UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA EX REL. BROOK JACKSON	CAUSE NO. 1:21-CV-00008
VS.	MARCH 1, 2023
VENTAVIA RESEARCH GROUP, LLC, ET AL.	2:06 P.M. BEAUMONT, TEXAS

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REPORTER'S TRANSCRIPT OF MOTIONS HEARING

BEFORE THE HONORABLE MICHAEL J. TRUNCALE
UNITED STATES DISTRICT JUDGE

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(OPEN COURT, ALL PARTIES PRESENT)

(P R O C E E D I N G S)

THE COURT: The Court calls the case of *Brook Jackson versus Ventavia Research Group, LLC, Pfizer, Inc., and Icon PLC* in Cause No. 1:21-CV-0008.

We are here on an oral hearing on Pfizer's motion to dismiss the Relator's amended complaint, Icon's motion to dismiss the Relator's amended complaint and Ventavia's corrected motion to dismiss.

I would ask that the attorneys introduce themselves to the Court and state your name on the record and introduce your clients and announce if you are ready to proceed.

MR. BARNES: Yes, Your Honor. Attorney Robert Barnes here on behalf of Brook Jackson here with co-counsel Warner Mendenhall and Lexis Anderson, Your Honor, and we are ready to proceed.

THE COURT: Thank you. And for the Defendant?

MR. CARROLL: Your Honor, for the record, Jack Carroll, Orgain, Bell and Tucker, for Pfizer, along with Carlton Wessel, Meagan Self and Andrew Hoffman.

THE COURT: Okay. You are here for?

MR. CARROLL: Pfizer.

THE COURT: We also have for I believe Icon, correct, Mr. Davis?

MR. DAVIS: Yes, sir. Scott Davis together with Eali Katz on behalf of Icon.

THE COURT: Very fine. And Icon is present too; is that correct? I mean, excuse me, Ventavia.

MR. GUTHRIE: Andrew Guthrie with my colleague Taryn McDonald for Ventavia Research Group.

THE COURT: Guthrie?

MR. GUTHRIE: With my colleague Taryn McDonald.

THE COURT: Very good. And I take it everyone is ready to proceed, announced and ready?

MR. BARNES: Yes, Your Honor.

THE COURT: The Defendants are ready to proceed?

MR. CARROLL: Yes, Your Honor.

THE COURT: Okay. That's fine. Couple of things I want to go over before we get into the arguments. I don't in most cases have oral arguments on motions to dismiss and other dispositive motions. However, it is my practice whenever a party requests an oral hearing as a matter of practice, I grant that. I feel that that is what due process is about, having an opportunity to be heard. So if a party feels that they need to be heard, I give that opportunity.

After I agreed to have a hearing, in reviewing

the matters before the court, it did occur to me that perhaps an oral hearing would be helpful to help clarify some of the issues. I am inclined to simply let the attorneys present their arguments to me with perhaps little or no interruption by me with questions or comments unless I feel inclined to do so at a specific point.

I will want to ask Mr. Barnes a couple of questions that might streamline things, perhaps. But I know that this case has gotten some attention through various means that a lot of cases don't get. And I think we need to be clear from the get-go this is a process and the Court will not rule from the bench a decision on these motions today. That's not what the Court does on something like that.

Instead, the Court issues a reasoned opinion based upon the pleadings, the facts that are presented and the law. And I might add we have already done our own independent research on the law. Found some cases that have actually not been cited by the parties. But we do appreciate the fine efforts and clear writing of the parties. But some of you may wonder why it takes time to issue opinions. Well, the notebook that's on my desk contains just pleadings associated with these motions, not all the pleadings that have been filed. And this is

just one of over 600 civil cases that I have, plus 20 percent of the criminal docket in the Beaumont Division. And every case is important no matter the size of the case. It is important to the litigants and so we take each case and handle each case with the greatest care that we possibly can.

So I just wanted not to disappoint anyone who may have traveled a distance to be here to watch this hearing. There will not be a decision rendered from the bench today.

I also want to remind everyone from our previous comments that were made in telephone conferences that I do insist upon certain decorum and dignity in the court. That is, lawyers with opposing counsel and lawyers to the court, and any comments that I may make or questions that I may make are not to be interpreted as leaning one way or the other of the Court. That would be a wrong assessment and I think the lawyers probably know that, but some others who may not be experienced in legal matters, that's not to -- just because I ask a question of one counsel doesn't mean that I'm against him or her or for him or her or make a comment. It may be simply to clarify something; it may actually be something, oddly enough, to confirm something in my mind.

So I just wanted to say that and I would

caution anyone that they should not take any actions of the Court and pronounce to the public as leaning one way or the other. So are we all clear on that?

MR. BARNES: Yes, Your Honor.

MR. CARROLL: Yes, Your Honor.

THE COURT: All right. Very good. Now, Mr. Barnes, why don't you just take the podium. And I will advise everyone for 34 years I tried cases in this courthouse. And I had federal judges tell me counsel, get on the microphone, get on the microphone. And I thought why in the world, what is with that? And until I became a judge, and realized that the acoustics are not good. You may be speaking in a tone of voice that you're confident the people around you can hear and that I can hear, but around that jury box and around here, I mean the sound just goes away. And, in fact, when I remind lawyers of that, I often get several jurors smiling at me saying thank you. They want to hear, but they couldn't hear. So please speak into the microphone so we can -- you can be heard.

What I wanted to ask you, Mr. Barnes, the reason I pulled you out of order, is because this might streamline some things. As you are aware, in a cross-claim case essentially there are three theories that are used, an express false certification, an implied

false certification, those I think were part of your complaint, but in reply, not really pled in your complaint, but certainly articulated in your reply, with even a mention that, you know, you would like to have an opportunity if you needed to amend to assert a fraud in the inducement.

Have you pulled back from the first two theories, that is, express false certification or implied false certification and tend to be relying more on the fraud in the inducement?

MR. BARNES: No, Your Honor. We are pursuing all three.

THE COURT: We can probably expect to hear argument on all three then. I just wanted to clarify. So that I am sure I see, I have a couple of things that I pulled and I'm sure there are other documents and perhaps some of you have some things, I don't know, what's called a statement of work, there is in Section 1.1.2 something called activities undertaken without government funding. These activities are described solely for background and context for the government funded deliverables itemized in Section 4 and then it goes on with the regulatory planning and it says that Pfizer will meet quote necessary FDA requirements close quote for conducting ongoing and planned clinical trials.

And then if you go to scope 1.2, there is a section that says the parties acknowledge and agree that such activities not related to large scale manufacturing are out-of-scope for this prototype project for Pfizer. And Pfizer, rather, will fund these activities without the use of government funding. So it is not that there was any attempt to elicit money for the funding; is that correct?

MR. BARNES: Yes, Your Honor.

THE COURT: All right. Now, the question is on Section 5.0 it says provided the FDA has granted approval or authorization, just read that part again, provided the FDA has granted approval or authorization, 100 million doses will be provided by Pfizer to the government.

So now, that provided the FDA has granted approval, that goes back, does it not, to what I -- the portion that I talked about from the very beginning in this Section 1.1.2 (a), that Pfizer will meet necessary FDA requirements?

MR. BARNES: Yes, Your Honor.

THE COURT: And it assumes, does it not, it doesn't specify, but it assumes that whatever information would be reliable; is that correct?

MR. BARNES: Yes, Your Honor.

THE COURT: Kind of an assumed implied term of the contract so to speak?

MR. BARNES: Yes, Your Honor.

THE COURT: Now, my next question is I see something called looks like a bill for $154,091,920. Are you familiar with that?

MR. BARNES: Yes, Your Honor.

THE COURT: And it's a bill from Pfizer looks like to Advanced Tech International. Who is that?

MR. BARNES: That's the consortium that was contracting on behalf of the Defense Department, Your Honor.

THE COURT: Okay. So that's the DoD essentially?

MR. BARNES: Yes, Your Honor.

THE COURT: Okay. Says I certify that the amounts invoiced are for costs incurred quote in accordance with the agreement. I use the word quote in accordance with the agreement and that the work reflected has been performed and prior payment has not been received.

What do you think that means "in accordance with the agreement"?

MR. BARNES: Our understanding, Your Honor, is that that meant that they complied with the agreement's

requirements in terms of what the deliverable was. So in this context they were going to deliver something that met the FDA's requirements for clinical testing that produced a safe, effective vaccine for the prevention of Covid-19. And that's what "in accord with the agreement means" in our understanding.

THE COURT: Is that what I -- to go back to what I read earlier, I want you to tell me if you think I am on the right page or the wrong page, okay?

MR. BARNES: Yes, Your Honor.

THE COURT: I see something here, go back to 5.0, provided the FDA has granted approval with the implied terms, proper approval, doesn't say that, but approved, FDA has granted approval, 100 million doses will be provided, is that what is referenced in this in accordance with the agreement?

MR. BARNES: Yes, Your Honor.

THE COURT: Is that your position I should say?

MR. BARNES: Yes, Your Honor.

THE COURT: Is there anything else I am missing from your standpoint to tie those things together?

MR. BARNES: No, Your Honor. The only thing I would say is that throughout the statement of the work,

there was a lot of repetition of what the Court is talking about. There's schedules of deliverables about FDA documents this, FDA clinical trial that, so on and so forth, but I think the Court has highlighted what we consider the two most critical parts of the contract.

THE COURT: All right. So you are still pursuing three theories, although one would require an amendment to -- an amended complaint in order for you to really pursue that; is that correct?

MR. BARNES: Yes, Your Honor.

THE COURT: All right. So we don't have anything that's not -- that narrows the scope. We can talk about some other things that may come up later in due course, materiality, and maybe everybody can kind of be thinking about this as if you don't have other things to think about. Who decides materiality? Is it the Court or is that a fact for a jury? I'm not asking for an answer right now. I am aware of Fifth Circuit authority that I think has been cited that perhaps suggests that that's a decision for the Court to decide, but I'm open to discussion about that. Talking about Rule 9(b)'s heightened pleading requirements for fraud, whether those have been met and later we may talk a little bit about ADR and also the scienter requirement I am interested in particularly on the Defendant's side

because could there be a difference in scienter amongst the Defendants. Namely, does Icon get a pass on that one or not. Just a question we may want to talk about.

So those are just a few of the things that are kind of on my mind, which you all feel free to address any of those as we go. Mr. Barnes, I believe that's all I have as a preliminary matter.

MR. BARNES: Thank you, Your Honor.

THE COURT: Okay. Who wants to present? Mr. Carroll, are you going to start for us?

MR. CARROLL: Just briefly, Your Honor.

THE COURT: Of course.

MR. CARROLL: First of all, good afternoon.

THE COURT: Good afternoon.

MR. CARROLL: Before -- the Court has noted, before the Court today are the motions to dismiss for Defendants Pfizer, Icon and Ventavia. And before you hear the three Defendants' arguments on those issues, we note that the Defendants have three pending motions that are somewhat time sensitive regarding the extension of stay of discovery that currently expires on March the 15th. Obviously, we are here today to argue the motions to dismiss, but at the conclusion of those arguments if the Court has any questions with respect to those motions, we are prepared to address those with the

Court today as well. With that, I will turn things over to Mr. Wessel who is going to argue for Pfizer.

THE COURT: Very fine. Mr. Wessel, you have the floor.

MR. WESSEL: Good afternoon, Your Honor, and thank you. Your Honor, this is a very unusual case as you might have gotten familiar as you read through all of the briefing materials and the background. But here all of the parties in interest, the Defendants Pfizer, Ventavia, Icon, and the United States of America, which is the Plaintiff and the real party in interest on the Plaintiff's side, all of those parties --

THE COURT: You noticed I did not mention them when I called the style of the case because they have refused to participate in this.

MR. WESSEL: Yes. I wasn't aware that they refused. I know they made their submission, but I wasn't sure whether they had recorded anything as to the argument.

THE COURT: I believe too, that Mr. Lockhart I think has been terminated, if I am not mistaken, as counsel. Am I wrong? No, it's not. It is just Dykeman has.

Well, the Court has been advised they are not going to join. But that if and of itself doesn't

automatically mean there's no materiality, does it?

MR. WESSEL: No, no. Of course, Your Honor. And, in fact, I think the Government's focus is really more on plausibility under *Iqbal* rather than materiality. We have a clear view on materiality. I think it's crystal clear that all of Relator's claims weren't material to the Government's decision to pay. But I can get into that at length, and, Your Honor, feel free to interrupt me. I can sort of give you our sense of the background in the case if that's helpful.

THE COURT: Yes, please.

MR. WESSEL: Great. So, really, as I mentioned, all of the parties in interest agree the case should be dismissed. The person who doesn't disagree is the Relator, Brook Jackson, and she brings her claim on behalf of the United States. So it's not her claim. It's the United States claim. And, really, what's happening here is by bringing this case under the False Claims Act, Ms. Jackson and her lawyers are trying to substitute their judgment about the safety and efficacy of Pfizer's vaccine for the judgement of the experts, the FDA. That's the Government agency, the policy agency, that's charged with making a decision on whether a vaccine or other drugs are safe or effective.

So that's really our sense of what's going on

here. We feel there's sort of three points here why dismissal is appropriate, three key points. One is what I have mentioned, all parties in interest agree it should be dismissed. And then the Relator's claims really aren't plausible and this is what the government has weighed in on in their statement of interest. They are not plausible as required by the Supreme Court in the *Iqbal* decision.

And then, finally, materiality which your Honor highlighted, and it's crystal clear that Relator's allegations just weren't material to the government's decision to pay for the vaccine. The Fifth Circuit has a case that's virtually on all fours here, *U.S. ex rel Harman versus Trinity Industries*.

And as the Fifth Circuit recognized in that case, where the interests of the government and the Relator diverge from each other, as we obviously have here, that kind of case is particularly ill suited to a False Claims Act case.

THE COURT: And in this instance, Ms. Jackson as I understand it from the facts that have been alleged, notified the FDA that certain protocols had not been followed, I think at least was it 1,700 of the test subjects as opposed to the total of over 40,000, I may be a little off on the number, but --

MR. WESSEL: Yes. Basically what the government ultimately concluded, when they got to their point about how the allegations were not plausible, they arrived at it basically by saying only three percent of the study subjects were in the sites that Ms. Jackson worked at. She worked at two sites, I guess out of that, for a matter of three weeks, less than three weeks.

THE COURT: If -- there are many times that in these types of cases that a Relator will go it alone. The government says not interested in pursuing it. And that doesn't mean we just say well, we do whatever the government tells us to do and therefore we throw the case out, do we?

MR. WESSEL: No. Agreed, Your Honor. In fact, the government declining to intervene, which I think is what Your Honor is referring to, is very common. It happens a lot and sometimes the Relator will dismiss after that and sometimes the Relator will go forward and litigate. That's very common.

What's really unusual here is the statement of interest. So we -- I mean the government will sometimes file a statement of interest in support of Relators like Ms. Jackson, that's fairly common. We haven't been able to find one case where the government has filed a statement of interest in support of Defendants. Not one

case; maybe it's out there. You mentioned you guys have gotten some more research beyond the pleadings and maybe you will find one, but we certainly weren't able to find one. So that's what's really unique about the case. Not that the government is not moving forward with it themselves, it is that they're saying we agree that the facts and the law merit dismissal of this case.

THE COURT: My question is, assume as I think I have to assume at this stage of the pleadings, that the allegations are correct. They may be completely false. They may be hocus-focus. I don't know. But given inferences, I have to give them all inferences that support their allegations at this point, correct?

MR. WESSEL: Yes. No, I agree with that, Your Honor. We are obviously not conceding that what they are saying is correct, but that's what the law requires.

THE COURT: If she -- if her claims -- assume they are accurate, that there were some protocols that were not followed in the testing procedures, and then she notifies the authorities at the FDA and they just for whatever reason they decide not to pursue it. Does that necessarily mean that her claims are not valid? In other words, it could be under one of the three theories I talked about earlier, a false claim was made in the

inducement for example.

And just because maybe for political reasons or otherwise a governmental agency decided to ignore her complaints, does that mean then that her complaints are invalid?

MR. WESSEL: Well, I'm not quite following what Your Honor might mean by "political reasons."

THE COURT: Well, I just said that. It could be other reasons. They felt a need to move on. Could be they said look, we have I think it was 44,000 test subjects and numbers she had from a scientific standpoint is not material enough and therefore we know and scientists agree it is not important and those minor violations in protocol don't matter. It's still valid test results. We can get approval for this.

MR. WESSEL: Right. That's essentially what they have said. They have said her allegations are not plausible because even if they were true, it wouldn't have impacted the study. And it wouldn't have impacted the approval or authorization.

THE COURT: So here we are in court after the fact. Who makes that decision on materiality now?

MR. WESSEL: Well, materiality, Your Honor, I believe --

THE COURT: That's what you are talking about

if you are going to cite the *Trinity Industries* case.

MR. WESSEL: Yes. That's the materiality piece. What I was just referring to there was the government's statement of interest which is the plausibility issue.

THE COURT: Okay.

MR. WESSEL: So materiality I think is crystal clear that the Court decides that. I think it's pretty clear in *Trinity Industries* and I think the Fifth Circuit and Judge Higginbotham were sort of trying to be kind to the trial judge, but basically what they told him is you got it all wrong and here's the law and we are reversing. And that case, it was even a jury verdict.

So that it is crystal clear that that's a decision for the Court. I think there's no question about it. Plausibility as well under *Iqbal*, but I do agree with you it's a little more squishy, right? It is not quite as clear there.

THE COURT: So you are talking more on a 12(b)(6) analysis now?

MR. WESSEL: Yes, exactly. Exactly. Under *Iqbal* and 12(b)(6) and there what is unique about this case, the government itself, so that's the Plaintiff in interest, the party that has the actual claim, is saying hey, Relator's theory, it just isn't plausible. It just

wouldn't have mattered, even assuming everything she said is true, which again, we are not conceding, but the law requires you to do, that would not have impacted our decision to grant an EUA, the emergency use authorization, or approve the product.

THE COURT: And you are telling me the Fifth Circuit says that decision is simply a matter of law essentially?

MR. WESSEL: Well, I believe, Your Honor, that the Supreme Court says that. Plausibility under the *Iqbal* decision the district court is required to assess, you know, if it's a well pleaded claim whether it is plausible. That's what *Iqbal* says.

And, again, what's unique here is the Court and the rest of us have the help of the government to weigh in on plausibility. So this again is very, very unique.

THE COURT: So the FDA gets it wrong.

MR. WESSEL: Yes.

THE COURT: They just get it wrong and we live with it? There's no oversight by a court; is that correct?

MR. WESSEL: That's correct, Your Honor. On materiality, that's exactly what the *Harman* court held because there was a dispute there going back and forth.

That case involved guardrails, not a vaccine, but that's exactly what the *Harman* court said.

If I might, Your Honor, maybe I could just read you Judge Higginbotham's reasoning there because I think it is right on point. Again, *Harman*, there was a disconnect and a dispute between the Relator and the government just like we have here. It is really on all fours. It involved guardrails, not a vaccine, but it is really the same issue.

And here's what Judge Higginbotham reasoned in that case. And I think it's on all fours here.

What Judge Higginbotham said is, "For the demands of materiality adjust the tension between singular private interests," right, that's the Relator here, "and those of the government and cabin the greed that fuels it," basically what he is saying here, private interest. "As the interests in the government and the Relator diverge, this Congressionally created enlistment of private enforcement," that's the False Claims Act, "is increasingly ill served. When the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud. Rather, it is concluding there was no fraud at all."

And that's exactly the situation we have here, Your Honor, which is a Fifth Circuit precedent decided by

the Court and right on all fours with this case. So that's the materiality issue.

THE COURT: Well, and I guess you would also cite that in conjunction with *Universal Health versus Escobar* too which comes out of the Supreme Court.

MR. WESSEL: Yes.

THE COURT: Now, that came out the year before. Did the Fifth Circuit -- the year before, I call it Trinity Industries only because I once represented Trinity Industries and I think of it better that way, but you call it the *Harman* case, which I will go with you on that. Does the *Harman* case cite the Supreme Court decision in *Escobar*?

MR. WESSEL: Does it cite the *Escobar* decision? I believe it does, but we can double check that. But my recollection is yes, Your Honor.

THE COURT: Okay. So what you are telling me is the Supreme Court and the Fifth Circuit say that if the government says we are not defrauded then --

MR. WESSEL: End of story, Your Honor.

THE COURT: Even though there's a lady here who says I saw the problems. I reported it, and that was not in compliance and then we go back to what I talked about before, you know, drawing the line, to the payments of 154 plus million dollars. After a while it gets to be

real money, doesn't it?

MR. WESSEL: Yes, Your Honor. And that was exactly the situation in *Harman*. That was exactly the Relator there was disputing whether the government bought the right guardrails. It's the exact issue and the government kept saying over and over again, we know what we are doing. We know what we are buying. We bought them. We continue to buy them. Just like here we continue to pay for the vaccine. And we weren't defrauded. That's really -- in some ways, Your Honor, that really should be the end of the story.

The government is the supposed victim of this fraud. And they're saying we weren't defrauded. So it is very difficult to see how you can make out a fraud case with those facts.

THE COURT: Well, unless -- not to sound cynical -- there might be some overriding reason why the government wouldn't want this to come to light.

MR. WESSEL: But, Your Honor, we have no evidence of anything like that. I realize there is various kinds of conspiracy theories and things of that nature out there, but Your Honor, everything in the complaint, all the allegations here, so I have heard, I have seen the Relator's briefing and this talk about the Biden administration and things like that.

THE COURT: I am not talking about any specific administration. This came out over two different administrations.

MR. WESSEL: I have said nothing about administrations in our briefs, but that has been raised in this matter. And, Your Honor, the critical information that went to the FDA when Relator went to FDA's hotline, the FDA was under the Trump administration. When Relator sat down as she says in her complaint for several hours with the FDA, that was under the Trump administration. And when the EUA, that's the operative approval here, the EUA was granted by the Trump administration. So this is not a political issue. It is just not. And to try to make it into one as Relator's counsel has done in the briefing, it's completely inappropriate, frankly. It is just not a political issue.

The vaccine is not a political thing. The FDA knows that the product works. The medical community knows the product works. There's just no question. It is not political. It just isn't. And the government has continued to buy the vaccine under this contract and throughout the pandemic. There is nothing political about it. There's no secret motive here or anything like that. It is just --

THE COURT: Let's take a hypothetical situation, though, where a governmental agency, I am not specifically referring to the FDA or anything necessarily on point with this case, but could there be a situation where a governmental agency for political reasons would just push something under the rug, the complaints of a whistleblower or somebody like that and they just don't want to have this come to light so they just cover it up for political or otherwise reasons and under these standards there's not a darn thing a court can do about it.

It is that kind of --

MR. WESSEL: I think that's probably what the *Harman* case says, Your Honor, but just to be clear, that didn't happen here, because as I mentioned --

THE COURT: I wasn't tying it to this case. Hypothetically, you're saying that even under those circumstances courts are frozen out.

MR. WESSEL: That is what the *Harman* case effectively says. But just to be clear, as I mentioned to you, there was numerous information conveyed by the Relator, all of the information she had was conveyed to the government. It was conveyed to both the Trump administration and it was conveyed to the Biden administration. So there's no big conspiracy boiling

here or someone is trying to hide things. It is just not happening, Your Honor. It is conspiracy theories. It is unjustified conspiracy theories is what we are hearing.

THE COURT: All right. Go ahead and let you get back to your -- I interrupted you there and maybe jumped the gun on you.

MR. WESSEL: No, I am happy to engage there, Your Honor. Perhaps -- I think you did put your finger on several of the key provisions of the contract between Pfizer and the government.

Let me just say one thing on that. The parties to the contract are Pfizer and the United States Government, specifically the DoD branch is the one that executed the contract. They are in full agreement on what the contract says. They don't dispute it. Everything in our briefing and everything in the government's statement of interest is completely in agreement of what the contract says.

So, yes, could Mr. Barnes or someone else speculate, you know, pick apart and try to say it means this or that. The two parties that entered into the agreement have already agreed on what it says. Your Honor kind of hit -- put your finger on the key provisions. So I just wanted to address that up front.

I can go through some more of the background,

I think it might be helpful and obviously interrupt me if --

THE COURT: Go ahead.

MR. WESSEL: -- if I am just going on too long here. But so we mentioned this, early on in the pandemic, this was in May of 2020, and this was under the Trump administration they launched what was called Operation Warp Speed. And this was an interagency partnership that was designed to accelerate the acquisition of Covid-19 medical products, including vaccines.

While Pfizer's product was still being studied, the government entered into this agreement with the company as part of Operation Warp Speed, and you talked about it, to purchase the first one hundred million doses of the vaccine, and the key there is if it was approved, because it wasn't approved at this point, or authorized by the FDA.

So the contract provides that the government will pay $19.50 a dose for the first hundred million doses of the vaccine and again that's contingent on the company first securing FDA approval or what they call an EUA.

An EUA is a little bit unique. It is not the full approval that many of us are familiar with. It is

something that the FDA uses to make vaccines and products available during public emergencies when they may be effective in fighting disease and they can make the product available to the public based on the best evidence available without waiting for full approval.

And in October of 2020, the FDA issued some guidance, and this is all -- everything here, by the way, Your Honor, is either cited in the amended complaint or in the government's statement of interest. But based on -- this guidance provided that based on the totality of scientific evidence that you could grant -- the FDA could grant an EUA if it was reasonable to believe that the vaccine may be effective to treat a serious or life-threatening disease or a condition that can be caused by Covid-19.

The second provision was that the known and potential benefits of the vaccine when used to prevent or treat a disease or condition outweigh the known and potential risks. So that's the guidance that the agency provided on granting an EUA.

As Your Honor pointed out, the contract explicitly states, and again both parties to the contract agree with all this. The contract explicitly states that Pfizer's clinical trials are out-of-scope and they are not related to the contract. That gets to the point Your

Honor was raising before. The government didn't fund the clinical trial. This was just a contract to buy the vaccine. That's what it was for. It was not to fund the clinical trial. Pfizer funded the clinical trial.

THE COURT: Except for the bill.

MR. WESSEL: No, that's for doses of the vaccine, Your Honor. Just to clarify.

THE COURT: I understand. But it makes reference to in accordance with the agreement and that was -- if you look at the agreement, and I am looking at Section 5.0 of the agreement, it says provided the FDA has granted approval or authorization, which it did, but if it did so under false pretenses, then you see the problem, potential problem.

MR. WESSEL: Yes, I do see that potential problem and that's something that the government talked about in their statement of interest, Your Honor. What the government says is yes, if there was any information that somehow subjects ended up in the placebo category that should have been in the category that got the vaccine.

THE COURT: They didn't warm it correctly, they warmed it in their hands.

MR. WESSEL: Well, that's what the allegations are. But what the government is saying is

warming in the hands is not going to impact the results of the study necessarily. What the government is saying is you need an allegation that somehow there was some hidden safety factor here, right, something that people hid or something -- or you miscategorized subjects into one category that should have been in the other category. Obviously, that could impact the outcome. What the government has clearly said is that's not an allegation that's here. And that's why they conclude that Relator's claims just aren't plausible.

So that's not what is happening here. So that would be -- that's that fraud in inducement theory which, by the way, has not been recognized. I think is really questionable. This is in our briefing. I think after *Escobar* I think it's very questionable whether it is a valid theory. But assuming arguendo it is, the government has come to this conclusion that those allegations just weren't there. There are no plausible allegations that Relator could make with regards to that.

So I think the important thing, Your Honor, about the contract, it's an acquisition agreement. It's a purchase agreement. It's not the funding of a clinical trial. We would be in a totally different situation.

THE COURT: Agreed with that.

MR. WESSEL: So that's really important

because that gets mixed up a lot. So that is crystal clear. The agreement goes on to say, again, this is all in the briefing, the pleadings, that the government has no right to withhold payment for delivered doses for any reason unless the FDA has withdrawn approval or authorization of the vaccine. That just didn't happen here, Your Honor. It didn't happen. Again, just I'm not trying to be political, but that's what this has kind of turned into.

THE COURT: They never withdrew their authorization, but the question is should they have granted it in the first place.

MR. WESSEL: Well, they made that decision. They granted it and they knew they granted it and they never withdrew it. So, again, that is what the *Harman* case says. It's a policy decision for the government. It's not for me to make. It's not for the Relator to make. It's not for Mr. Barnes to make. It's the government's decision. They are the policy making body. We can't have everybody else in the world weighing in. They are the experts who are charged, whether you like them or not, they are charged with deciding whether the vaccine is safe and effective and they did decide that and they have continued to support it and express confidence in the data and the government has continued

to buy it.

THE COURT: I think you haven't really discussed it, but there may actually be a little bit stronger quote out of the *Escobar* Supreme Court decision. If the government pays a particular claim in full, despite its actual knowledge that certain requirements were violated, that is to say, they had actual knowledge of what Ms. Jackson has told them, that is very strong evidence that those requirements are not material.

MR. WESSEL: Yes. And that's exactly the language that Judge Higginbotham quoted in the Fifth Circuit case. Precisely the same language. I jumped ahead to the conclusion there, but obviously that's exactly the language that the judge put forth and that's obviously from *Escobar* and from the *Harman* case.

So I think it's important, Your Honor, just to kind of understand all the touch points and all the instances where Relator made the government fully aware of all of her claims. Because, again, this gets to that whole materiality issue which is from the *Harman* case.

So shortly after the contract was entered into, Pfizer launched what became known as the landmark study for the vaccine. This was a placebo controlled randomized study to evaluate the safety and efficacy of the vaccine against Covid-19.

I'm sure most of us are familiar with what placebo controlled means, but essentially what happens is one arm gets the vaccine and the other arm gets a saline injection and that's how it worked. As Your Honor mentioned, there were about 40,000 participants and it was conducted by doctors and staff at 153 clinical research sites across six countries.

THE COURT: Including three in Texas that Ms. Jackson was involved with.

MR. WESSEL: Yes, there were three in Texas that were run by Ventavia. I think she actually worked at two of those three, but, yes, there's three Ventavia sites in Texas, three out of 153, just to be clear.

Ventavia managed these clinical sites. Those are the places that subjects would go to receive the vaccine or receive the placebo. As you are well aware, she claims that Ventavia committed a number of clinical protocol violations and then she listed those throughout her complaint and in the briefing documents. The clinical trial protocol is a document that describes how the study, a clinical trial, is going to be conducted. And the protocol was not part of this contract. That's crystal clear again. All parties agree. As we talked about, clinical trials were out-of-scope and not related to the contract.

THE COURT: Again, I asked Mr. Barnes and I guess I will ask you the same question, contracts often have implied terms, do they not?

MR. WESSEL: They certainly might. But there are specific terms --

THE COURT: The question is --

MR. WESSEL: Absolutely.

THE COURT: First year law school. Contracts can have implied terms.

MR. WESSEL: No question about that, but here the contract had specific terms saying this is not included. This is not included. Because, again, this gets back to our discussion before, the government --

THE COURT: It was not included in terms of payment because Pfizer was going to pay for that out of their own pocket, the developmental cost, but when you get to that other section that I read, 5.0, it talks in terms of provided the FDA has granted approval, and I asked Mr. Barnes, and his position was there's an implied term there, that FDA granted approval based upon valid test data.

MR. WESSEL: Well, there's nothing in the contract that talks about that. Obviously --

THE COURT: It would be inconceivable to have a contract that would say provided FDA has granted

approval based upon fraudulent test data.

MR. WESSEL: Agreed, Your Honor. And that is not what anyone is arguing here. That's what the government specifically addresses in their statement of interest. I mean, they talk about that and they basically say hey, those allegations aren't here. Those allegations aren't made. Now, maybe in another lawsuit Relator can come up with those allegations. But they're not here. They are just not in the complaint. Which is the things that the government was told, right? So they are just not there.

So as I mentioned, you know, so her last day, she worked there for roughly three weeks, less than three weeks. On September 25th of 2020, her last day at Ventavia, this is all from her complaint, she called FDA's hotline to report the clinical trial protocol violations and patient safety concerns that she witnessed. The FDA contacted her shortly thereafter and according to the complaint spoke to her for several hours regarding the violations she witnessed at Ventavia. This is in the amended complaint, paragraphs 262, paragraphs 266.

THE COURT: And after she made that complaint I think a few hours later she was fired, was she not?

MR. WESSEL: That's the allegation, Your

Honor. Of course, Pfizer had nothing to do with her firing, but she says that -- I don't remember exactly when she says it, but she does say she was fired after communicating with FDA.

THE COURT: Okay.

MR. WESSEL: So that's kind of what was told -- she told the FDA and, again, it's the Trump FDA. I am not trying to get political, but some people are, so this is the Trump FDA. And on November 18th Pfizer announced the initial results from the landmark study. And essentially what that said, there was more than 36,000 trial participants demonstrated the vaccine was 95 percent effective and safe. The safety data from 38,000 participants suggest a favorable safety profile and raise no specific safety concerns that would preclude issuance of an EUA.

Based on that Pfizer asked the FDA to grant the EUA. That's the condition. That is the one condition of the contract is it's got to be approved or authorized. And, in fact, the Trump administration issued the EUA on December 11th of 2020. As I pointed out, prior to issuing that EUA the FDA was well aware of what Relator was claiming. And then the government began to purchase the vaccine, you have seen one of the invoices, I think the first one was sent in the end of

December of 2020. You have quoted for us the exact language in the invoices. It's fairly simple.

The government has continued to purchase the vaccine throughout the pandemic and even after the EUA was issued, there are numerous other ways that the Relator told the government about her concerns. All this is really important to that materiality question. Before the complaint was filed, and again this all comes out of her amended complaint, before the complaint was filed, she had submitted a prefiling disclosure statement describing her concerns to the Department of Justice. She also sent a prefiling disclosure statement to the Department of Defense which as we talked about was the government entity that actually entered into the contract.

THE COURT: What is your cite in the record for that?

MR. WESSEL: That's in the amended complaint paragraph 38. I can go through each one of them. Amended complaint paragraph 38 talks about the prefiling disclosure, paragraph -- that goes to the DOJ, same paragraph talks about the prefiling disclosure that goes to the Department of Defense, and again before filing her complaint, and if Your Honor would like I can give you some time to look for this, but, again, this is in

paragraph 38 of the amended complaint.

THE COURT: Which would be page -- well, Document 17?

MR. WESSEL: Let me just try to get you the exact cite, Your Honor.

THE COURT: Is that it? It is.

MR. WESSEL: So this is all in there. And I will tick through it. So kind of going back to the beginning. So before the complaint is filed, right, she submits a prefiling disclosure statement describing her concerns to the DOJ. A prefiling disclosure statement to the DoD, which that's the government entity that entered into the contract. Before filing the complaint she submitted an original disclosure statement. And then quote as well as substantially all material evidence and information. All material evidence and information. This is according to the complaint. She submits that and then she submits that to the DOJ and then she submitted all material evidence information to the U.S Attorney right here in this district. This is according to her complaint.

And then on January 8th of 2021 she files the complaint which has all of her allegations in it. So the government gets all of this information even -- they get the information before the EUA is granted and after the

EUA is granted. They have gotten all this information.

The complaint remained under seal, as Your Honor is aware, after it was filed. That's a standard thing under the statute. The complaint was filed under seal. Relator's counsel suggests in their briefing that somehow the sealing of the complaint and the extension of the seal show that the government initially recognized the merits of Relator's claim but somehow changed its mind. I'm sure Your Honor is aware that the sealing of the complaint --

THE COURT: That's not an issue for me.

MR. WESSEL: It's really just not an issue. So the FDA granted full approval. So having known all this, all of this, I can tick through it all again and kind of wear it out, but the FDA knew all of this and they granted full approval of the product on August 23rd, 2021. So they had the EUA and then they had full approval.

And when they granted full approval, they explained that it went beyond the EUA. It was based on quote, this is again ECF 70 at page five, it was based on incredibly thorough and thoughtful evaluation of the vaccine which included review of updated data from the clinical trial which supported the EUA and included longer duration followup in a larger clinical trial

population. So now you are going well beyond what was even considered in the EUA, the number of subjects.

THE COURT: I would assume Ms. Jackson would disagree there has been an incredibly thorough and thoughtful evaluation of the vaccine by the FDA.

MR. WESSEL: She might, Your Honor. But again, getting back to the *Harman* case --

THE COURT: But she's not the FDA.

MR. WESSEL: That's what the *Harman* case says. What the *Harman* case says is that the government -- it's a classic policy decision. Deciding whether to purchase a guardrail or whether to purchase a vaccine, they are classic policy decisions to be made by the United States Government, not for the Relator, not for their counsel, not for a jury. That is what *Harman* says.

So then there was additional information out there. The Relator spoke to the *British Medical Journal* and there was some articles published by the *British Medical Journal* in November of 2021. And in response to that the FDA responded and said quote, "FDA has full confidence in the data that were used to support the Pfizer vaccine's authorization and approval."

That's ECF 70 at page six.

THE COURT: So they doubled down on it.

MR. WESSEL: Yeah. I wouldn't say double down. I would say they were consistent time after time with expressing their support for the efficacy of the vaccine and purchasing the vaccine.

And importantly, Your Honor, they looked at every single allegation she made. They sat with her for hours. She filed her complaint. Everything went to them. And they still kept the authorization and approval of the vaccine.

So, again, there's our classic policy decision. People may not agree with them. You are certainly entitled to disagree, but you are not entitled to bring a False Claims Act case, Your Honor. You can disagree. That's what we are entitled to do as U.S. citizens, but you can't bring a False Claims Act case based on it. That's what the *Harman* case says.

So I think I have hit most of those things. The key thing, Your Honor, is right here. This is key, right here, this is the government's statement of interest that we have been talking about. This is very unusual as I have said. We have never seen this done in support of the Defendant. It has happened many, many times in support of Relator. But practically never. We have talked about the two key legal issues here, right, plausibility under *Iqbal*, the government has weighed in

very strongly there.

We could go back and forth, Your Honor, on where Relator is with their legal theories because I know Mr. Barnes has taken a position here earlier, but I will tell you that their opposition to the motion to dismiss says Relator's opposition -- it concedes and it says the invoices do not contain false statements. So that's what they say.

THE COURT: That's why I asked that question of Mr. Barnes if he had given up theory number one and theory number two.

MR. WESSEL: That's what ECF 35 at 10 says. But I guess he has decided he has changed his mind here, but that's what it does say.

Again, that really should be the end of the analysis. We talked about fraud in the inducement. I think there's a real question whether that's good law in light of the Supreme Court's *Escobar* decision.

THE COURT: I mean if you -- again, it's not your position, but under the inducement to make the payment for the hundred million units of the vaccine or 154 million and some change, is based upon it would be, I know you don't agree with this, but the only thing that the Court would look at would be this one sentence that says the certification that all costs incurred in

accordance with the agreement, in accordance with the agreement, having that implied term that they are going to seek FDA approval.

MR. WESSEL: Yes.

THE COURT: Is there anything else that you know of that would tie?

MR. WESSEL: Well, there's a lot of things in the agreement, Your Honor, so I don't think there is one thing. I mean, the key thing in the agreement, right, as we talked about is that Pfizer needs to get an EUA or full approval. That's really the key, right? And that's the only way that the government doesn't have to pay. That's clear. That's in the briefing. That's what the government says in their statement of interest. So they talk about that. So it is not really they're not -- when they basically -- and the government, you know, concededly is supportive of this fraud in the inducement theory. Although I think there's a real question if you look at our briefing whether it's valid.

But what they say is that that theory is implausible here because what you would need under that theory, I talked about this before, you need to show that a person went into the placebo group that should have gone into the vaccine group or something of that nature or that there was some safety risk out there that they

covered up. They erased it. They did something like that. And, again, that's just not there. So that's why the government says that's implausible.

THE COURT: Go ahead.

MR. WESSEL: Again, for materiality purposes, I don't think any of that would matter. Even if the fraud in the inducement theory is a good one, and probably even if she had pled it, which she didn't, and pled it accurately and pled, it was well pleaded --

THE COURT: I was going to ask you about that. I understand your *Iqbal* analysis under 12(b)(6). I'm not really hearing you argue their 9(b) component.

MR. WESSEL: Yes.

THE COURT: Because there is a lot, and I want to know if you feel, I often ask myself, when you are doing an *Iqbal*/*Twombly* analysis, don't just give me a bunch of legal allegations. Give me some who, what, when, where, give me some meat to it. And her amended complaint is -- you have to admit -- is jam packed with a lot of facts.

MR. WESSEL: It has a lot of stuff in it, I will agree with that.

THE COURT: Allegations for purposes of where we are in these proceedings I have to assume are true.

MR. WESSEL: There is a lot of stuff in

there.

THE COURT: Whether they are or not, I don't know, but I have to assume they are true. Would the amount of facts they have alleged satisfy 9(b)?

MR. WESSEL: On 9(b), if it's okay with Your Honor, we have sort of split up the argument among the Defendants. So maybe we could hit that after me.

THE COURT: Got it.

MR. WESSEL: As I said, the fact -- we think this concession should be the end of the analysis. Obviously Mr. Barnes has now changed his mind or something is happening here that we don't understand, but anyway, we will continue here. And, again, we don't think the fraud in the inducement theory is a good theory, but assuming arguendo it is, the government has already weighed in and said that they don't think the allegations of fraud in inducement are plausible here.

And we talked about those things. We can just quickly go through those again. In their statement of interest the government points out that the Relator makes no allegation that the data from the Ventavia sites caused the FDA to authorize the vaccine or that the FDA would have revoked authorization had it known about the alleged clinical trial violations by Ventavia. This is the government saying this. They further point out

Relator has made no allegation that the alleged violations resulted in the FDA receiving fabricated, inaccurate or misleading data about safety or efficacy. This is where they go on to reason that Relator's conclusion that the criteria for issuing the EUA would not have been met without the Ventavia data is implausible. This is under *Iqbal*, because one, the decision to grant the EUA was based on the totality of the evidence. So even if you get to a point that the Court needs to accept her allegations as true, even though we don't concede that, but that's not what the approval is based on. The EUA is based on the totality of the evidence. That's what I talked about before. Not just the Ventavia data.

And then the complaint -- and the complaint alleges Ventavia enrolled only about three percent of the patients in the study. So this is the reason the government, not me, concludes that her allegations are just not plausible. That's what they say. And I think we went through this before, but they sum it up.

They say, "In sum, Relator's complaint lacks factual allegations that would support a plausible claim that Ventavia's clinical trial violations masked problems with the vaccine that were so serious that FDA would have withheld or withdrawn its authorization of the vaccine

had it known the truth such that Pfizer's subsequent claims for government payment for the vaccine could be rendered false."

So I think they are saying, Your Honor, that as you sort of pointed out, there could be a theory here, but it is just not -- her allegations aren't plausible. This is the government, right? This is the supposed victim of the fraud saying all this. So, again, not me.

Maybe briefly we can hit materiality. I think we have talked about that, but just to reiterate sort of my points there.

It is really crystal clear that the allegations by the Relator weren't material. I went through sort of step by step and I will just tick those off again. The government, the scientific community knows the vaccine is safe and effective. The real world data shows that. The government has continued to express full confidence in the data underlying the vaccine despite being aware of Relator's allegations and they have continued to purchase the vaccine.

Again, just reiterate some of the points I hit, the amended complaint, and this is all in there, the Relator called the FDA hotline, sat with the FDA for several hours, filed this prefiling disclosure with DOJ, filed the same thing with DoD, submitted the original

disclosure statement, and I went through and gave you the cites for all this, to the DOJ, submitted substantially all material evidence and information to the U.S. Attorney here in this district and then filed her complaint which again has all of her allegations. And despite knowing all this, the government issued the EUA and issued full approval, the conditions of the contract and they have continued to express full confidence in the data. And most importantly for our purposes, they continue to purchase the vaccine. This is exactly what happened in the *Harman* case. Exactly what happened.

So as I said in the beginning, what Relator and her counsel are trying to do is argue that their views on the safety and efficacy of the vaccine should be substituted for the views of the FDA.

Your Honor, that's very dangerous territory. We can't allow everybody in the world to weigh in. That is for the experts at the FDA. Whether you like them or not, whether you agree with them, you can express your view, but what the *Harman* case says is you can't bring a False Claims Act case that way.

It is a classic policy decision for the experts, not for the Relator, not for her counsel, not for a jury. There is this extreme disconnect between the two, right? The Relator wants to move forward with the

case. The government says the case should be dismissed. So you couldn't get more of an extreme disconnect. I read the language from *Harman*. I think it's just right on point. It's up here on the screen again. And that is precisely the situation that we are facing here. So I don't know if Your Honor has more questions, but I can kind of sum up.

THE COURT: You may go ahead.

MR. WESSEL: In conclusion, Your Honor, the case should be dismissed because all the parties in interest agree, the U.S. Government has pointed out that Relator's claims are simply not plausible and Relator's allegations were clearly not material to the U.S. Government which has continued to express full confidence in the vaccine and pay for it. The Court should heed the United States Government's request to dismiss the case. And, most importantly, the Court should follow the reasoning and precedent of the Fifth Circuit in *Harman*. And the Court should dismiss Counts I and II of the complaint.

THE COURT: All right. Thank you very much. I'm going to go ahead and let the other defendants speak, and I understand there may be three other issues that have not really been touched on. Well, we talked about 9(b) so that's fine, but the ADR component of this, I

don't know if that's going to be discussed or that's even important. I don't know that it is, but you all may want to address that and also the scienter element. There may be other issues. What else would you like to talk about?

MR. DAVIS: I would like to talk about a great deal more, Judge, but first I want to return to the discussion you just had about *Trinity*. Because that case is not only controlling, it's determinative of the outcome here. And the language the Court used in the *Trinity* decision should provide guidance to you in your decision here. The Court noted in *Trinity* that, "Congress enacted the False Claim Act to vindicate fraud on the federal government, not second-guess decisions made by those empowered through the Democratic process to shape public policy."

In other words, when the government makes a decision and perpetuates that decision despite being presented with the evidence of alleged fraud by a Relator, in that case after a trial verdict, in that case after a case involving public safety in which the specifics of the alleged fraudulent statements were far more specific than anything that has been alleged in the entirety of this complaint, the court deferred to the federal agency in that instance because that deference was due based on the public policy choices that had been

made. And the government's decision not to pursue the claim in *Trinity* was as you noted quote very strong evidence. It is not they did not conclude in *Trinity* that it is an irrebuttable presumption. It is a strong presumption.

THE COURT: I simply cited language out of the Supreme Court decision in *Escobar*.

MR. DAVIS: That is correct. And *Trinity* was decided, Judge, not only after *Escobar*, that was a question you asked, but after the *Escobar* decision that was final in the First Circuit following a remand and contains the discussion and a survey of other sister circuit's laws regarding similar issues. And came to the conclusion in that particular case that -- remember, this was a trial judge, "The judgment before us falls short of the FCA's true setting and fails to account for its Congressional purpose in drawing upon private litigation to protect public coffers. The government has never been persuaded that it has been defrauded."

And because of that, the Court overturned the jury verdict and rendered as a matter of law that there could be no recovery in that case.

The statement that you were shown a moment ago from the U.S. in this case, that there was no plausibility to the claims that had been asserted, is a

statement just as it was in *Trinity* that the government has never been persuaded that it has been defrauded. And that is strong, compelling evidence that can only be overcome by specific allegations strong enough to overcome the deference due to that public decision.

THE COURT: I'm sure you will appreciate I am obligated to follow the rulings of the opinions of the Fifth Circuit as well as the Supreme Court, and the Fifth Circuit did as I recall in the *Harman versus Trinity* case rely upon rulings from the First, Third, Seventh, Ninth and DC Circuit courts. My question to you is --

MR. DAVIS: That's correct.

THE COURT: -- are there any other circuits that might take a differing view on this?

MR. DAVIS: I don't believe there are. No. I believe while the specific context of the legal discussion in those other circuits sometimes varied because sometimes as the *Trinity* court noted it is difficult to distinguish between plausibility and materiality and causation. They exist as I think the Court noted at a conceptual juxtaposition. And some of the cases talked about one, some talked about the other. But the courts all shared the fundamental view that a government decision to continue to make payments despite knowledge of the alleged falsity at issue in a particular

False Claims Act case was at a minimum strong evidence of a lack of one of those legal concepts, materiality, plausibility or causation, or perhaps all three.

THE COURT: Let me just ask a question. It's strong evidence as the courts have said, but at this phase, at a motion to dismiss phase, perhaps not at some other phase or proceeding, I am to presume and assume that all the allegations of the Plaintiff are correct.

MR. DAVIS: Well, Judge, you noted that. And, yes, you are as a general proposition, but you are actually only required to give that assumption to facts that are well pled, that are specific, that are not speculative.

THE COURT: These are specific, would you agree with that?

MR. DAVIS: No, not at all, as we are going to see in just a moment if we can go to the Elmo.

THE COURT: Go ahead.

MR. DAVIS: They are not specific. They are speculative. They are conjectural. They are --

THE COURT: Based on her personal knowledge, aren't they?

MR. DAVIS: No, Judge. They are not. Because her personal knowledge is limited. That's a critical point here. She worked for three weeks at two sites

among 160 sites worldwide. She doesn't have personal knowledge of what happened in the details of the study after her departure after only three weeks. She doesn't know or have personal knowledge other than what she may have read in reports that are published or government websites, but she doesn't have personal knowledge of anything that happened after her departure. And her tenure was so limited in scope and time that she cannot have the sufficient specificity required to meet Rule 9(b) standards. And she certainly can't meet that standard in regard to Icon which is an entirely extraneous party to this proceeding. You alluded to that earlier in connection with the case. Icon did not contract with the government. It was hired by Pfizer. Icon did not receive payment from the government. It received payment from Pfizer. Icon did not, could not have and never would have submitted certifications for payment to the government false, true or otherwise. Icon did not, could not and would never have made statements directly to the government in support of a payment to be made by the government because it wasn't a government contractor.

THE COURT: I was -- I mentioned before that perhaps your client Icon might have perhaps a stronger defense than the other Defendants perhaps, with -- and I

recognize you all are sitting at counsel table and probably want to cooperate as much as possible, but with the scienter element, Icon was the middleman in this process, correct?

MR. DAVIS: It is not even the middleman. It wasn't directly -- it wasn't the contractor for Ventavia. They were both contractors to Pfizer. It is more akin to an owner's representative or a safety inspector at a construction project who is there to help manage, coordinate and supervise the work being performed on behalf of other people and that was necessary here because of the size and the scope of the global trials that were occurring all over the world at 160 different sites.

And so Icon is more of an inspector, of a manager, a coordinator, than it is a middleman in connection with this case. And to your question about is our argument stronger, well, Judge, I think the argument on behalf of all three or all the Defendants is at least a ten. And if you are familiar with the phrase, in Icon's case it goes to 11 because it had no role whatsoever in anything to do with presenting a false claim.

THE COURT: Even though the Plaintiff claims you should have used more due diligence I guess I should

say to investigate the underlying data for the information that was being sent up to you?

MR. DAVIS: Well, Judge, fortunately we do not even have to characterize what the allegations were because in the Relator's opposition to motion to dismiss at pages 15 and 16, they helpfully summarize for us what those allegations were. And they list nine. Icon is barely mentioned in the complaint. Mentioned even less frequently in the exhibits that are attached to the complaint. Here at these -- in these nine numbered paragraphs, the Relator identifies those allegations of false claims and false statements made by Icon.

And if you look at them, Judge, the first five don't involve statements of any sort. Certainly not false statements. Certainly not false statements made with scienter. There are for example, the fact that Icon had access to all trial data. Icon had access to electronic diary data. Icon and Pfizer are responsible for data management. Those are background facts. Those are not allegations of fraudulent conduct. Those are not allegations of false statements. Those are details.

The next four -- and that's true of all of the paragraphs I through V. Beginning in VI, there are three alleged violations of various statutory provisions, regulatory requirements, that are generic. There is

nothing specific again in regard to a specific statement that was made. No who, what, when, where and how. Any particular communication. It's simply the bold and conclusory allegation that Icon violated 21 CFR Section 312.64(b).

Even if that were true, which it is not, even if that was true, that wouldn't qualify under the False Claims Act. As we have cited to in our brief, there are a number of cases and specifically the *Thompson versus Columbia Health Care Corporation* decision from 1997 when the Fifth Circuit held that alleged regulatory violations don't qualify as false claims, false statements under the FCA. And they noted there in coordinating the approach with a Ninth Circuit decision that, "The Ninth Circuit has taken a similar approach concerning the scope of the FCA. In *United States ex rel Hopper versus Anton*, the Court held that violations of laws, rules or regulations alone do not create a cause of action under the FCA. The Court concluded, however, that false certifications of compliance create liability under the FCA when certification is a prerequisite to obtaining a government benefit."

And when I said earlier that these allegations lack specificity, it is not merely that in regard to Icon they are conclusory, they are arguments, they are legal

conclusions rather than factual bases, it's that there's no connection. There is no allegation, we will see the only one that exists in a moment, that this alleged failure to comply with these regulatory provisions, it was a prerequisite to obtaining a government benefit.

First of all, as I noted, Icon didn't obtain government benefits. Second of all, there's no link between these alleged violations and the subsequent payments that were issued to any other party, nor is there any indication that these alleged violations were in any way material or caused the government to make a payment it would not otherwise have. And, in fact, that argument is contradicted by the allegations in the complaint that were discussed with you earlier regarding the disclosure to the FDA. Whatever the Relator in this instance is alleging that Icon did in failing to immediately report all adverse incidents to Pfizer, she did when she reported it to the FDA. So there can be no causation. Her allegations are contradicted by the details contained in her complaint.

That lack of specificity, that lack of scienter, that lack of fraud, is similarly true for enumerated paragraphs seven and eight from the Relator's response. Eight in particular is -- seven in particular is interesting. It says Icon and Pfizer violated a CFR

provision by electing not to properly secure compliance or discontinue shipments of the vaccine.

First of all, it is hard to imagine a greater speculative leap than assuming that the information which Ms. Jackson obtained during her brief tenure at Ventavia and its small portion of the global trials that were being conducted here justified halting work on a vaccine in the midst of a global epidemic. But it's even more ridiculous when you consider the fact that she herself reported that information to the FDA and they chose not to act.

Again, nothing in this allegation, none of the eight we have seen so far involve falsity, presentment, a knowing statement, the requisite scienter, none of it satisfies Rule 9(b). None of it -- by the way, none of these allegations identify who made the alleged statement. Of course there are no statements. They were either background facts or alleged regulatory violations, so there can't be any specificity as to who said what, when, to whom, how and why because they are not statements. And that's nowhere more apparent than in paragraph 9, the last, the last allegation made against Icon. And that is that Icon failed to follow up on 100 outstanding inquiries about missing or inconsistent data. That isn't a statement. That isn't false. And to my

point earlier, Ms. Jackson does not even allege a basis on which she could know that to be true. That is a speculative allegation. She was there three weeks. She doesn't know that the day after she left follow ups were done. Maybe they were, maybe they weren't. She can't know it and she doesn't allege it. She just comes to this conclusion regarding Icon's conduct, none of which has any application or scope within the False Claims Act.

Perhaps in recognition of that deficiency, though it is not an enumerated paragraph, the Relator does in the opposition go on to talk about a form that was submitted. Form FDA 1572. And it says that Icon certified in its form FDA 1572 it would abide by those protocols and regulations. And then it goes on and says in the same paragraph that it wasn't submitted to the government. It was submitted to Pfizer. Pfizer may have packaged it and submitted it to the government as part of its overall application for the emergency approval, but Icon didn't submit it. It is not required to be submitted to the government.

And the only case we have ever found that even references Form 1572 was a decision called *Gross versus Aids Research Alliance* from 2005. It was one of several forms cited by the Relator in that particular case which was I believe a Medicare fraud case that was being

brought. The Court in the *Gross* decision said, "In our view the insufficiencies in Gross's second amended complaint relate instead to the first element of the claim which in a nutshell requires that the fraudulent statement's purpose must be to coax a payment of money from the government."

And that's language I would like the Court to remember in just a moment when we look at this form.

The form that you submit has to be submitted or prepared or at least signed for the purpose of coaxing payment from the government. Well, there was no coaxing here by Icon. We weren't paid by the government. There was no allegation that we were paid by the government. There's no allegation anywhere in the complaint that Form 1572 was in any way central to a payment made to us by anyone for that matter. We are going to see the form in just a minute.

The Court went on and said, "As the statute itself puts it, liability attaches only when a false statement is used to get a false or fraudulent claim paid or approved by the government. Gross failed to plead this element with the specificity required by 9(b)."

Ms. Jackson has failed to plead that element with the specificity required under Rule 9(b) certainly in regard to Icon, but in regard to any of the

Defendants. That's the missing link. That's what is not contained anywhere within what you identified as a very lengthy complaint with a lot of words, lot of paragraphs, lot of pages.

But nowhere in there is there any specific allegation demonstrating that the alleged false statements, some of which are not even statements and none of which in regard to Icon are false, but there's no connection between those alleged statements and getting a false or fraudulent claim paid or approved by the government. That's what's missing in the entirety of the complaint.

And by the way, that Form 1572 talking about Rule 9(b), it's interesting to note the Icon Form 172 is attached as Exhibit 5 to Plaintiff's amended complaint except Exhibit 5 of the amended complaint is blank. It's a representative sample the Relator alleges. But without demonstrating again who made an allegedly false statement, to whom, for what purpose and how it relates to a payment to be made by the government, there is no False Claims Act liability and that's particularly true of this particular form which actually isn't even signed by the company. It is signed by a clinical investigator on behalf of the company. It is to certify their qualifications and experience before they begin working

on the project, not after, not in connection with the payment. It is not a certification of compliance. It is a certification that I have the requisite required experience and attached is a copy of my curriculum vitae.

THE COURT: But with regard to this form, the Plaintiff may not have the completed form because they don't have it, that's not made available to the public; and second, the Defendants in this case asked for an abatement of discovery pending these motions so they haven't been able to find it. The actual document might very well have information that might --

MR. DAVIS: It would --

THE COURT: -- substantiate a claim.

MR. DAVIS: It would not. And that's my point. If you look at it, if you look at the information that's being requested, none of it would substantiate a claim. Discovery would not be warranted. The curriculum vitae of the doctor who signed this particular form would not connect to a false presentment of a claim for payment from the government. It's a form that is signed before the investigation begins. That's my point. Their representative sample alone, even without the details, demonstrates that Form 1572 not only is not, cannot be the basis for a False Claim Act as that was decided in the *Gross* case because it doesn't have any connection, it

doesn't have as the court there put it, a connection to coaxing a payment from the government.

This is a statement of qualification equivalent to filling out a bar application to appear before you here in the Eastern District of Texas. The fact that I may subsequently violate one of the court's local rules or those of the Eastern District doesn't mean that at the time I filled out my form saying I would follow those rules in which I do and which I did, I filled out a form just like this to become a member of the Eastern District.

The fact that I subsequently failed to do so doesn't mean that at the time I signed that document it was fraudulent. It was as -- the degree of specificity that is required here was described by the Fifth Circuit in *Longhi versus Lithium Power Technologies* in which the court there discussing a case, fraud claim that was pursued by the U.S., by the way brought by Relator but picked up by the U.S. and ultimately successfully, but in discussing the law the Court said that in order to prevail on its claims the U.S. must "demonstrate both the statements or omissions were literally false at the time they were made and that LBT," the Defendant in that case, "actually knew of and was willfully blind to or acted with gross negligence plus regarding the falsity of those

statements or omissions."

This form can't qualify as the basis for the imposition of liability under the FCA and there are no allegations in the complaint, nor could there be, regarding the person who signed it on behalf of Icon or Ventavia for that matter, had knowledge of the falsity of those statements at that time that they were made.

They couldn't have predicted the future. They couldn't have anticipated what might have occurred at some point in the future and, you know, in one of the Fifth Circuit cases that is particularly controlling, I think the Fifth Circuit put it really well.

In *Johnson versus Kaner Medical Group*, the Fifth Circuit said, "Under the FCA a lie is actionable, but not an error."

And that's what the Relator is claiming. Setting aside the question and the fact that she disclosed all of those alleged errors to the FDA which continued regardless to approve the drug and make payment for it, what we are talking about, what is required at its heart in a False Claims Act is a case. This form -- I am sorry -- is a lie. This form is not a lie. It can't be a lie. Doesn't matter who signed it. Doesn't matter what the curriculum vitae was or their home address was. It wasn't a lie. There may have been

errors in the subsequent prosecution of the trial, although I would note for the court that identifying those errors which are inevitable in any large scale study of this nature was the purpose of hiring Icon in the first place.

Finding errors, trying to address them, trying to correct them in the management of the study is what Icon was hired to do. But if it made a mistake in connection with that process, that's not a lie. It may or may not be a regulatory violation. It wasn't. And the government has never suggested otherwise. It may or may not have been a mistake. It may or may not have been an error, but it was not, it cannot be a lie. And the Relator attempts to evade that. In paragraph 277 of the amended complaint which is in essence the only allegation in the entire complaint in all of these hundreds of paragraphs regarding the alleged scienter of Icon, what they say is in connection with that Form 1572, they say the acknowledgement and certification, and they mean the Form 1572, was rendered false by Ventavia and Icon's violations of the clinical trial protocol, FDA regulations and fraudulent conduct described supra.

Rendered false is not actionable under the FCA. As I noted a moment ago in the *Longhi* case, you have to show that at the time a statement was made it was

false, the Defendant knew it was false or acted with gross indifference to its falsity at the time the statement was made. Because as the Fifth Circuit has noted, the FCA sanctions lies, not errors. Nothing can be rendered false subsequently.

Judge, it's the equivalent of taking a breach of contract case and claiming that every breach is a fraud. It is not. The fraud, the knowledge of a false statement has to exist prior to the execution of that contract.

That wasn't the case here. It can't be the case here. It could never be the case here regarding that claim. All of the allegations, even if you assume they are true, every single allegation regarding Icon and to the most part Ventavia as well and Pfizer, they are allegations of errors. Not allegations of lies. And not only do they need to be allegations of lies, those lies have to connect. Those lies have to have a causal connection to a payment that was received. And that's what the False Claims Act boils down to. Those two elements. There are all kind of details, all kinds of ramifications, but that's it. You got to have a lie and that lie has to be connected to a payment. And despite the plethora of allegations and innuendoes that are contained within this complaint, there are no lies,

certainly not as to Icon, and there's no allegation of how that connected to a payment.

And when you take those two facts, those two inevitable conclusions, and couple that with the materiality issue that's indicated by the decision by the United States not only to not pursue this claim, but to file the notice of interest that it did, there's no question that this claim should be dismissed and it should be particularly so in regard to Icon. Which, and I'm not exaggerating, we have just reviewed Relator's own characterization and summary of all of the alleged false statements by Icon. None of them were even statements. They were certainly not lies. And there was no allegation of how they related to a claim for payment submitted to the government.

The question then becomes whether or not the dismissal should be with prejudice. And I submit to you that it should, Judge, because certainly in regard to Icon, and we believe in regard to the other Defendants as well, amendment would be futile because of what I just discussed. Errors cannot give rise to a basis. Subsequent errors cannot render a previous statement actionable under the False Claims Act and the Fifth Circuit recently addressed that in the *Ex Rel Porter versus Magnolia Health Care Plan* in which the court dealt

again, I think this was Medicaid this time payment violations, in a really remarkably analogous situation. It was a Mississippi case involving a nursing home care provider who was rendering and billing for services which the Relator claims could only be rendered or provided by registered or licensed nurses. That was the fundamental issue in the underlying case. And that just like here, just as the Relator here asserts, that those regulatory violations gave rise to false claims, but that case was stronger. Because in that case there were actual certifications that were submitted to the government in connection with actual payments regarding regulatory compliance. That was after the fact. That was when I send my bill, not when I get hired as is the case with the Form 1572. And in the *Porter* case the Fifth Circuit said, "A misrepresentation cannot be deemed material merely because the government designates compliance with a particular statutory, regulatory or contractual requirement as a condition of payment."

That's what they are alleging here in regards to 1572. It isn't true in regard to 1572. But even if it were, under the *Porter* case a generic requirement that you follow the laws, that you comply with the FDA rules and regulations, is not sufficient to give rise to liability under the FCA. The court -- here the district

court concluded that the contracts between Magnolia and Mississippi can, "Contain broad boilerplate language generally requiring a contractor to follow all laws," which is the same type of language.

In that situation, the Fifth Circuit, the district court found and the Fifth Circuit ruled the same, that when the alleged reliance was on this broad regulatory compliance that was contained within the contracts, and this is in a case where they actually paid money to people who probably did not comply with the applicable regulatory scheme, they concluded that it would be futile to allow them to amend because those allegations can never give rise to liability under the False Claims Act. And though they did not say so, the rationale was clearly what they had said earlier in the other case I referenced you to, and that is the False Claims Act only governs a lie, not an error. And that can never be different here for us or for any of the other Defendants and we, therefore, ask that you dismiss the claim against Icon and that you do so with prejudice.

THE COURT: Thank you very much, Mr. Davis. Let me just ask the question about how much time will Ventavia need?

MR. GUTHRIE: I think I can probably get through it in 10 or 15 minutes.

THE COURT: That's fine. And then I'm going to give Mr. Barnes an adequate opportunity to respond as well. But we have been going a pretty good time here. And I think that it is appropriate that we all take a ten-minute comfort break. So we're going to be in recess for ten minutes and we will resume.

(Recess, 3:50 p.m. to 4:05 p.m.)

THE COURT: Are you ready to proceed?

MR. GUTHRIE: Yes, Your Honor. Thank you, Your Honor. May it please the Court. I am going to try to not replow all the same ground that you have just heard. I will say I just want to add to the last point that Mr. Davis was making on the *Porter* case, I just wanted to kind of throw that on the pile for materiality because that is a recent Fifth Circuit case where the court affirmed the dismissal of a pleading at the Rule 12 stage based on a materiality consideration. You have heard all about it. I am not going to go into it. I would just note that for your reading that the court there said when the government continues to pay despite knowing about these allegations, that's this very strong evidence of materiality and the court said the Relator there did not meet it. This Relator has not met it. I said I wouldn't talk about it. I'm going to move on.

THE COURT: Let me just add one thing. I have

heard the term strong evidence. But I haven't read a case yet, maybe you are aware of one, that says conclusive evidence. Is there?

MR. GUTHRIE: And that's the point that I am making from the *Porter* case, Your Honor, is that when you have got continued government approval.

THE COURT: That's not conclusive.

MR. GUTHRIE: It's not conclusive, but what the Fifth Circuit says is that's very strong evidence and the Relator there did not meet his increased burden, I think it might even say substantially increased burden, to plead materiality in the face of that fact.

So I'm agreeing with you, it is not conclusive. But the Relator still has a burden to meet her pleading burden in the face of that really high bar. Look at the *Porter* case. The *Porter* case says the Relator didn't meet it. This Relator hasn't met it.

What I am going to do in my time and what I have been tasked with doing is focus on two issues that pertain just a little bit more closely to my client, Ventavia. The first issue is the Relator's failure to allege causation for her theories of False Claims Act liability against Ventavia. You heard a little bit about that from Icon. I really am going to try to edit and not overlap. But that claim requires dismissal as to

Ventavia. Second, I'm going to focus on the retaliation claim which only goes to Ventavia because only we were her employer. But that claim also fails as a matter of law under settled Fifth Circuit precedent and even if you take everything that she says at face value.

So those are the two things that I'm going to hit. Let me start with causation. As I said, I think, it's important to frame that we agree with everything that Mr. Wessel and Mr. Davis said, that this claim fails as to every Defendant. For the failure to plead the details of a false claim, for lack of materiality, I'm skipping past that and I am going straight to this causation element.

And the reason why this matters is the False Claims Act is a penal statute. The Relator has an obligation to plead every essential elements of her claim against every individual Defendant. She doesn't just get to lump a bunch of Defendants together. And she has not pled that Ventavia itself violated the False Claims Act. Why is that? Two points. One, there's no dispute Ventavia did not directly submit any claims for payment to the government, did not receive any government funds, and the Fifth Circuit has said time and time again that false claim for government payment is the core element of a claim under the False Claims Act.

She cannot get there as to Ventavia. She can't get there as to Icon as you just heard. The only even arguable false claim here is Pfizer's invoices to the government. So we are two layers removed and that's not false for all the reasons that you have heard.

But when we are talking about Ventavia, we are two layers removed from that so she's got an uphill battle. Now, it is possible to have what we have called indirect theories of False Claims Act liability, but to do that, she has got to allege again with the particularity required by Rule 9(b) that Ventavia caused Pfizer to submit a false claim or that Ventavia made or used a false record or statement that caused the submission of a false claim. So this is a causation standard. It's a proximate causation standard. The Relator has not challenged us on that. This is a standard that says to show that you caused the submission of a false claim requires more than just even knowledge that a false claim was being submitted or passive acquiescence. There must be an affirmative act on the part of the indirect Defendant that was a substantial factor in inducing the submission of a false claim for government payment. And she cannot get there.

And if you read her response, I don't even think she argues that she can get there. Because in her

response, all she does is allege this but-for chain of causation. Right? She says but for the alleged clinical trial violations at Ventavia the FDA would have never granted this approval, there never would have been any payments. That's wrong. You have heard a lot about it. I will talk about it in a second.

But even if you took that at face value, that's a but-for standard, not a proximate causation standard. I mean, every first year law student knows but-for is a lower standard than proximate causation and she hasn't tried to meet that proximate causation standard. She certainly hasn't done so with the who, what, when, where, why required by Rule 9(b).

Let's take her allegations at face value just for now. I don't even think she has alleged but-for causation as a matter of pleading under the federal pleading rules. You have heard this. I won't go over it again. The participants at Ventavia sites were less than three percent of the overall clinical trial. I think she says 1,500 in her complaint. I think the real number is 1,100. We can use whichever number you want. It's less than three percent. And there is no allegation anywhere in the complaint that any of those data points, much less all of them, were the defining factor in the FDA granting approval of this vaccine. And that wouldn't make sense,

right? There's 42,000 other data points to go off of. And the United States in its statement of interest, Mr. Wessel touched on this briefly, I'm not going to go over it again, but the United States said on page 11 and 12 of the statement of interest that first of all, she hasn't connected up her alleged violations of the clinical protocols with problems of the safety and reliability data, but we can put that to the side for a second. The United States says even if, even if she had alleged problems in the data, it would not have changed the approval decision because it's based on the totality of the scientific evidence and there are these 42,000 other data points. So this does overlap to some extent with materiality, but causation is an independent element. It is one that she has not pled with particularity under Rule 9(b).

At a minimum, at a minimum that means that her claims against Ventavia, probably Icon as well, fail on the merits. That's Counts I and II under the False Claims Act.

I want to say more, I am going to move on to respect your time and talk about the retaliation claim which is the only claim that on the defense side I can talk about because we at Ventavia sort of stand alone because only we were her employer. We were her employer

for all of 18 days, but that's 18 days more than any other Defendant. So we are the only Defendant she could even conceivably bring a retaliation claim against. But that doesn't mean it's viable, not even close.

And in some ways, Your Honor, this is the most straightforward claim for dismissal because it does not require you to wade into all of the merits of her False Claims Act theory. We think we are right, we think we should have dismissal on the merits, but for the retaliation piece, the only question that is relevant, and this is under Fifth Circuit authority that I'm going to talk about in a second, the only question is whether Ms. Jackson was engaged in protected activity under the False Claims Act at the time of her termination. She was not as a matter of law, and even taking her allegations at face value, and so in some ways the retaliation claim is a quintessential claim for dismissal.

THE COURT: If we apply the McDonnell factors, how would that -- even assuming they were true, how would it affect Icon or Pfizer?

MR. GUTHRIE: On the retaliation claim I don't think it would, only Ventavia, and I believe in her complaint, Your Honor, she has only alleged this claim against us. So this really does go to us. Counts I and II go to everybody. We think you should dismiss as to

everybody, and we have sort of allowed the other Defendants to take the lead on the argument today, but we have got our own arguments in our brief. Count III only goes to us; that's what I am to going to focus on just to divide up our argument time.

So I think this is sort of the most important fact, that the Fifth Circuit, and most especially in the *Patton* case, P-A-T-T-O-N, not patent. The *Patton* case has drawn a clear line between the kinds of internal reports that do qualify as protected activity under the False Claims Act and the kinds of internal reports that do not qualify. So to be protected activity to give rise to a retaliation claim, the Relator must have complained about false claims to the government, not merely criticized the company's business practices. And this is not just a technical distinction.

So what the Fifth Circuit explained in *Patton* is as an employer I am entitled to take a suggestion for improvement as what it is and not as a precursor to litigation. So if you tell me you think I'm doing things the wrong way, that doesn't give rise to a retaliation claim because you haven't told me that you think I am committing fraud on the government. And that's important because what the Fifth Circuit says is the only way that an employer can have the retaliatory intent necessary to

give rise to a retaliation claim is the employer must know that the employee is raising concerns about false claims for government payment.

We don't have that here. Ms. Jackson does not allege, if you go look in her response, what she says is I complained repeatedly about violations, alleged violations, of the clinical trial protocols and about FDA regulations. Those are not complaints about false claims for government payment. That's what goes to the heart of an FCA claim. That's what's required for protected activity and it makes sense that she wasn't talking about false claims for government payment because Ventavia didn't get any government payment.

THE COURT: Payments hadn't been made yet.

MR. GUTHRIE: Say that again?

THE COURT: The payments had not been made yet.

MR. GUTHRIE: Ventavia never got any money from the federal government. The trial was privately funded. So the only party who ever asked for money from the federal government was Pfizer, so she wouldn't have even been thinking about false claims for government payment.

And so that failure, and I'd commend you to go look at the *Patton* case. The *Patton* case from the Fifth

Circuit was a Rule 12 stage dismissal. The district court dismissed the retaliation claim. The Fifth Circuit affirmed because there was no protected activity. And what happened in that case is the Relator said I was fired because I complained about fraudulent construction mistakes on a project funded by the federal government. He called it fraudulent. At least that's what he said. And the Fifth Circuit said that's not protected activity. Because the substance of his complaints were about the construction mistakes. They were not about false claims for payment to the government.

Here's what the court said at page 372. "Mere criticism of Shaw's construction methods without any suggestion that *Patton* was attempting to expose illegality or fraud within the meaning of the FCA does not rise to the level of protected activity."

And that's what we have got here. Because what she was complaining about was these alleged protocol violations. She says, hey, I am different from *Patton* because I have complained about FDA regulations. That's irrelevant. That misses the point. Because go look at the *Escobar* case, right? I think Your Honor might have cited the language earlier. The False Claims Act is not this like generalized regulatory enforcement mechanism.

So even if we had violated FDA regulations, we

did not, even if we had, that doesn't give rise to a claim under the False Claims Act. What matters is were there false claims for government payment. And for the retaliation claim what matters, did you complain about false claims for Government payment. She does not allege that. She doesn't allege it in her complaint. She doesn't try to clean it up in her response.

I will say because Your Honor asked about this earlier, about this alleged call to the FDA. Go look at what she says in her complaint specifically. I don't think it's an accident how precise the terminology is. I believe it's paragraphs 263 and 264 of the complaint.

All she says is she called the FDA the day she was fired. She doesn't even allege that she told Ventavia she had called the FDA. The reason she doesn't allege that is because it didn't happen. She didn't tell us. We didn't know. That's the other requirement here, is that she must be engaged in protected activity. The employer must know that she was engaged in protected activity. Those elements were not met here and for that reason the retaliation claim needs to be dismissed.

I would just point you to two other opinions. I think I promised settled Fifth Circuit law. So I better cite you to at least one more Fifth Circuit case. The *Robertson* case from the Fifth Circuit, that's a 1994

case. That was a case where the Relator raised complaints about billing charges to the federal government and the Court said that's not protected activity as a matter of law. Because it was his job to raise concerns about bills. He didn't say I'm going to bring a qui tam action. He didn't say this is fraudulent or illegal or unlawful. He just raised concerns about the bills.

At best her job here was to raise concerns about the clinical trial protocol. That's what she was doing. Even if we take her allegations at face value.

I will also point you to the *Reddell* opinion from this division. Judge Crone dismissed the retaliation claim at the Rule 12 stage because, again, the Relator there raised a billing concern, did not raise any concerns about illegality within the meaning of the False Claims Act.

So agree with everything that they have said, counsel went into should be dismissed as to everybody, but on retaliation, where we stand alone, she just has not met the elements of pleading a violation.

THE COURT: While I have you here, and perhaps you can speak for all of the defendants here, there is this issue about whether or not this agreement needs to go to some sort of Dispute Resolution Procedure. Is that

really a non-issue?

MR. GUTHRIE: Your Honor, we were not a party to the contract and so I'm not an expert like Pfizer is.

THE COURT: That's one of the points I was going to make.

MR. GUTHRIE: What I would say is I think Pfizer has made the point, I think there's valid grounds for that. I think there are stronger maybe even public interest-type grounds that come in the analysis before you even got to the ADR piece. And so not being a party to the contract I am not going to tell you how to read it. I would just say I think there are stronger grounds here for dismissal.

MR. CARROLL: Your Honor, if I can, Mr. Hoffman -- I think that's the only point that you raised in the early stages of the hearing that we had yet to cover on the defense side. And Mr. Hoffman was going to give you a few minutes on that.

THE COURT: Okay. That's fine.

MR. GUTHRIE: Your Honor, if you have no further questions, I'm happy to sit down. We would ask you to dismiss all three complaints as to Ventavia.

THE COURT: Thank you. Mr. Hoffman, I will let you address this dispute resolution procedure issue.

MR. HOFFMAN: Thank you, Your Honor. It is a

real hurtle for the Relator in this case, the ADR provision. We have been going for almost two and-a-half hours.

THE COURT: Now, she's not a signatory to this contract.

MR. HOFFMAN: She is not, but --

THE COURT: How can it apply to her?

MR. HOFFMAN: It certainly applies to her because she stands in the shoes of the United States Government. This is not a personal cause of action to her. Set aside the retaliation piece. The ADR provision does not apply to the retaliation claim. That's her only claim that's personal to her. Counts I and II are claims brought on behalf of the United States Government. And she stands in the government's shoes and any defense that could be raised against the United States apply equally to the Relator.

And in this case there is clear contractual language in the contract for the initial purchase of the vaccine where the government agreed that before they brought any claim, that's extremely broad language, any claims arising under the agreement, that they had to take those to an administrative proceeding before they could pursue an action at law.

THE COURT: Is this a claim under the

agreement?

MR. HOFFMAN: It absolutely is. I would like, Your Honor, if you would -- with your leave here, to please focus on the actual language of the Dispute Resolution Procedure which is paragraph 7.02, base agreement. That's Exhibit A to Pfizer's motion to dismiss, document 37.

THE COURT: I have it.

MR. HOFFMAN: If you go to paragraph 7.02, it says that the ADR provision applies to, "Any disagreement, claim or dispute among the parties concerning questions of fact or law arising from or in connection with the agreement," and this is the key language, "and whether or not involving an alleged breach of the agreement."

To give the language effect, that means it is not just breach of contract action, it is not just contract based actions. It's any claim, contractual or statutory, that relates back to this agreement. This is extremely broad language between the real parties in interest in this case, the federal government and Pfizer. And any claim that relates to this agreement has to go to a mandatory administrative process before there can be an action in federal court over the dispute.

And it's not unusual for these sorts of

provisions to be in government contracts. Courts have enforced similar Alternative Dispute Resolution provisions in government contracts to block the United States from pursuing False Claims Act claims when they fail to first pursue ADR. We cite this in our brief in the Pfizer brief, docket 37, page 29. There is the *Bankers Insurance* case.

There the Fourth Circuit said, "We do not share the trepidation of the government regarding arbitration of its FCA claim. The government should comply with its contract obligations and it cannot avoid them merely by invoking a statutory civil claim such as one contemplated under the FCA."

And I would also inform Your Honor or ask Your Honor to take note that when the Relator filed her opposition brief on this point they never say that the contractual ADR provisions don't apply to us because I wasn't a signatory to the contract. That's not what they say. They say oh, that's a permissive provision. It says may. That's a complete distortion of what the contract says. I would -- what it really says is, "Any disagreement, claim or dispute among the parties concerning questions of fact arising from or out or in connection with the agreement, whether or not involving an alleged breach of the agreement, may be raised only

under this article."

THE COURT: Well, the way you read that, you kind of de-emphasized the word "may."

MR. HOFFMAN: Well, I can read it with full emphasis, Your Honor, but you have to give effect to the word "only."

THE COURT: But there is a difference between "may" and "shall." Is there not? Doesn't say it shall be.

MR. HOFFMAN: I think that saying may only and shall are synonymous. That's the argument they actually make to try to get out of this pickle. But it's actually a controlling pickle. They can't get out of it.

The ADR provision has to be satisfied before this action can proceed before Your Honor.

THE COURT: Okay.

MR. HOFFMAN: With that, unless you have any other questions.

THE COURT: Thank you very much. Mr. Barnes, we have not forgotten about you. Would you like to be heard?

MR. BARNES: Yes, Your Honor.

THE COURT: Please.

MR. BARNES: We are going to break up the arguments as follows, Your Honor. I'm going to deal with

sort of a general overview on the materiality question and the express and implied fraud claims. Mr. Mendenhall will address fraudulent in the inducement and the ADR claims and anything that I fail to cover.

And then last, Lexis Anderson is going to be addressing the retaliatory discharge claims. As we have provided notice, she is a newer attorney and actually this will be her first oral argument in any matter. I just wanted to say I appreciate the Court having those kind of protocols available. It is increasingly difficult to get opportunities for newer attorneys.

THE COURT: One of the first things I did after assuming the bench was to put that as a general order. I have noticed that a lot of new lawyers did not have an opportunity to get into court as they did when I got out of law school. I tried my first lawsuit a week after I was licensed. That's the way it was. And there's no better way to learn the craft of being an advocate or a lawyer than actually getting into the courtroom and do it.

And so I put in a general order that for new lawyers, even if we don't need a hearing, they can request -- a new lawyer can request a hearing and we will give a hearing to any new lawyer. So how long have you practiced?

MS. ANDERSON: A little over a year.

THE COURT: Good. Well, I am glad to see you take advantage of it. You may proceed.

MR. BARNES: Thank you, Your Honor. As we look at the overarching aspect, I really like Justice Thomas's opinion in *Escobar* because he kind of breaks down the brass tacks. It's a unanimous decision of the Supreme Court. Defendants agree it's the most important in this context.

And Justice Thomas is trying to explain materiality. He is like okay, why are we deciding that there is actually -- we are going to allow an implied theory, we are going to allow people to pursue false claims when there has been no express condition of payment, when there has been no overt false comission statement, when it's only been by omission?

And Justice Thomas gives an example. He says imagine the government bought firearms. And it turned out when they got the firearms the firearms didn't fire. They didn't work to actually be able to shoot anything. He goes imagine that there was no express condition of that anywhere. Imagine there was no regulation or statute that said hey, by the way, if you sell the government a firearm it's got to actually fire. He goes we all recognize that goes to the very essence of the

bargain.

And when we are looking at these False Claims Acts, we should step back and look at what is the essence of the bargain? What is being negotiated here? What is being sought here?

Here, the reason why this statement of the work has all these references over and over again to the clinical trial process and FDA approval and FDA authorization is because what the federal government is buying is as it describes in the statement of work, a safe, effective vaccine for the prevention of Covid-19 that Pfizer is going to get on extraordinary scale and speed. Now, why was there doubt about the speed function of it? Why is the government even involved in this? Why isn't it something Pfizer is doing on its own?

It's because no vaccine had ever been produced in such a record time frame. Hence the label Operation Warp Speed. And that's why what Pfizer was proposing, the statement of work keeps talking about is hey, we have a unique way to get through the clinical trials in incredible speed. We have a new MRNA platform delivery mechanism that will allow us to race through this process and yet still get a safe, effective vaccine for the prevention of Covid-19. Not for its diagnosis, not for its treatment, but for the prevention.

And it is in that broader context that is the scam being disclosed in the amended complaint by Brook Jackson. They focus a lot that she only saw one little piece of it in a period of time. But it was enough to witness disturbing violations of the most elemental rules. Indeed, the statement of work actually says what kind of clinical trial Pfizer is going to do. It refers to it on page 4 of the statement of work which is for the court reporter at docket 17-1, Exhibit 10 to the second amended complaint.

It talks about it being a multi-stage, this is about middle under the clinical and regulatory approach, that Pfizer will be doing a multi-stage and multi-phase trial, including the pivotal efficacy portion designed to generate the data needed to achieve FDA approval or authorization for use of one of the vaccine candidates.

This is a randomized placebo controlled observer blind dose finding and vaccine candidate selection study in healthy adults. The study is evaluating the safety of the vaccine. Indeed, that will be repeated, I mean I thought about going through all of them, but that would be probably duplicate of time. But I have over a dozen instances where the statement of work is referencing either FDA authorization, FDA approval, safety of the process, clinical trials, we need the

clinical trial data. They are even required to produce to the Defense Department what they are also giving to the FDA to include them in audit inspections, to notify them of any risk or any problems or any warnings or any issues. That's there because that's the essence of the bargain. We are going to have this incredible clinical trial process that is going to uniquely achieve speed and scale that will give you a safe, effective vaccine for the prevention of Covid-19, words that are used I think a half dozen times.

As we stand here today, when Brook Jackson filed this, she had just witnessed every clinical protocol violation that she could have ever seen in all of her work all happened at once. She saw it at every level. She saw it at such scale, at such severity, she reported it to everyone she could. And when she went up the food chain, she was ultimately fired after she reported it to the FDA.

What she was witnessing is what we now know and what the world now knows, according to the government's own vaccine adverse event reporting system, this particular drug turns out not to be very safe, not to be very effective, not to even be a vaccine, because it doesn't even prevent Covid infection which is what the statement of work was all about obtaining. That's why we

claim that the invoice is false because the invoice uses the language about we attest, we certify, that this is -- I think the exact words are in accordance with the agreement and right after that it says the work reflected has been performed, the work in the statement of the work. That language is not coincidental. That invoicing language comes from the statement of works reference back to the base agreement which is at document in the docket 37-1. And in provision 5.04 (a) which is under 5.04 invoicing instructions, and it talks about payment method types. And what are they talking about? They have all these different ways you can invoice, but in each one the same language keeps coming back. Provided that it has verified compliance with the statement of work, provided it has verified compliance with the statement of work. It says that I think a half dozen times in that section.

Indeed, that exact language, I have certified that the amounts invoiced are for costs incurred in accordance with the agreement, that the work reflected has been performed, that language is required by the contract. It also requires that they contain the date of the invoice and contain what agreements that they are in agreement, what agreements that they are in compliance with. They say the base agreement and the project agreement number, the invoice that Your Honor identified,

I believe it's docket 37-2, has that right at the top. It says this is billing for complying with these agreements.

What's in these agreements all the way through is as it says as Your Honor identified at the very beginning, regulatory planning, it doesn't say Pfizer will try, doesn't say Pfizer may. It says Pfizer will meet the necessary FDA requirements for what? For just getting authorization? No, it says for conducting ongoing and planned clinical trials. It makes further clear that the only reason there isn't a bunch of the additional clinical trial language in it, it says here is why. By the way, it says assuming the clinical data supports the application, that's all the way through there as well, they constantly say the clinical data has to support what you are doing. It says, "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."

Here everything about this, going back to Justice Thomas's provision where he talks about what materiality is, about the firearm that didn't fire, where here we had the vaccine that wasn't a vaccine, that wasn't safe and it wasn't effective, that it didn't work as designed, which is a big difference between this case

and some of the cases cited by the Defendants, is he talks about does it have the potential to influence, the capacity to influence a decision maker. Do we have any doubt that if Pfizer had come to the FDA and the Defense Department and said by the way, this drug, we can't tell you it is safe because our clinical data has been compromised. We can't tell you its effective. We can't tell you that it's even a vaccine. We can't tell you it will actually prevent Covid at all. Does anybody believe that that could not have influenced the Defense Department in writing those checks up to $1.9 billion? Or couldn't have impacted the FDA?

And that's the critical issue here. Now, to the degree that there's ambiguity in the contract, then that's reasons for discovery. If there is a need for more particularity, that's a reason for an amendment rather than dismissal. Indeed, I think the words of the Fifth Circuit is there has to be certainty there could never be a claim for dismissal with prejudice to be the remedy.

But to give just one illustration, they cite a case from the First Circuit, *Depuy*, I think they used a different word for it, but it's at 865 F.3d 29, First Circuit 2017. What they fail to mention in that case even though the FDA continued to pay, the Court found

that the violation of FDA regulations such that it led to the device not being the same as the one that was supposed to be the deliverable made it a sufficient claim to get past the motion to dismiss stage.

Indeed, *Escobar* is a perfect example of this. In *Escobar*, the government was apprised and the relevant agencies were notified of the allegations. Yet the First Circuit on remand said the claim survived at the pleading stage. Because unlike the *Trinity* case, which went all the way through trial, the court emphasized that at the pleading stage, it has to be assumed it is material unless there is evidence to the contrary presented in the discovery stage.

So it might be a summary judgment, maybe the evidence will overwhelmingly come in that the FDA will come and say we agree that everything Brook Jackson alleged is true, we have actual knowledge that is true, it doesn't change our position whatsoever. And the Defense Department may say the same. But that's not part of the four corners of the pleadings at this stage of the case. Indeed in *Escobar*, even though they had -- the U.S. Government had not intervened, even though the government had continued to pay the bills at issue, both the Supreme Court and the First Circuit said the claim survives a motion to dismiss. That is for the same

reason as here.

In the end, the statement of work references the FDA will meet these standards because the entire essence of this bargain was a safe, effective vaccine for which the best metrics were clinical trials that complied with the best rules for that safety and efficacy. We now know, Brook Jackson saw, they weren't complying with it. And now the whole world has the consequences. Tens of thousands of recorded deaths according to the government's own vaccine adverse event reporting system, millions of people reporting disabilities and it's because -- not because the FDA has said what Brook Jackson said is true, right now the FDA and the government is taking Pfizer's word for it. They are saying we can't prove it. That's not an argument for dismissal, that's an argument for discovery. Thank you, Your Honor.

THE COURT: Thank you very much, Mr. Barnes. We have more argument.

MR. MENDENHALL: Thank you, Your Honor.

THE COURT: I am just curious, Mr. Mendenhall, you are not in the same law firm; is that correct?

MR. MENDENHALL: That is correct, Your Honor.

THE COURT: But you all work together on cases?

MR. MENDENHALL: We do, yes. Thank you.

THE COURT: Go ahead, Mr. Mendenhall.

MR. MENDENHALL: Mr. Barnes was very expansive in his comments and I think covered a lot of the ground that I was thinking about covering. Nevertheless, the fraudulent inducement issue, I want to make sure that we do emphasize that. And I do -- before I get going on that, I want to talk about some of the cases. I was writing these down as they were being mentioned. *Cimino versus IBM* was one that came up. And the IRS had continued to pay on that case. I just want to go over these cases real quickly. That case did not get dismissed on 12(b)(6). It went into discovery. And it got dismissed after that. Then *U.S. versus Aerodex*, which Attorney Barnes mentioned. They had a generator that they delivered, they were supposed to deliver. Then they had another generator that would do the same thing and they slapped a label on it claiming it was made by a different company. So even though it was the same -- it did the same thing, that lie, that lie, which is the basis of these claims, caused it to be a false claim.

In *Thompson versus HCA*, which I believe was claimed to be very similar to this, I think it was on all fours, they cited that a regulatory violation does not equal a false claim, which we agree with. But this case

did go through discovery again. So it got into discovery as to whether some precursor to the regulation which we have here, the request for an EUA, some precursor activity had occurred. And that did again, it went into discovery. I am arguing against the 12(b)(6) dismissal.

Magnolia Health, that *Porter versus Magnolia Health* is curious to me as well because in reading that case, whether you can use an RN versus an LPN for your staff, you find out that there was no regulation in that case. There was no regulation that they had signed off on.

Here there were regulations and I'm going to move on from these, but most of these cases it turns out they went beyond this stage that we are at now, the 12(b)(6). That's my point. I think we need to get into discovery and to explore particularity, materiality and we also need to explore this issue of fraudulent inducement and what the FDA knew and when it knew it.

And my point with the FDA itself is that Ms. Jackson's complaint, the actual complaint, was filed after the approval. It was filed on January 8th, 2021, whereas the approval came out in December.

And, Your Honor, my experience with the government, and our filings, I hate to say, we submit documents to the government in preliminary disclosures

and they are rarely dealt with in a serious manner.

Only when you get that complaint filed and you're pushing to get their attention do you get those AUSAs in a room to really discuss what's going on. I am just talking about what's going on in the background here. So our federal bureaucracy does not pay much attention to those preliminary filings. Once you have put your name on a complaint and you filed it, that's where you get the attention.

So for me to -- for the FDA to approved it prior to really reviewing Ms. Jackson's complaint, I get that. It fits what I know how our bureaucrats proceed. And then there was a little bit of discussion about the year that went by in terms of the investigation. I think the year does show that some people at the FDA were concerned about what was happening here. And why were they concerned? Because there was apparently a fraudulent inducement to the FDA to grant this EUA. The data that was submitted was fabricated, altered and compromised. And we know from Brook Jackson who was in that site for a little over two weeks what happened there. And some of these may seem minor, some of these may seem more major. But let's just go down the list that she has in her complaint.

Fabrication and falsification of blood draw

information, vital signs, signatures and other clinical trial data. Your Honor, signatures were not on the informed consent forms. They didn't do the informed consent until sometimes after the person had been injected with either a placebo or a vaccine. That informed consent came later. That's not how this works.

Enrollment and injection of ineligible clinical trial participants, including employee's family members. They were paid to come in and participate in this trial. They brought people in who had conflicts of interest, had improper relationships. That is not the type of person that you want to have in a trial.

Failure to maintain temperature control. Basic stuff for the vaccines. And part of that has to do with the failure to hire competent people. People as Your Honor may know who had worked at a taco stand a few weeks before. Failure to monitor patients after injection. Principal investigator oversight failures. They weren't even present. They weren't doing the oversight that they were supposed to do to review and make sure that the clinical trial participants were being treated properly and that this was being managed properly. It just goes on and on. Improper injection of the vaccine, over diluting it, under diluting it, using the wrong needle size, putting it in the wrong place, not

aspirating the needle. It goes on and on.

Safety and confidentiality issues, including HIPAA violations. And I think one of the biggest things that happened that is most important here in any clinical trial is that this was unblinded. There was general unblinding with the patients. This is critical to having proper data that can be analyzed that it is blinded.

And this was generally unblinded. So another criticism that I heard over here was the but-for issue. Well, but-for does have a role to play. But for the false data this EUA would not have been granted. And there's a lot of but-fors that actually matter here. There's the investigational new drug application that had to be submitted. There's the Form 1572 that had to be submitted. There's the IRB reporting requirements that had to be fulfilled. And the DoD as Attorney Barnes mentioned is relying on the FDA and relying on these processes to be carried out properly. It says it right in the statement of work. That's critical. These are all things, but for the failure to follow the IND requirements, the 1572 requirements, the statement of work requirements and the institutional review board requirements, but for that, I mean, all of those things they wouldn't have gotten an EUA unless they had lied about the fact that they weren't following those

requirements.

These regulatory violations destroyed the integrity and scientific value of the data that was submitted to the FDA. That's what all of these requirements are to do, is to maintain that integrity. And the violations caused that integrity to lapse.

The other thing that I want to point out, the other transactional authority contract with ATA, and I think this is really interesting. The government has -- you know, they are talking about payment, how payment keeps going on and on. They won't stop the payments, right? The government under that contract has no right to withhold payment. Come on. No wonder it is continuing. The government has no right to withhold that payment.

One of the things with a national emergency is -- the False Claims Act was passed during a national emergency, the Civil War, and what Lincoln really cared about was the truth and the integrity of our contractors. And that's where we are having a problem here. The truth and integrity has been destroyed in this process and it's resulted in an EUA that is now injuring one out of every 20 people who takes the shot apparently.

I wanted to say a couple of things about the Alternative Dispute Resolution. First of all, I don't

agree that the alternative dispute is arising from the agreement. In fact, when you have a fraud in the inducement, what happens is the agreement becomes voidable, and we think that with the facts that Brook Jackson has brought forward that that agreement can be voided and that requirement for ADR within that agreement then is no longer valid.

The second thing is, this is not pled in our -- or is not briefed, but I want to raise an issue of executive versus legislative power. And I think there is an issue in terms of the legislature, our Congress laying out a process for recovery under the False Claims Act and for a recovery for whistleblowers, and they are not saying anything about ADR. And I think that the executive, this is not a private company now, this is the government, so the executive and the government coming in and signing a contract that gives away a right that Congress created for the whistleblower and for the American taxpayer, I think that's a violation of the separation of powers, Your Honor, and just as I was sitting here listening to the statements that really struck me and I want to make sure the Court is aware of it. I know the Court can take judicial notice of it's -- our legislative versus executive power. The separation of power.

I have a note here about the statement of interest by the federal government as well. You know, it's not whether or not the fraud did influence the decision, which we do think it did. But the standard of the court at this point under 12(b)(6) is could the fraud and the falsity have potentially influenced the decision. We don't have to have -- prove at this stage that it did influence the decision, just that it could have potentially influenced that decision. So I think that's the standard on that and thank you very much, Your Honor.

THE COURT: I just want to ask you, you touched on something and I asked it by way of questions. Under -- what's been suggested is the law that I must follow is set forth by the Supreme Court and the Fifth Circuit, that notwithstanding all these things that you mentioned, that these variations, these failures to abide by procedures, policies, procedures, et cetera, add all that together, assume it is all true, once the government says or an agency says we got that, we are just ignoring that, we are going to go a different route. That's a decision that's not reviewable by the courts and typically we have a series of checks and balances in our Constitution, but apparently under what's been argued, case law says that in this area I as a judge don't have that authority to check and balance on that particular

point. What is your response to their legal arguments?

MR. MENDENHALL: Are you particularly focused on the *Harman versus Trinity* case?

THE COURT: Yes, I am.

MR. MENDENHALL: I think that first of all, if the U.S. Government, if it wants this case dismissed, it can come here and dismiss this case. And it did not do that. So it has allowed the case to continue for whatever reason. I don't pretend to understand what they're thinking. But we have been allowed to continue, and if it wants to dismiss it, it can do it tomorrow. Your Honor is aware of that. And they have been doing that more and more in recent years under the False Claims Act. It is not doing that. Instead, what it did, it said hey, Relator, your fraudulent inducement theory actually is correct, that is one of the ways to go after this, but we think maybe you lack some materiality here.

Guess what? I think what needs to happen then is we need to have discovery, not just against these companies, we also need to have discovery with the federal regulator and the FDA and talk to them about what the standards are. And, Your Honor, I can tell you I have done that in other cases. And it is very interesting to talk to the bureaucrats about what their decision-making is and what the standard should be. And

that's what I think we should be able to do here.

And if the government wants this case gone, why, they can come in tomorrow and get it gone, Your Honor. But for us, I want to say one other thing about that because I think this is something that gets lost a lot. It's been a concern throughout my career.

I think Your Honor and I, Robert, we have seen the power of the jury be diminished over the last several decades. And I think that the sovereign in this country, it is not the FDA. Guess what? It is not even President Biden or President Trump. The sovereign are the people and the people are who sit on that jury and they decide whether our regulations were properly applied, whether our bureaucrats did the right job and whether there were lies told in order to get an EUA in order to get three or $4 billion out of the U.S. taxpayer. That's who needs to make this decision and that's who sovereign is and that's the interest that's material here, is the interest of the people.

THE COURT: I appreciate your comments.

MR. MENDENHALL: Thank you.

THE COURT: All right. Ms. Anderson.

MS. ANDERSON: Good afternoon, Your Honor. May it please the Court.

THE COURT: Yes, indeed.

MS. ANDERSON: And to re-emphasize what Mr. Barnes said, I do appreciate the encouragement and opportunity to participate in oral argument like this. So I will be discussing --

THE COURT: If lawyers don't develop the craft, we might as well take our Seventh Amendment right to a trial by jury and rip it out of the Constitution because we don't have any lawyers who can effectively assert their clients rights in front of the jury and diminish the right of the people to exercise a right of a trial by jury. So I commend you on your joining a great profession and I hope you will continue to develop.

MS. ANDERSON: Thank you, Your Honor. So as was mentioned, I will be discussing the retaliation claim which is exclusively against Ventavia Research Group.

Now, just to start off, I want to emphasize that a retaliation claim is its own entity. A Relator does not have to bring a winning, although Ms. Jackson has sufficiently alleged claims for fraud against the government under the FCA, she would not have to bring those claims or have a winning claim in order to maintain a retaliation claim against Ventavia, her employer.

Now, as was mentioned, to satisfy a retaliation claim she does need to prove that she was engaged in protected activity, that Ventavia knew of that

activity and that she was retaliated against as a result and she has more than sufficiently pled all three of those claims.

Now, Defendant Ventavia focuses primarily on two distinct cases which are both distinguishable from the case at hand and not determinative for a variety of reasons. Now, primarily they do not sufficiently address the 2009 and 2010 amendment to the FCA which expanded the retaliation provision to include acts done by the individual in furtherance of an action under this section or other efforts to stop one or more violations of this subchapter.

So the *Patton* case that was referenced, first of all, is distinguishable on its facts because it was brought by a carpenter against his employer, a construction company. And he complained primarily about faulty construction that was unrelated to certifications or contractual provisions required for government payments, did not reference any federal regulation violations, unlike this case at hand.

Secondly, the *Patton* case perhaps because it failed on the merits to begin with did not address the amendments to the FCA in 2009 and 2010. Similarly, the *Robertson* case was decided before those amendments were even implemented and so should not be determinative here.

Now, we do have some guidance from *Thomas v. ITT Education Services* which is a Fifth Circuit case that expands on the rule for protected activity. Stating, "A protected activity is one motivated by a concern regarding fraud against the government."

This is certainly what we have in this case now. And other circuits have also provided guidance for the Fifth Circuit and shown that to qualify as protected activity, an employee's actions must be aimed at matters that could have reasonably led to a viable claim under this act or shown a distinct possibility of litigation under the FCA.

Now, the Fifth Circuit does not have a published opinion explaining in detail or emphasizing their position on this new amendment and so we can look to other circuits and the unpublished opinion in *Thomas* for guidance on that.

Now, turning to this case at hand, there have just been a bevy of examples of Relator reporting all of the violations that she saw to her employer, Ventavia. From the enrollment and injection of ineligible trial participants, falsification of data, unblinding of the study, issues with adverse event reporting, use of unqualified staff as vaccinators and many other violations that my co-counsel have mentioned; these are

not light allegations. They go to the very heart of clinical trial practice and Ms. Jackson as an expert in this field for a very long time recognized these violations and gave them the weight they deserved and tried at every opportunity through personal conversations, phone conversations, texts, e-mails to communicate these issues to her employer. And she was terminated as a result.

Now, it was clear that Relator was attempting to expose the illegal activity which she knew was going to be used -- these clinical trials were going to be used for the basis of all of the vaccine rollouts coming out and the basis of a very -- I mean an enormous government contract and something that was going to affect the public health of every single citizen in this country. So Ventavia knew that she was attempting to expose all of these federal regulation violations and illegal activity. It was clear that she was investigating these allegations and these violations through photographs that she took, through conversations she had with her employers and her supervisors, through her efforts to contact Pfizer regarding these violations and ultimately her phone call with the FDA alerting them to these fraudulent activities.

Now, Defendant wants to point to the fact or

allege that these do not rise to the level of indicating that there could be a suit. But when you have somebody going to the FDA, a government agency, reporting these violations, it is quite clear that there is more than a distinct possibility of legal action in this case and that she is trying to report illegal activity. And this is exactly the kind of whistleblower activity that retaliation provision is designed to protect.

And as for the third prong that she was retaliated against, I think it's very clear she was only working there for 18 days. She reported a numerous number of violations. On the exact same day that she spoke to the FDA she was terminated.

Now, what Ventavia knew or did not know is something that we have not been able to get into because we haven't been able to engage in discovery, but at this stage it is very clear that they took adverse employment action against her, retaliated her because of all of her complaints, and indeed, a lot of movement that she had made in pausing enrollment and getting them to address violations was essentially reversed as soon as Ms. Jackson left her position.

So for those reasons that I have articulated, Ms. Jackson has sufficiently pled a claim for retaliation against Ventavia and it should not be dismissed.

THE COURT: Very good argument. Thank you. Okay. Is there anything else anyone wishes to bring to the Court's attention?

MR. WESSEL: Your Honor, if I just might briefly respond.

THE COURT: That hasn't already been mentioned?

MR. WESSEL: I will try not to go over already well trod ground and just respond to Relator's counsel's arguments here.

One I do see the courts potentially struggling a little bit with are there sort of implied terms here, right, to the contract and I think possibly the struggle here is this kind of basic assumption, doesn't Pfizer have to comply with the FDA rules and regulations, right, the things that kind of govern clinical trials? And the answer to that is yes, they do. This is an extremely heavily regulated area. And they need to comply with those rules and regulations.

But that's not part of the contract. That has nothing to do with the contract. Now, how could that implicate the contract? Well, if the FDA concludes Pfizer didn't comply with the FDA rules and regulations, they can pull the EUA. They can pull the authorization and then boom, they don't have to pay a nickel. So

that's how that works. But those are not implicitly kind of built into the contract. They are not there and as we saw the clinical trial activities are specifically excluded from the contract. Both Pfizer and the government agree with that. So that's that point.

I hear Mr. Barnes saying his belief that the vaccine isn't safe. It is not effective. It's not even a vaccine. He's entitled to have that belief. That belief is up to him as we talked about, but that doesn't create a False Claims Act case. Mr. Mendenhall talks about how we should have jury trials and let the jury kind of look at this. Well, let me just go back --

THE COURT: That stems to one of my first questions, who decides materiality.

MR. WESSEL: Yes, it is from the *Harman* decision, crystal clear from the *Harman* decision that the court decides that, not the jury. It's fascinating because they get right on that point and they kind of gently chastise the trial judge for allowing the case to go to the jury, so that gets to this whole issue of well, that one got to trial. They are basically saying, judge, you messed up here, trial judge. They say it nicely, but that's what they say.

And then they talk about this policy difference, the difference in opinions which is exactly

what you have here. You have the difference of opinion between Relator and the government. The government has been crystal clear in support of the vaccine, expressing confidence in the data and continuing to pay. Obviously, Mr. Barnes and the Relator and others have different opinions, which they are entitled to have, but they just can't pigeonhole that into -- wedge it into a False Claims Act case.

I am just going to read a little more from the *Harman* case where the court says, "We can assume that this and contrary views are debatable." They are talking about there the debates about the guardrails.

"But we must accept that the choice among them lies beyond the reach of seven citizens of Marshall, Texas, able though they may be. As revered as the jury is in its resolution of historical fact, its determination of materiality cannot defy the contrary decision of the government here said to be the victim."

Then we go on to the language we talked about before.

"When the government at appropriate levels repeatedly concludes that it has not been defrauded, it's not forgiving of fraud, rather, it is concluding there was no fraud at all."

And that's the binding precedent here. As

much as they would love to get this to a jury, as much as they have their own theories and disagreements with FDA, all that is fine, but what the *Harman* case says is that doesn't make it a False Claims Act case. That doesn't make it a fraud. That is crystal clear and that is binding precedent here.

Maybe just one other real quick point. Mr. Mendenhall talks about signatures not being on the informed consent, family members being allowed in the trial, temperature control violations, things of that nature. Again, this is where the government's statement of interest is very good. They say, and this is right in the very first page of their statement of interest, "In the instant case the complaint does not plead a sufficient nexus between the alleged clinical trial violations and the alleged request for payment from the government to support such liability."

The lack of a signature just doesn't allow for a sufficient nexus there. So at the end of the day, the government's position there that this is implausible I think is very strong in light of their description of the alleged violations.

THE COURT: Thank you very much. I will give everybody a chance to get one last word in.

MR. DAVIS: Very briefly, Judge. In the

Relator's response, we heard two basic arguments. One was they would like to debate the relevant merits of this vaccine as was just discussed. That's not an appropriate vehicle for discussion under the False Claims Act and the *Trinity* case is clear in that regard. That is one of three Fifth Circuit decisions which we believe to be binding, controlling and determinative in this particular case and which we would direct your attention.

The second argument that we heard was in essence well, you know what? They're right about the law. One of the attorneys even conceded that regulatory compliance -- a failure of regulatory compliance is not a basis for a False Claims Act alone. It is not. The law is clear on that. But, they say we need to get past the 12(b)(6) motion stage and the courts tend to give us a break. That's the essence of the argument that we heard.

But, again, the Fifth Circuit has already addressed this. You were told for example, about the distinction between the *Trinity* case and the *Escobar* case on remand. The Fifth Circuit specifically addressed that when they were doing their survey of all of their sister circuits in concluding that materiality was to be determined by the court and was controlling and that deference was to be given by the decision of the government to proceed with full knowledge of the alleged

falsity. The *Trinity* court says, "Our sister circuits offer guidance on the impact of the government's continued payment. On remand the First Circuit in *Escobar* applied the holistic approach to materiality laid out by the Supreme Court in determining that the Relator there had met its burden to pay in full despite actual knowledge that requirements were violated. Unlike in the case we decide today, the court found no evidence that the relevant government agency had actual knowledge of any violations when it decided to pay the claims. The court did not decide whether the government's actual knowledge alone disproves materiality."

In other words, in that *Escobar* case on remand, there were no allegations from which it could be determined that the government had full and actual knowledge of the alleged false statements at the time that it made the decision to continue payment. That's not true here. In fact, the wrongful termination claim that's been brought against Ventavia depends upon the allegation that she complained to the FDA disclosing what she now details in her complaint about these alleged failures of the clinical trial.

You can't have it both ways. If that's true, and that disclosure was made, and I understand there's reason to believe that it was not, but that is the

allegation, if that is true, then the government clearly had full knowledge. And it has full knowledge today as represented in its statement of interest where it describes the claims being brought as implausible.

The Fifth Circuit also specifically addresses the question of materiality in the *Porter* case. Mr. Mendenhall told you that he looked at the *Porter* case and determined there weren't any regulations at issue that actually required the use of the licensed nurses. That's not true. That is not what the case says. We would direct you to review it carefully. In fact, quite to the contrary, what the Fifth Circuit found was there was nothing in the contract that required the use of the licensed nurses, but they said specifically that they accepted the Plaintiff's allegations regarding Mississippi law to be true and that they would therefore constitute material fraud.

"We assume arguendo that Plaintiff-Appellant's characterization of the Mississippi statutes and regulations is correct. But the Supreme Court has explicitly rejected the argument that any statutory, regulatory or contractual violation is material so long as the Defendant knows that the government would be entitled to refuse payment were it aware of the violation. Indeed, a misrepresentation cannot be deemed

material merely because the government designates compliance with a particular statutory, regulatory or contractual requirement as a condition of payment."

That is the sum, substance and essence of this case. They are alleging that the obligation, the contractual obligation, to comply with the generic and general FDA regulations and statutory requirements relating to clinical drug trials was the basis for the false claim. The Fifth Circuit has already said that's not a basis for a false claim. It can't be a basis for a false claim. And they went on and said in this *Porter* case that, "Continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the Relator in establishing materiality. Plaintiff-Appellant has not met that burden."

They went on to discuss as I told you earlier in my argument that boilerplate language in a contract requiring compliance with regulations is not a false statement, it cannot be the basis of a False Claims Act case and they found just recently that amendment would be futile. This is the controlling case. This is the determinative case that decides that this case should be dismissed, and it should, and it should be dismissed with prejudice.

One more note. What I didn't hear in Realtor counsel's response was any, among other things, the words Icon or any refutation of the points that I made regarding the supposed allegations of false statements which they themselves have summarized at page 15 and 16 of their opposition brief. Those aren't statements. They are not false. They are not alleged to have been made with payment -- with knowledge of their falsity, and they are not alleged anywhere to be made in connection with the issuance of a payment.

As I think you were told by Ventavia, we weren't paid by the government. This was a privately funded trial. Ventavia and Icon were paid by Pfizer. There is nowhere in the complaint, nowhere in the opposition, nowhere in the argument that you heard today any suggestion that there was any fraud on the part of Icon. And as I mentioned earlier, the Fifth Circuit determined this too in the *Johnson versus Connor Medical Group* case. First of all, they noted there that, "Mismanagement alone of programs that receive federal dollars is not enough to create FCA liability," and that's the essence of the complaint here, that's what they are saying we did, was mismanagement of this program. That's not an FCA claim because as the Fifth Circuit said, and I told you earlier, under the FCA a lie

is actionable, but not an error. There's no allegation of a lie. You didn't hear any argument that there was a lie. There were no lies and, therefore, this claim should be dismissed. Thank you.

THE COURT: Anything further?

MR. GUTHRIE: I will go quickly, Your Honor.

THE COURT: Yes.

MR. GUTHRIE: Let me touch briefly on the retaliation case. You heard this reference to the 2009 and 2010 amendments to the retaliation provision. That doesn't fix anything. We addressed this in our briefing. What those amendments did at best is made clear that you don't have to be bringing a qui tam lawsuit at the time of your protected activity. We have never alleged that that's the problem here. What those amendments do not do, and we have cited the text in our brief, what they don't do is they don't change the law on this internal reporting that you have to report concerns about false claims for government payment, not criticize business practice.

The *Thomas* case that Relator's counsel cited doesn't change that. It says you still have to be motivated by fraud on the government. The *Melchior* case out of the Western District that they rely on emphasizes this point and again Judge Crone in *Reddell*, that came

after the amendments, the 2009 and 2010 amendments to the retaliation claim. Judge Crone applied the same law that we have cited to you from *Patton* and *Robertson* about when internal complaints can be protected activity and when not. So those amendments don't solve anything.

On the merits, I will just say briefly we heard a lot of Judge, please just let us have discovery. The Relator has a burden and it is a substantial burden to even open the door to discovery when we are talking about complaints of fraud when Rule 9(b) applies. Your Honor knows that law. The Fifth Circuit has been consistent about the screening function that Rule 9(b) plays when we have got fraud complaints in the False Claims Act context. The *Nunnally* case, we have cited it in our brief; the *Grubbs* case, I think you have seen that in everyone's brief, that this is not just a matter of oh, can I throw out some -- there is a lot of detail required, and Your Honor is right. There's a lot of detail in the complaint. What there is not, this is not about detail for the sake of detail. There is not the who, what, where, when and why of the essential elements of liability under the False Claims Act. She does not have the details of false claims submitted for payment to the federal government that were material to the government's payments decisions. And she certainly

doesn't have it against all three Defendants. So because she can't meet that pleading burden under Rule 9(b) what does the Fifth Circuit say in *Porter?*

"We apply Rule 9(b) with bite and without apology," and that's what we ask Your Honor to do. Thank you.

THE COURT: Thank you. Anything further from the defense? Mr. Barnes, any last words?

MR. BARNES: Just briefly we do think materiality is a jury decision when there is a dispute in evidence. We think it's a summary judgment decision when there is no dispute in the evidence. But at the pleadings stage it is not something that is grounds for dismissal. If they were right about their main claim that there is an absolute rule that when the government knows about an accusation and doesn't take action that means the Relator cannot even pursue it past a pleading stage, then *Escobar* itself would not have survived it and it did. Thank you.

THE COURT: Thank you very much. I just want to make a comment to all the lawyers. I want to congratulate you for your presentation today on both sides. I also would like to point out I thought the briefs were very well written on both sides and the Court appreciates such fine workman -- quality of the lawyering

and also that you were prepared for today's hearing and made good use of your time.

You advocated strongly for your clients. So my hat is off to all the lawyers who appeared in court and I know there are others probably back at the office who also worked on this, so my congratulations to you.

We will continue to take this case under advisement and we will prepare a written opinion regarding my decision. With no further business to come before the court, we are adjourned.

(Proceedings concluded, 5:22 p.m.)

COURT REPORTER'S CERTIFICATION

I HEREBY CERTIFY THAT ON THIS DATE, MARCH 10, 2023, THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS.

Ruth C. Weese

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RUTH C. WEESE, RDR, CSR

TEXAS CSR NO. 9493 Expiration Date: 07-31-2024