see as many patients as possible each day, sometimes vital signs and other procedures were performed before the patient had signed the informed consent forms for each visit—a serious ethical violation.

- Clinical trial participants were sometimes injected with the wrong needle size for their body weight, in violation of the clinical trial protocol.
- To preserve blinding, the vaccines and placebos, per the trial protocol, were to be given 30 minutes of preparation time, notwithstanding how long it would take to actually prepare them. In Ventavia's rush to see as many patients as possible per day (and maximize their per-patient payments), vaccinators disobeyed the 30-minute requirement by, *i.e.*, holding the frozen vaccine in their hand to thaw it faster.
- Ventavia failed to promptly submit some Serious Adverse Event reports to Icon and Pfizer, causing regulatory violations.
- In Ventavia's rush to see as many trial participants as possible per week, participants often had to wait for five hours at the trial site before being seen. Some patients became angry about the long wait times. Ventavia employees were instructed to give these patients gift cards to placate them—a form of additional compensation that was not approved by the IRB.

All of the above constituted violations of the clinical trial protocol that should have been immediately reported to Pfizer (and, in some cases, to the IRB as well). The majority of them were not. When issues were documented, that was done via "notes to the file," which are buried in each patient's case file. Instead, they should have been documented and sent to Pfizer right away in "corrective action plans." Ventavia's choice to use "notes to the file" rather than corrective action plans resulted in many recognized problems not being corrected, because no plan of action was developed.

In addition, Relator also observed the following safety and confidentiality issues during her employment:

- Used vaccination syringes were disposed in biohazard bags rather than sharps containers.
- Ventavia staff did not undergo training required by clinical research standards, including training related to shipment of biologics.
- HIPAA was not being complied with; patient information was left out in the open and on a publicly-visible calendar until Relator stopped the practice.

As noted previously, Pfizer is responsible for "quality checking" all clinical trial data under its clinical trial protocol. Relator observed that Pfizer and Icon monitored Ventavia's documentation during the trial, often sending e-mails about missing data or laboratory specimens. Relator also observed, however, that not all issues were followed up on. Pfizer and Icon had access to source documents and received e-mails that raised red flags regarding falsified data and trial protocol noncompliance—impacting the integrity of the entire clinical trial. However, Pfizer and Icon elected to turn a blind eye to the issues, keep Ventavia's test sites, and continue enrollment, racing for the coveted accolade of "first COVID-19 vaccine."

During her employment, Relator reported concerns about trial protocol compliance, patient safety, and the overall integrity of the Pfizer-BioNTech trial to her supervisors. The Principal Investigator for the Fort Worth side even acknowledged that Ventavia needed to "clean up" the issues before they were audited. When Relator reported these issues to management in an effort to stop fraud, her supervisor asked her to provide specific patient names for each issue after the

fact. The issues were so widespread and systematic that this was not possible (and Relator did not always have access to all the specifics), so Ventavia let the issues continue unabated.

On September 17, 2020, Relator recommended pausing trial enrollment altogether due to the seriousness and pervasiveness of the issues. Ventavia briefly paused enrollment in order to "catch up" on "quality control." Ventavia misrepresented to patients why clinical trial enrollment was paused, concealing their data mismanagement. As previously mentioned, Ventavia's "quality control" involved falsifying data, used unqualified personnel, and did not stop fraud on the United States. Before addressing its "quality control" completely, Ventavia lifted the enrollment pause and doubled down on recruiting new clinical trial participants soon thereafter.

On September 24, 2020, Relator met with two supervisors, Quality Control Director William Jones and Director of Operations Marnie Fisher. Relator met with Jones and Fisher to discuss, among other issues, photographs Relator had taken of used vaccination syringes being disposed of in biohazard bags instead of sharps containers—a serious employee safety issue. Relator had previously been asked to document improper use of biohazard bags because Ventavia was charged by weight for their disposal. Relator was falsely accused of taking the photos for an improper purpose, and of improperly taking patient information out of the office. When Relator raised concerns about unblinding, she was instructed to discipline Fort Worth's vaccinators for failing to safeguard information. Management appeared more concerned with punishing employees than investigating the extent of the issue. After discussing other issues raised by Relator, Ventavia's Director of Quality Control, William Jones, opined that not all the issues could be fixed (despite the fact that Ventavia was required to do so), stating "we have to pick something." Relator also brought up patient monitoring failures—a systematic protocol violation affecting all patients—and was told again to make a list of the patients affected. Management questioned whether the lack of monitoring was actually a safety issue.

Relator called a hotline maintained by the U.S. Food and Drug Administration ("FDA") on the morning of September 25, 2020, discussing many of the issues noted above. Ventavia terminated Relator that same day under the pretext that she was "not a good fit" for the position. Relator had never been disciplined or reported for any failure regarding her job performance before her termination.

Relator's efforts to stop fraud on the United States unfortunately fell on deaf ears. Pfizer and Ventavia continued enrollment in the Pfizer-BioNTech trial after Relator's termination, even expanding the clinical trial population to add 4,400 young teenagers in October. Trial enrollment has now completed; only required periodic monitoring of patients is still ongoing. However, due to Ventavia's aforementioned fraudulent practices, even this monitoring is affected, and may result in concealment of side effects or other material information from the United States.

Pfizer, Icon, and Ventavia's Fraud on the Department of Defense

Pfizer and Icon, despite access to the source documents, and despite informing Ventavia of missing information and discrepancies, failed to investigate the extent of Ventavia's protocol violations by reviewing the source documents Ventavia provided to them. The source documents raised obvious warning signs of falsified data, such as listing blood clot times of exactly 30 minutes

for 10 patients in a row. Pfizer and Icon failed to "follow up" on information that put them on notice of serious protocol violations, FAR and FDA regulatory violations, and falsification of data. For example, Pfizer should have investigated the extent of unblinding when it received e-mails from Ventavia inquiring about documents in patient files that could have unblinded patients and blinded site staff. To give another example, some patients had vital signs taken before they gave informed consent—a breach of the protocol and FDA regulations. The obvious discrepancy in times should have alerted Pfizer and Icon to an informed consent issue for those patients.

Pfizer was responsible, under federal regulations, for monitoring Icon and Ventavia, as its subcontractors, and was required to ensure compliance or stop shipping BNT162b2 to Ventavia's test sites once it discovered any protocol noncompliance. *See* 21 C.F.R. § 312.56. Icon, Ventavia, and Pfizer were all obligated to conduct the BNT162b2 clinical trial in accordance with FDA regulations. *See* 21 C.F.R. §§ 312.23(a)(v), 312.52, 312.53. All three companies were "subject to the same regulatory action . . . for failure to comply." 21 C.F.R. § 312.52(b).

Pfizer's contract with the U.S. Department of Defense requires Pfizer to submit monthly claims for payment (invoices) in connection with each delivery of the 100 million purchased vaccines. These claims were rendered fraudulent due to implied false certifications.

First, when Pfizer submitted the 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. Pfizer, Ventavia, and Icon violated FAR and multiple FDA regulations when conducting the BNT162b2 clinical trial, rendering this certification false. For example, Ventavia, Icon, and Pfizer were required to prepare and maintain "adequate and accurate case histories" for every clinical trial participant reflecting informed consent and including all pertinent data. 21 C.F.R. § 312.62(b). This was clearly not complied with, as participants' case files lacked adequate informed consent and contained falsified data. To provide another example, Pfizer should have stopped using Ventavia test sites once it was made aware of Ventavia's noncompliance with the clinical trial protocol. *See* 21 C.F.R. § 312.56(b).

Documents Pfizer submitted to the FDA for EUA warned Pfizer explicitly that submitting false statements is a criminal offense. Pfizer submitted false clinical trial data and source documents to the FDA, rendering this acknowledgement false.

Pfizer is also required, under Federal Acquisition Regulation 52.232-32, to certify the correctness of any claim for payment submitted. Pfizer's claims for payment are rendered fraudulent by Pfizer's submission of false data and violation of FDA regulations.

The United States would not have paid Pfizer for the vaccines had it known that Pfizer submitted false data and that Pfizer, Icon, and Ventavia violated FAR and FDA regulations. As a result, the implied false certifications at issue were material to the United States' payment decision.

Ventavia and Icon caused—and Pfizer used—false records material to false and/or fraudulent claims. Those records include falsified source documents and the clinical trial protocol itself. The source documents and trial protocol are material false records because they go to the heart of what the United States contracted for. The United States contracted to purchase vaccines found effective by a valid clinical trial conducted according to a protocol submitted by Pfizer. The

integrity of the entire clinical trial was compromised by the clinical trial protocol violations, false source documents, and the false data that resulted, which calls the vaccine's EUA into question. The United States would not have paid for the vaccines had it known of the material false records.

Although Ventavia only managed 3 sites out of the 160 total in the BNT162b2 trial, Pfizer and Icon's lack of oversight and fraudulent misconduct vis-a-vis Ventavia bring the entire clinical trial into question. It is beyond the scope of Relator's knowledge, but it is likely that similar fraud occurred at clinical trial sites managed by other subcontractors of Pfizer.

Potential Recovery

As noted previously, potential damages in this matter are over $1.95 billion—the cost of the first 100 million doses. The contract at issue also permits the Department of Defense to order 500 million additional vaccines, at a rate of $19.50 per dose. As a result, additional future damages of up to $9.75 billion are possible.

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We are still in the process of drafting our pre-filing disclosure and anticipate sending it to the United States Attorney's Office and Department of Justice on December 31, 2020, with the original disclosure and complaint following shortly after that. Please do not hesitate to contact us if you have any questions in the interim.

Sincerely yours,

BERG & ANDROPHY

/s/ Rebecca L. Gibson
Joel M. Androphy
Rebecca L. Gibson