

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA)
ex rel. BROOK JACKSON,)
) Case No.
Plaintiff,) 1:21-CV-00008
)
vs.)
)
VENTAVIA RESEARCH GROUP,)
LLC; PFIZER, INC.; ICON,) Beaumont, Texas
PLC,)
)
Defendants.)

TRANSCRIPT OF MOTION HEARING
May 1, 2024
BEFORE THE HONORABLE MICHAEL J. TRUNCALE
UNITED STATES DISTRICT COURT

APPEARANCES:

For the Plaintiff:

MR. ROBERT E. BARNES
Barnes Law
700 South Flower Street, Suite 1000
Los Angeles, California 90017
robertbarnes@barneslawllp.com

MR. JEREMY L. FRIEDMAN
Law Office of Jeremy L. Friedman
2801 Sylhowe Road
Oakland, California 94602
jlfried@comcast.net

MR. WARNER MENDENHALL
The Law Offices of Warner Mendenhall
190 North Union Street, Suite 201
Akron, Ohio 44304
warner@warnermendenhall.com

APRIL HARGETT, CSR, RPR, RVR
Federal Official Court Reporter
300 Willow Street
Beaumont, Texas 77701

1 APPEARANCES (Continued):

2 For the Defendant Ventavia Research Group, LLC:

3 MS. TARYN M. MCDONALD
4 Haynes and Boone, LLP
5 2801 North Harwood Street, Suite 2300
6 Dallas, Texas 75201
7 taryn.mcdonald@haynesboone.com

8 For the Defendant Pfizer, Inc.:

9 MS. MEAGAN D. SELF
10 DLA Piper LLP - Dallas
11 1900 North Pearl Street, Suite 2200
12 Dallas, Texas 75201
13 meagan.self@dlapiper.com

14 MR. CARLSON WESSEL
15 DLA Piper LLP - Washington
16 500 Eighth Street Northwest
17 Washington, D.C. 20004
18 carlton.wessel@us.dlapiper.com

19 MR. JACK P. CARROLL
20 Orgain, Bell & Tucker LLP - Beaumont
21 470 Orleans Street, Suite 400
22 Beaumont, Texas 77704
23 jpc@obt.com

24 For the Defendant Icon, PLC:

25 MR. ELAI KATZ
McDermott Will & Emery
One Vanderbilt Avenue
New York, New York 10017
ekatz@mwe.com

MR. SCOTT L. DAVIS
Husch Blackwell LLP
1900 North Pearl Street, Suite 1800
Dallas, Texas 75201
scott.davis@huschblackwell.com

1 APPEARANCES (Continued):

2 For the Movant United States of America:

3 MR. JAMES G. GILLINGHAM
4 United States Attorney's Office - Tyler
5 110 North College Street, Suite 700
6 Tyler, Texas 75702
7 james.gillingham@usdoj.gov

8 MS. ERIN COLLERAN
9 United States Department of Justice
10 175 North Street Northeast
11 Washington, D.C. 20002
12 erin.colleran@usdoj.gov

13
14
15
16
17
18
19
20
21
22
23
24
25

1 Proceedings reported by stenotype. Transcript
2 produced by computer-aided transcription.

3 ---0---

4 (The following proceedings were held in open
5 court commencing at 2:14 p.m., reported as
6 follows:)

7 (Call to order of the Court.)

8 THE COURT: Thank you. Please be seated.

9 Good afternoon, everyone. It's good to see
10 some familiar faces and welcome back to Beaumont, Texas.

11 We're here today in the case of *United States*
12 *of America, Brook Jackson, plaintiff, v. Ventavia*
13 *Research Group, LLC; Pfizer, Inc.; and Icon, PLC* in
14 Civil Action 1:21-cv-8. We're here on four matters:
15 Pfizer's motion to dismiss the second amended complaint,
16 which is Docket 119; Icon's motion to dismiss the second
17 amended complaint, which is Docket No. 120; Ventavia's
18 motion to dismiss the second amended complaint,
19 Docket No. 121; and the government's motion to intervene
20 and to dismiss, which is Docket 137.

21 Although I recognize lawyers from our
22 previous hearings in this matter, I would like all of
23 you to formally introduce yourselves on the record and
24 your clients and also advise the Court if you're ready
25 to proceed on these matters.

1 MR. FRIEDMAN: Morning, your Honor, or
2 afternoon, your Honor. Jeremy Friedman, attorney for
3 relator Brook Jackson.

4 THE COURT: All right. Thank you.

5 MR. MENDENHALL: Yes. Good afternoon, your
6 Honor. Warner Mendenhall on behalf of Brook Jackson.

7 Thank you.

8 THE COURT: Thank you.

9 MR. BARNES: Good afternoon, your Honor.
10 Robert Barnes on behalf of Brook Jackson. And, yes,
11 your Honor, we are ready to proceed.

12 THE COURT: Very good. And Ms. Jackson is
13 with you?

14 MR. BARNES: Yes. Yes, your Honor.

15 THE COURT: All right. Let me just remind
16 everyone, if you would please, to -- if you're going to
17 address the Court -- and it may be easier ultimately
18 from the lectern -- but please speak into the
19 microphone. I know you may think you're projecting and
20 you may well be, but the acoustics are not that great
21 here and -- for us, namely my court reporter, as well as
22 myself to be able to hear you, we're going to need you
23 to speak into the microphone.

24 Okay. And for the defendants?

25 MR. GILLINGHAM: Your Honor, actually,

1 James Gillingham on behalf of the United States.

2 THE COURT: Okay.

3 MS. COLLERAN: And Erin Collieran on behalf of
4 the United States.

5 THE COURT: All right. Thank you.

6 MR. GILLINGHAM: And we're ready to proceed
7 on the United States's motion to intervene and dismiss.

8 THE COURT: All right. Just give me one
9 second, please.

10 Okay. So, of course, you come from Tyler and
11 Washington, D.C.; is that correct?

12 MS. COLLERAN: Yes.

13 MR. GILLINGHAM: Yes, your Honor.

14 THE COURT: All right. And continuing down
15 this row.

16 MR. WESSEL: Good afternoon, your Honor.
17 Carl Wessel with DLA Piper on behalf of Pfizer.

18 MS. SELF: Good afternoon, your Honor.
19 Meagan Self on behalf of Pfizer.

20 THE COURT: All right. Thank you.

21 MR. CARROLL: Your Honor, Jack Carroll,
22 Orgain, Bell & Tucker, on behalf of Pfizer.

23 THE COURT: Thank you very much.

24 MS. MCDONALD: Your Honor, Taryn McDonald on
25 behalf of Ventavia Research Group.

1 THE COURT: All right. Thank you very much.
2 All right.

3 MR. KATZ: Your Honor, Elai Katz, McDermott
4 Will & Emery, on behalf of Icon, PLC.

5 MR. DAVIS: Your Honor, Scott Davis on behalf
6 of Icon, PLC. And we are ready to proceed.

7 THE COURT: I would like to start with the
8 government's motion to intervene and their motion to
9 dismiss. And I would go ahead and ask Mr. Gillingham
10 to -- I guess you'll be taking lead on this -- to
11 proceed.

12 MR. GILLINGHAM: Thank you, your Honor.
13 And may it please the Court?

14 THE COURT: Yes.

15 MR. GILLINGHAM: Assistant United States
16 Attorney James Gillingham on behalf of the United
17 States.

18 Your Honor, we're here on the United States's
19 motion to intervene pursuant to 31 U.S.C. § 3730(c)(3)
20 and for purposes of dismissing this case over the
21 relator's objections pursuant 31 U.S.C. § 3730(c)(2)(A).
22 Because the United States has good cause to intervene,
23 it's provided the relator notice of its intent to
24 dismiss, and as we see here, the Court is affording the
25 relator a hearing. All statutory prerequisites to

1 intervention and dismissal have been met, and the Court
2 should allow the United States to intervene and dismiss
3 this case pursuant to (c)(2)(A).

4 THE COURT: Let me ask you -- well, before I
5 ask, I will say I'm allowing a hearing on all of these
6 motions today. Frankly, the Court could probably decide
7 these without the benefit of a hearing. However,
8 hearings were requested on these different motions, and
9 I do believe in giving everyone an opportunity to be
10 heard and to tell me what you feel like you need to tell
11 me either for your motion or in opposition to a motion.

12 One question that is not -- about the subject
13 of good cause, that's a phrase that's not defined in the
14 statute you cited. I recognize there's some case
15 authority on good cause, but I want to hear from the
16 government what you think is good cause for intervening
17 in this case.

18 MR. GILLINGHAM: Your Honor, the
19 United States's position on good cause is that although
20 it's not defined in the statute, it's been developed in
21 the case law. And it's really, kind of, a -- it's not a
22 burdensome concept. It's something that's a flexible
23 standard that really just boils down to whether or not
24 there's a legally sufficient reason. And in this case,
25 your Honor, the legally sufficient reason is set forth

1 in the United States's motion.

2 And the good cause for intervention is -- is,
3 kind of, a number of factors that boil down to the
4 United States's decision here. And these are the same
5 factors that support the motion to dismiss under
6 (c)(2)(A). And, your Honor, as set forth in the
7 United States's brief on Page 7, it has investigated the
8 relator's claims in her complaint and all of her amended
9 complaints. The FDA, as previously been discussed in
10 the prior motion to dismiss hearing in the statement of
11 interest, has -- it was aware of Ms. Jackson's
12 allegations prior to the EUA and has been aware of those
13 since issuing additional EUAs. The new information
14 contained in the amended complaint is based on
15 information that's in the public record that the FDA is
16 aware of. The FDA continuously monitors the market, the
17 incidents, the COVID results, and it's simply reached a
18 different conclusion than the relator's conclusion here.

19 And I think that that's summarized pretty
20 succinctly in the JAMA article that was cited in our
21 motion where the FDA's view is that the COVID vaccine is
22 effective and it has saved tens of millions of lives.
23 So the United States in that aspect has decided that the
24 likelihood of success here is small. But
25 there's also --

1 THE COURT: Likelihood of success in terms of
2 the relator continuing the action against the
3 defendants, the success is low? Is that what the
4 government thinks?

5 MR. GILLINGHAM: Your Honor, that's -- that's
6 the government's view, especially given the FDA
7 continuing to authorize these, monitoring the COVID
8 vaccine data. It's our belief that the vaccine is safe.
9 It's protected tens of millions of lives.

10 But then the second factor here, your Honor,
11 that I think is important is that continuing this
12 lawsuit will impose a substantial burden on the
13 Department of Justice, the FDA, HHS, potentially even
14 DOD in the obligation to respond to discovery, to
15 continue to monitor this case. As your Honor is aware,
16 this has been a litigious case. The government's
17 already had to file a statement of interest in this
18 case. We're seeking now to terminate our involvement to
19 avoid these continued burdens of discovery and the
20 potential for privileged documents to be disclosed as
21 part of that.

22 THE COURT: Now, normally, you, the
23 government, certainly is given an opportunity to
24 intervene. There are times the government decides that
25 they wish to join with a relator, help with the

1 prosecution expenses and work together against some
2 other person who allegedly -- a person or company that
3 has allegedly defrauded the government, correct?

4 MR. GILLINGHAM: Correct, your Honor.

5 THE COURT: There are other times the
6 government says, well, it's an interesting case, we are
7 not interested in investing resources in the case, but
8 we're not opposed to the -- a relator, in what is called
9 a qui tam action, going after someone for alleged fraud.
10 And, of course, if successful, the government would get
11 a recovery of money and out of that recovery pay the
12 relator and her attorneys money for their efforts in
13 pursuing that action, correct?

14 MR. GILLINGHAM: Your Honor, mostly correct.
15 Although the obligation to pay attorney's fees doesn't
16 come from the government. That would be a statutory
17 right to recover from defendants.

18 THE COURT: All right. But the bottom
19 line is -- that's fair. But there would be money going
20 back to cover the litigation expenses, correct?

21 MR. GILLINGHAM: Yes, your Honor. The false
22 claims --

23 THE COURT: So those are two scenarios that
24 the government could have had -- could have taken
25 advantage of in this case. The government chose neither

1 one of those two, correct?

2 MR. GILLINGHAM: The government initially
3 declined to intervene in this case, your Honor.

4 THE COURT: All right. Now -- then the
5 government came along and prepared a statement of
6 interest where they essentially said they did not want
7 this -- they didn't think this was an appropriate case.
8 It wasn't a valid case and scientific data didn't
9 support it -- many different things.

10 Is that a rare thing for the government to
11 do?

12 MR. GILLINGHAM: Your Honor --

13 THE COURT: In terms of all the qui tam
14 actions that are out there on all sorts of different
15 actions?

16 MR. GILLINGHAM: Your Honor, I'd say -- I
17 wouldn't say it's a rare thing for the government to
18 take a position -- a statement of interest on a variety
19 of issues, but I wouldn't say it's also the most common
20 thing.

21 THE COURT: Okay.

22 MR. GILLINGHAM: I think it's really a
23 case-by-case basis depending how the issues present.

24 THE COURT: All right. So that's a third
25 option and that was done early -- well, not early on,

1 but some time ago in this case. And now there's a
2 fourth option, which we have, which is your motion to
3 intervene, correct?

4 MR. GILLINGHAM: Correct, your Honor.

5 THE COURT: And, ultimately, a motion to
6 dismiss. How often do you do that?

7 MR. GILLINGHAM: Your Honor, the --

8 THE COURT: In qui tam cases?

9 MR. GILLINGHAM: The option of intervening
10 for the purpose of dismissing is probably the least
11 common of those -- those scenarios, your Honor.

12 THE COURT: All right. And even though the
13 government could stand to benefit financially in the
14 event Ms. Jackson and her team were successful against
15 these defendants; is that correct?

16 MR. GILLINGHAM: Yes, your Honor.

17 THE COURT: All right. I didn't mean to
18 interfere with your argument, but go right ahead with
19 your comments.

20 MR. GILLINGHAM: No need to apologize, your
21 Honor.

22 But to follow up on the last point, I think
23 that it's worth a little bit of additional discussion.
24 The mere fact that the government could recover
25 something down the road even -- even if it's projected

1 to be billions of dollars does not outride -- does not
2 outweigh the government's analysis of whether or not to
3 proceed here. And the Supreme Court considered that
4 exact argument in the *Polansky* case, your Honor.

5 In the *Polansky* case, the defendant -- the
6 relator's position in opposing the government's motion
7 to intervene for purposes of dismissing was that it was
8 a strong case and the government was leaving billions of
9 dollars on the table for what it characterized as merely
10 a months' worth of time doing some discovery. And the
11 Supreme Court said there it's not the relator's position
12 to make that, you know -- that cost benefit analysis.
13 The government always has the primary interest. We're
14 the real party in interest, and the qui tam purposes of
15 the False Claims Act are to vindicate the government's
16 interests.

17 But for the reasons set forth in our brief
18 and what we've already articulated here, the
19 difference -- the different view of this COVID vaccine
20 by the FDA and the imposition of burdens on the
21 government to continue this litigation, those have
22 almost been uniformly held to support good cause for
23 intervention and dismissal. And that's what happened in
24 *Polansky* and that's what should happen today, your
25 Honor.

1 THE COURT: Now, was good cause actually
2 defined in the *Polansky* case?

3 MR. GILLINGHAM: No, your Honor. In
4 *Polansky*, the Court, again, looked to -- I think it
5 discussed the Third Circuit's language regarding it
6 being a flexible capacious concept that's really a low
7 bar. And I think that's -- that's the most important
8 part of this, is that --

9 THE COURT: But there are other cases that
10 discuss -- not this particular Supreme Court case -- but
11 there are other cases that define -- that put parameters
12 around what is good cause for the government to
13 intervene. And you have essentially summarized some of
14 those points here in this hearing.

15 Is there anything else you wanted to add
16 about good cause?

17 MR. GILLINGHAM: No, your Honor. I think
18 that the biggest takeaway from my perspective and the
19 United States's perspective on good cause is that it's a
20 low bar. And I think that *Polansky* cautioned that a
21 Court should think, not just once, not twice, but many
22 times before denying the opportunity for the government
23 to intervene for purposes of dismissal.

24 THE COURT: Now, the *Polansky* case was
25 decided eight justices to one, and Justice Thomas wrote

1 a dissent in that case.

2 Why do you think *Polansky* applies in this
3 case and why isn't Justice Thomas's dissent worthy of
4 consideration by this Court?

5 MR. GILLINGHAM: Your Honor, a few points. I
6 think *Polansky* applies because it fairly well tracks the
7 situation here where the government offered concerns
8 about the viability of the case balanced against the
9 imposition on the government of continuing to monitor
10 the case and get involved in discovery. And the Court
11 agreed that the government's decisions that -- analysis
12 was a rational reason for it to step in and dismiss.
13 That tracks exactly what the government is doing here,
14 your Honor.

15 And in both cases, the relator argued that
16 there was billions of dollars on the table and it was a
17 strong case; but the Court still affirmed the dismissal.
18 Now, Justice Thomas's involvement in False Claims Act
19 cases is interesting. Justice Thomas, I think, has an
20 issue with the False Claims Acts relator -- relator
21 provisions altogether. And so I think that there's a
22 reason that he was the outlier in that case. And I -- I
23 don't think there is anything about Thomas's dissent in
24 that case -- in the *Polansky* opinion that guides this
25 Court's analysis here.

1 And as the Court's aware, that -- his dissent
2 doesn't have any precedential value and what the Court
3 should do is recognize that *Polansky* said that we could
4 intervene at any time. And, in fact, we're doing it
5 much earlier in this case than *Polansky*, which was much
6 further into discovery at that point. And that once we
7 do intervene for good cause, that the -- the Court
8 settled the debate on what the standard was for
9 dismissing the case.

10 THE COURT: I think the *Polansky* case said
11 that the intervention could come some time during the
12 litigation. So even though this case has been on for
13 several years -- of course, there's been a lot of
14 procedural issues that have made it last that long -- I
15 think it's probably the oldest case on my docket since
16 most of my cases are concluded within about -- or,
17 actually, less than 12 to 18 months. But be that as it
18 may, it is what it is. And here we are.

19 The timing of your intervention is not really
20 an issue?

21 MR. GILLINGHAM: No, your Honor.

22 THE COURT: All right. Now, the -- the
23 *Polansky* decision did affirm a dismissal of the case
24 under Federal Rule of Civil Procedure 41(a), which is a
25 rule that allows a plaintiff to basically dismiss a case

1 if there hasn't been an answer on file by the
2 defendants. For whatever reason, they decide we don't
3 want to pursue it anymore or we've gotten into it and we
4 don't feel comfortable pursuing it. Maybe they settled
5 it. Who knows? There's just some reason. And those
6 types of dismissals are routinely granted by courts,
7 correct?

8 MR. GILLINGHAM: Your Honor, I would agree
9 with most of that. I think that under 41(a)(1)(A),
10 there is no adjudicatory function of the Court. It's
11 done by a notice and it's self-effectuating in a sense,
12 but --

13 THE COURT: It really is, isn't it?

14 MR. GILLINGHAM: Yes. But, yes, your Honor.
15 They're very common. They may be done for a variety of
16 reasons. But, again, I think that the Court's -- the
17 Court did recognize that Rule 41 provides the proper
18 standard. And as we know, 41, the standard would depend
19 on where we are in the litigation.

20 THE COURT: And in this case -- the
21 defendants in this case have simply filed motions to
22 dismiss, not a motion for summary judgment, which if
23 they had done that, Rule 41(a) dismissal -- voluntary
24 dismissals would not be appropriate, correct?

25 MR. GILLINGHAM: We would be under 41(a)(2),

1 your Honor, yes.

2 THE COURT: All right. So they haven't
3 answered. They have filed a motion to dismiss. Does
4 that then allow -- there is nothing in that rule -- that
5 would apply here that would prohibit a dismissal just
6 because they filed a motion to dismiss; is that correct?

7 MR. GILLINGHAM: Your Honor, I'm not aware of
8 anything. Given that there has been no answer and no
9 motion for summary judgment, I think we're squarely
10 within the ambit of 41(a)(1)(A).

11 THE COURT: Okay. All right. Continue with
12 your evaluation of the case.

13 MR. GILLINGHAM: And, your Honor, since we're
14 on the topic of 41(a)(1)(A), again, similar to the good
15 cause burden, this is extremely a low burden. You know,
16 41(a)(1)(A) is a non-adjudicatory function that's done
17 on a notice. However, it is subject to other applicable
18 rules. Therefore, in this context, although 41(a)(1)(A)
19 applies, we still have to look to the False Claims Act
20 under (c)(2)(A), which does require notice to the
21 relator and the opportunity for a hearing.

22 And so -- so that's why we're here today,
23 your Honor. Those two aspects, the notice and hearing,
24 aren't inherent in 41, but the catchall 41 does say we
25 have to make sure that we comply with other applicable

1 statutes.

2 THE COURT: And the relator in this case
3 takes issue with your position and the government's
4 position that you have good cause?

5 MR. GILLINGHAM: Yes, your Honor.

6 THE COURT: All right.

7 MR. GILLINGHAM: And I think that the -- the
8 reality is there's a very strong difference of opinion
9 on the ultimate issues relating to the COVID vaccine and
10 that's a big fight. But it doesn't change the fact that
11 the reasons the government has provided to dismiss and
12 for intervention that the -- you know, that the agency's
13 aware of this, that it's continuing to prove the EUAs,
14 that it's aware of all the data that Ms. Jackson's
15 complaint -- amended complaint is based on, and that
16 we're trying to avoid the burdens of continued
17 litigation. That -- those factors have been routinely
18 upheld here.

19 So the government -- the United States in
20 this case believes that it does have good cause for
21 those reasons and also satisfies all -- once
22 intervention has taken place, satisfies all of the
23 requirements under 41(a)(1)(A). I don't believe that
24 the issue of notice is really at issue today. I think
25 that's checked off. And the hearing being provided

1 today satisfies the other element. So at this point,
2 the government has satisfied all statutory requirements
3 and complied with the *Polansky* decision and the Court
4 should allow it to interview and effectuate a dismissal
5 pursuant to (c)(2)(A).

6 THE COURT: All right. Anything else?

7 MR. GILLINGHAM: Your Honor, just a couple of
8 points, I think, on some issues that will likely be the
9 topic of the relator's presentation.

10 The United States's view of what's required
11 by the hearing for purposes of satisfying (c)(2)(A) is
12 merely what we're doing right here, is this hearing.
13 There is no requirement for an evidentiary hearing.
14 There's nothing in the rule that requires an evidentiary
15 hearing. That would be inconsistent with the 41(a)(1)
16 standard that -- as we've discussed. A notice -- the
17 Court doesn't have an adjudicatory function.

18 And so we believe that there's no need for an
19 evidentiary hearing in this case. And the courts
20 generally have in the (c)(2)(A) context when addressing
21 this evidentiary -- the question of an evidentiary
22 hearing has almost uniformly said no evidentiary hearing
23 because the point of today is not to have a mini trial
24 on the merits of the underlying case. This is the --
25 the point of the hearing today is for the relator to

1 have an opportunity to be heard, for the United States
2 to put forth its reasons for dismissal, and for the
3 Court to ensure that there is no, maybe, constitutional
4 issues with -- with the dismissal.

5 And the constitutional issues we don't
6 believe are present in this case, your Honor. The
7 fourth footnote in the *Polansky* decision does reference
8 the possibility that -- in trying to determine what's
9 required by a hearing, when the underlying rule that has
10 been adopted allows dismissal upon notice, the Court
11 posited that it may be for purposes of the Court to
12 confirm that there's no constitutional harm to the
13 relator affected by this dismissal. And it identifies
14 equal protection and due process as potential issues. I
15 don't think that anyone has raised an equal protection
16 challenge to the United States's dismissal here. And
17 the United States believes it has complied with all due
18 process requirements pursuant --

19 THE COURT: Does Rule 24 impact the
20 government's right to intervene and the ability to show
21 good cause as relator argues?

22 MR. GILLINGHAM: No, your Honor. The Rule 24
23 analysis is really separate and apart from the
24 intervention and the False Claims Act. The False Claims
25 Act provides its own basis for intervention by the

1 government in these situations. Rule 25 is a more
2 general rule --

3 THE COURT: Twenty-four, you mean?

4 MR. GILLINGHAM: So sorry. Yes, your Honor.
5 Rule 24 is the general rule for intervention in general
6 civil litigation. This is a more -- the False Claims
7 Act has its own specific rules that apply to the
8 United States seeking to intervene. And that's --
9 that's why we're moving under 3730(c)(3) and (c)(2)(A).
10 And, your Honor, for instance, in the *Polansky* decision
11 when the Court was determining what the standard for
12 intervention -- whether or not it was allowed in the
13 standards -- it never looked to Rule 24. And the Court
14 imposed the burdens under Rule 3730(c)(3). So the
15 United States's view is that 24 -- although a general
16 rule on intervention -- doesn't apply here.

17 THE COURT: With regard to evidentiary
18 hearings, I understand it, among other things -- you
19 talked about cause -- you did make some statements that
20 the government felt that the vaccine was effective.
21 Some people disagree with that. Some people think it's
22 even harmful. But -- and I state that just having read
23 a newspaper or two over the last few years. But the
24 real issue here is that Ms. Jackson claims that she saw
25 some variations in the testing protocol when they were

1 testing that -- you know, maybe they didn't -- they may
2 have given the vaccine to someone when they were testing
3 it, but they didn't wait the full allotted time watching
4 the person to see if they had a reaction or they
5 didn't -- when they injected it in the test people, that
6 they didn't necessarily have it at the right temperature
7 or things of those nature. Those are factual claims
8 that she's making.

9 Your position on this evidentiary situation
10 is that given the procedural nature of the case, with
11 your motion to intervene and your motion to dismiss,
12 the -- an evidentiary hearing on the ripeness of her
13 claim is not really what we do here. It's simply the
14 government, in this instance, has evaluated her claims
15 and determined in the government's view that her claims
16 are not worthy of pursuing in a court of law. And for
17 that reason, it's the government's claim -- because it
18 was the government that was purportedly defrauded by
19 these defendants over here -- and you all don't want to
20 pursue that, and you have the right under the statute to
21 intervene and dismiss the case.

22 Have I basically summed up what you're saying
23 on the evidentiary hearing aspect of this?

24 MR. GILLINGHAM: Absolutely, your Honor.
25 These are -- the United States is always the real party

1 in interest. The case law makes very clear that our
2 interests are always predominant. And as *Polansky* said,
3 if the government offers a reasonable argument that the
4 burdens of continued litigation outweigh the benefits,
5 the Court should grant the motion.

6 THE COURT: Okay.

7 MR. GILLINGHAM: That's exactly our position,
8 your Honor. So for those reasons, and then the fact
9 that there's no requirement for an evidentiary hearing
10 in the statute, it'd be consistent with Rule 41(a)(1)(A)
11 and, frankly, the legislative history of the False
12 Claims Act. We don't believe an evidentiary hearing is
13 required. We think the hearing requirement probably
14 could have been satisfied on the papers, but it is
15 definitely satisfied here today.

16 And I think the -- the final issue, your
17 Honor, is just to touch on -- go back to these
18 constitutional concerns. Again, no equal protection
19 violation, procedural due process. I think that the
20 notice, the briefing, this hearing satisfy all of that.
21 And there's no substantive due process concern because
22 the decision the government's making is not arbitrary in
23 a constitutional sense. We have offered a well-reasoned
24 opinion -- a reasoned basis for our decision. It's not
25 arbitrary in the constitutional sense; and, therefore,

1 there's not going to be any due process issues.

2 THE COURT: Okay. Anything further?

3 MR. GILLINGHAM: No, your Honor. If your
4 Honor has any further questions, I'm happy to address
5 them. But, otherwise, we'd sit down. -

6 THE COURT: I'm sure you probably feel like
7 you've had enough questions from me already.

8 MR. GILLINGHAM: Your Honor, I'm always happy
9 to assist the Court in any way I can.

10 THE COURT: If I think of another one, I'll
11 let you know.

12 MR. GILLINGHAM: Thank you, your Honor.

13 THE COURT: All right. Okay. Now, did
14 you -- I was going to let Mr. Barnes respond to the
15 government's motion. But do you want to --

16 MR. WESSEL: If I might, your Honor, just a
17 few points that I would add to the government's motion.
18 It might make sense logically to hit those now.
19 Obviously --

20 THE COURT: Well, I guess I might as well let
21 the defendants -- let their load -- unload on you, and
22 then you can respond to all of it when -- when I give
23 you a chance, okay?

24 Yes, sir. Go right ahead.

25 MR. WESSEL: Thank you, your Honor. Good to

1 see you again. Carl Wessel on behalf of Pfizer.
2 Pfizer's position is that its motion to dismiss under
3 12(b)(6), 12(b)(1) is really mooted in light of the
4 government's motion.

5 THE COURT: Well, that was going to be one of
6 the first questions.

7 MR. WESSEL: Yes.

8 THE COURT: Now, if I deny the government's
9 motion, then I will need to make an opinion -- a
10 decision on all of your motions to dismiss. If I grant
11 the government's motion, then all of your motions to
12 dismiss will be essentially moot because --

13 MR. WESSEL: Essentially. And I can parse
14 through that. There's a little subtlety there because
15 of the retaliation claim.

16 THE COURT: I was going to ask you about
17 retaliation because that's the one thing that -- the
18 government cannot dispense with her claim for
19 retaliation -- she was fired, as I recall the facts,
20 like a day or two after this event. I may be off a
21 little bit on my facts -- but shortly after. Maybe even
22 that day. I don't remember exactly. But that -- you
23 don't -- you're not moving to dismiss that, are you?

24 MR. WESSEL: Yeah. I believe, your Honor --
25 and obviously that's a claim against Ventavia. Pfizer

1 is not named in that claim.

2 THE COURT: Right.

3 MR. WESSEL: But -- I will -- you know, just
4 to assist the Court, you know, our sense is that claim
5 will remain, that cannot be dismissed by the
6 government's motion --

7 THE COURT: Regardless of what happens with
8 the government's motion or with all of your motions?

9 MR. WESSEL: That's correct.

10 THE COURT: Okay.

11 MR. WESSEL: That's correct. And maybe just
12 to run through briefly, your Honor, if it's helpful. So
13 Counts One through Four, these are the False Claims Act,
14 the qui tam claims, right? And they're against Pfizer,
15 Icon, and Ventavia. These would be gone if you grant
16 the government's motion. So those go. And that ends
17 all of the claims against Pfizer and Icon, so, again,
18 unnecessary to address our 12(b)(6), 12(b)(1) motion.

19 THE COURT: Well -- now, hold on. I'm going
20 to have the relator respond to the motion to dismiss,
21 and then I'm going to go ahead and have a hearing on
22 y'all's motions to dismiss since you're all here. I
23 wouldn't want to have everybody come back, if necessary,
24 for another time. I mean, it's expensive for everybody
25 to fly here and all of that. I want to go ahead and get

1 that portion of the hearing done. Whether or not we
2 ultimately decide -- need to decide on that, we'll see.

3 MR. WESSEL: Yes. That's certainly fine. If
4 the Court wishes to proceed that way, that's fine with
5 Pfizer. I don't think there -- as you know, we spent a
6 lot of time discussing the issues there, the *Harman*
7 case, et cetera back in March. Those are essentially
8 the same issues. We can talk a little bit about that.

9 THE COURT: Yeah.

10 MR. WESSEL: But just to, kind of, finish it
11 out, I do think that if -- if you grant the government's
12 motion, all of that is moot. The Counts Five and Six,
13 those retaliation claims, you know, which are brought
14 under the False Claims Act in state law, they would
15 apply to relator's former employer Ventavia. And,
16 obviously, I'm going to let their counsel address those
17 because -- those are still live and, you know, probably
18 could benefit from argument.

19 THE COURT: Sure.

20 MR. WESSEL: But if I might, your Honor, just
21 a couple of points on the government's motion because I
22 just think it's important to -- you know, that that's
23 obviously an essential piece of the litigation here.
24 And I think -- I mentioned the *Harman* case, and you and
25 I discussed that at length back -- I guess it was a

1 little more than a year ago. And that obviously -- the
2 essential issue in there is that materiality issue, but
3 there are other issues in there that I think are -- are
4 quite significant to this litigation.

5 So if I might just -- you know, if you, kind
6 of, boil down the relator's objections to the
7 government's motion and, sort of, put aside the
8 inflammatory rhetoric and things of that nature, it's
9 really a disagreement about, you know, the safety and
10 efficacy of the vaccine. The FDA has a position that
11 the vaccine is safe and effective and saves lives, and
12 the relator obviously strongly disagrees with that. But
13 that's not really relevant to the motion, right? We
14 talked, and the government spoke -- spoke very well
15 about what the law is, and that's the essential issue
16 here.

17 But the -- and the reason why I raised that
18 *Harman* case is the Fifth Circuit -- so, obviously, you
19 have the *Polansky* precedent, which was discussed, I
20 think, very effectively there. But -- but in the *Harman*
21 case, the Fifth Circuit also addresses a very, very
22 similar issue. When they went through, sort of, a
23 survey of the case law, they quote from a First Circuit
24 case called *D'Agostino*, very approvingly in that case,
25 and that case was postured in a similar way. And in

1 that case, this is what -- the *Harman* -- the
2 Fifth Circuit said about the First Circuit. It talked
3 about the First Circuit affirming a dismissal in that
4 case under 12(b)(6). And what the -- the *D'Agostino*
5 court, the First Circuit said is: The fact that the
6 Centers for Medicare/Medicaid Services have not denied
7 reimbursement -- and this was a device case, not a
8 vaccine.

9 THE COURT: Okay.

10 MR. WESSEL: But, obviously, a lot of
11 similarities --

12 THE COURT: And it's a 12(b)(6) case --

13 MR. WESSEL: Yes. Both 12(b)(6). But, I
14 think -- again, what it, kind of, circles back on is
15 this whole disagreement between the relator and the
16 government, which I think the Fifth Circuit is, sort of,
17 warning against.

18 THE COURT: Okay.

19 MR. WESSEL: So what the First Circuit said
20 is: The fact that the Centers for Medicare and Medicaid
21 Services have not denied reimbursement for the device in
22 the wake of the relator's allegations casts serious
23 doubt on the materiality of the fraudulent
24 representations that the relator alleges. This is this
25 whole materiality issue we talked about at length. Then

1 the Court goes on to say: Allowing the False Claims Act
2 claim to go forward -- and now here it's quoting from
3 the First Circuit -- would be to turn the False Claims
4 Act into a tool with which a jury of six people could
5 retroactively eliminate the value of FDA approval and
6 effectively require that a product be withdrawn from the
7 market even when the FDA itself sees no reason to do so.

8 And, basically, what the Fifth Circuit says
9 is these cautions remain forceful on the materiality
10 context -- in the materiality context. The False Claims
11 Act exists to protect the government from paying
12 fraudulent claims, not to second guess agencies'
13 judgments about whether to rescind regulatory rulings.
14 So -- so I think in a lot of ways, even though the
15 *Harman* case really addresses materiality at various
16 stages in the litigation -- and we talked at length
17 about this, your Honor. I don't want to go --

18 THE COURT: I see how you're connecting --

19 MR. WESSEL: Yes. Yes. Exactly. And you'll
20 recall, you know, the conclusion of the *Harman* case,
21 what the Fifth Circuit said is: For the demands of
22 materiality, adjust the tensions between the singular
23 private interest and those of the government and cabin
24 the greed that fuels it. As the interests of the
25 government and the relator diverge, this congressionally

1 created enlistment of private enforcement -- that's the
2 False Claims Act -- is increasingly ill served when the
3 government, at appropriate levels, repeatedly concludes
4 it has not been defrauded, it is not forgiving a fraud,
5 rather it's concluding that there was no fraud at all.

6 THE COURT: So as a general principal, under
7 Fifth Circuit authority that I'm duty bound to follow,
8 as well what you're saying is Supreme Court authority,
9 which I'm obligated to follow, even if a lot of people
10 might disagree with the decision to prove -- to approve
11 a medical device or the decision to evaluate the testing
12 protocols of a vaccine and -- that later determined that
13 whatever variations there were, were not material to the
14 ultimate decision to approve the drug, which is really
15 the gist of the fraud claim.

16 You know, that's to say these defendants,
17 your client, kind of tricked the FDA into approving this
18 because they didn't use proper test protocols. I know
19 the government denies that. They say it's not true.
20 But that decision to say, no, we're satisfied with the
21 government's decision -- we're satisfied with the test
22 protocols and -- that -- a lot of people may disagree
23 with that decision. But these cases are saying if
24 that's what the agency has decided and if the government
25 has decided they don't want to pursue this for the

1 reasons he described, they can have a case dismissed.

2 MR. WESSEL: That's correct, your Honor.
3 That's what the Fifth Circuit said relying, again, on
4 First Circuit precedent. And effectively getting to the
5 government's motion, that's what *Polansky* -- you know, I
6 know there are separate issues of materiality in the
7 government's motion to dismiss.

8 THE COURT: Right.

9 MR. WESSEL: But really -- really those two
10 precedents are binding on the Court.

11 THE COURT: Okay. That's interesting. I
12 hadn't really -- in coming out here today, I hadn't
13 really -- I remembered your arguments on materiality,
14 but I didn't really -- I wasn't focused on those. It's
15 probably good to --

16 MR. WESSEL: It was some time ago,
17 your Honor, and I think we were here for hours. So I
18 had to go back and refresh myself.

19 One other quick point on our motion to
20 dismiss because I know you -- you wanted to, you know,
21 hear that in case --

22 THE COURT: Well, I wanted to hear the motion
23 to dismiss after --

24 MR. WESSEL: That's fine. I'll save that and
25 just --

1 THE COURT: I think it would be cleaner.

2 MR. WESSEL: No problem. Happy to do that.
3 You know, just a couple of points on -- on -- just to
4 highlight some of the things --

5 THE COURT: And the reason I want to do it --
6 still have it is I want to hear arguments on the
7 government's motion to dismiss. And I'm going to
8 consider that separate and apart from the defendants'
9 motions to dismiss. If, obviously, I agree with the
10 relator, then I need to then consider what the arguments
11 are on the motions to dismiss. And I don't want to have
12 to have everybody come back again if -- in that
13 eventuality to hear -- to have y'all do it. I want to
14 have it one-stop shop and get it all done today.

15 But by the same token, if -- even though you
16 will have argued the motions to dismiss, should the
17 ultimate evaluation of this Court be that the
18 government's motion to intervene and motion to dismiss
19 is valid, then I think the motions to dismiss will
20 simply be -- the claims will be dismissed as -- granted
21 as moot or actually, I guess, denied as moot because it
22 really -- and you will have argued it, but so what? You
23 know, you're prepared to do it.

24 MR. WESSEL: We agree with that, your Honor,
25 and that seems like a sensible way to proceed to me.

1 THE COURT: Okay. All right. Anything else?

2 MR. WESSEL: Just maybe a couple quick points
3 and just staying with the government's motion because
4 then we can --

5 THE COURT: That's what I want. That's what
6 I want.

7 MR. WESSEL: -- get into some of the others
8 the next time around.

9 You know -- so I think there are a couple of
10 key points there. And, obviously, I defer to the
11 government who has far superior knowledge of this area.
12 But since the Supreme Court clarified the law in
13 *Polansky*, I have not seen any case law where a District
14 Court declined to dismiss after the government filed
15 such a motion as they have here. Also, again, since
16 *Polansky*, I have not seen any District Court hold an
17 evidentiary hearing. So we talked about whether that
18 was necessary. So I think those points are worth -- are
19 worth considering.

20 And as your Honor has pointed out, if you
21 grant the motion, the case -- the case is done
22 essentially. Again, there's that subtlety around the
23 claims against Ventavia, but --

24 THE COURT: You talked about you didn't find
25 any cases where the government moved to dismiss. Let me

1 just ask you: In qui tam cases -- and considering
2 Rule 24 -- did you find --

3 MR. WESSEL: After -- after the *Polansky*
4 decision, the Supreme Court's decision last year?

5 THE COURT: Well, I'm talking about any
6 before or after *Polansky*.

7 MR. WESSEL: Yeah. No. No.

8 THE COURT: You know, Courts look to Rule 24
9 to determine what is good cause. Did you find any cases
10 in qui tam cases where you found that the government
11 didn't have good cause to intervene?

12 MR. WESSEL: I think I'd defer to the
13 government because they're probably the experts on that
14 particular question.

15 THE COURT: Okay.

16 MR. WESSEL: But I'm not aware of any off the
17 top of my head.

18 THE COURT: And I'm going to ask that
19 question to relator here in a minute because I'm curious
20 about that. Maybe there is a case out there. I want to
21 know about it.

22 MR. WESSEL: Yes. We can look at that.

23 Again, quickly -- your Honor, again, this
24 case would be gone if you grant the government's motion
25 to dismiss.

1 THE COURT: Right.

2 MR. WESSEL: And it's not only our position.
3 And all of the defendants would agree with that, and
4 obviously that's the government's position. But when we
5 argued back in March, that was the exact same position
6 that Mr. Mendenhall took with the Court. And, again,
7 I'm quoting from the transcript back then, Page 108,
8 where Mr. Mendenhall told the Court, "I think that,
9 first of all, if the U.S. government, if it wants this
10 case dismissed, it can come here and dismiss this case."
11 And then on the next page, 109, Mr. Mendenhall says
12 again, "And if the government wants this case gone, why,
13 they can come in tomorrow and get it gone, your Honor."
14 So --

15 THE COURT: And that was before the *Polansky*
16 decision came out, which I think was in December.

17 MR. WESSEL: Yeah. This was in March, your
18 Honor. Yes, that's correct. Correct.

19 THE COURT: Okay.

20 MR. WESSEL: But that's all I have, your
21 Honor. We obviously would support the government's
22 motion to intervene and dismiss.

23 THE COURT: All right. Thank you very much.

24 Does anybody else care to comment? All
25 right. You're saving your bullets for later then, huh?

1 MR. DAVIS: On the government's motion,
2 Judge?

3 THE COURT: Yes. On the government's motion.

4 MR. DAVIS: No. We'll wait until we address
5 our own.

6 THE COURT: I'll give you a chance.

7 All right. Mr. Barnes, I assume -- are you
8 going to be the lead-off hitter for the relator?

9 MR. BARNES: I will be just addressing
10 Counts Five and Six, the retaliation counts, your Honor.

11 THE COURT: Okay.

12 MR. BARNES: So I'll wait for that.
13 Mr. Mendenhall will be addressing Counts One
14 through Four.

15 THE COURT: All right. Very good.

16 MR. MENDENHALL: Your Honor, I'm actually
17 trying to get an answer to your last question. There --
18 it does appear that there is one case. It's *U.S. ex*
19 *rel. Odum v. Southeast Eye Specialists*. That was in
20 February 24th, 2021.

21 THE COURT: Do you have a cite on that one?

22 MR. MENDENHALL: I'm sorry?

23 THE COURT: Do you have a cite?

24 MR. MENDENHALL: I'll give you the case.
25 It's Case No. 3:17-cv-689, Middle District of Tennessee.

1 THE COURT: Okay. Did you get that?

2 MR. MENDENHALL: Yeah. I'm sorry. I don't
3 know --

4 THE COURT: You don't know if it was
5 published or not?

6 MR. MENDENHALL: I don't know.

7 THE COURT: Okay. Well, that's pretty good.

8 MR. MENDENHALL: Well, I knew I had it
9 because we have had this discussion in the office and it
10 was in our chat.

11 THE COURT: Okay. That's good. So y'all --
12 great minds think alike then.

13 What year was that?

14 MR. MENDENHALL: It was February 24th, 2021.
15 I'm sorry I don't have more than that, but that's -- I
16 knew we had it somewhere.

17 THE COURT: We'll run our traps and find it.

18 MR. MENDENHALL: Your Honor, obviously there
19 is a lot to address here. And we're in a very
20 interesting -- I'm sorry.

21 THE COURT: No. I hear you.

22 MR. MENDENHALL: We're at a very interesting
23 stage. And one of the things that I did, which is
24 reflected in the brief, is we went back to the Senate
25 reports and the House reports on the Federal False

1 Claims Act. And, you know, one of the things that
2 the -- there is a role that the relator plays,
3 particularly when there's this effort to dismiss a case,
4 and they say it. They say the relator is a check on the
5 government. You know, and who's really sovereign here
6 are the peoples. I think that's the Senate reminding us
7 of that; that the relator is a check on the government.
8 And the other thing is -- I think good cause is being
9 brushed off as almost nothing.

10 THE COURT: It could really be a detriment to
11 the attorneys in qui tam litigation since the government
12 could intervene at any phase in a litigation after some
13 attorneys have invested significant sums of money
14 developing a case and have it evaporate on them late in
15 the litigation. That could be a hard pill to swallow.

16 MR. MENDENHALL: Your Honor, I can tell you
17 how hard it is to swallow. And I have it on appeal. In
18 fact, they cited to one of my cases. I will say -- and
19 that's the *Wolf Creek* case. But I will say this about
20 the judge's opinion in *Wolf Creek*, which I thoroughly
21 disagree with there. The judge, at least, said, look,
22 there was an issue with the reliability and trustfulness
23 of the relator. He said there were significant
24 discovery issues in that case that were being considered
25 with NASA. That's a NASA case.

1 So, at least, the judge in that case --
2 although I fully disagree and it's on appeal and briefed
3 at the Sixth Circuit Court of Appeals.

4 THE COURT: Okay.

5 MR. MENDENHALL: He listed the issues. He
6 looked for reasons -- good cause reasons. It wasn't
7 just that, oh, the government came in and wanted to
8 dismiss. It was -- there were very specific reasons for
9 dismissal. And if you look down at all the cases that
10 are cited -- and we did. And I don't think we cited
11 *Harman* in our brief opposing the U.S. government's
12 motion to dismiss. But if you look down in all of those
13 cases, there are real issues. In *Polansky*, for example,
14 what happened is they had set up a discovery schedule.
15 They were deep into discovery. And the judge actually
16 intervened to limit the discovery, to cabinet. They set
17 up a plan. They had very particular data requirements
18 and controls.

19 And guess what? The relator and their
20 lawyers, I guess, in that case completely ignored the
21 directions of the judge and the agreements that they had
22 met with the U.S. government to limit discovery and make
23 sure that it was not a burden on the U.S. government,
24 that discovery. The other thing the relator did in that
25 case was had 14,000 pages that the relator had not

1 turned over in the discovery, which came late and
2 completely upended the Court's schedule and everything
3 that had been planned along with the U.S. government and
4 the defendant. So *Polansky* has a very interesting
5 history.

6 One other thing I want the Court to be aware
7 of in that history in *Polansky*, the judge both
8 considered the government's motion to dismiss, but also
9 went on to rule on the defendant's motion to dismiss.
10 So it was not an either-or proposition. The judge did
11 not moot out the defendant's -- the defendant's
12 positions and, in fact, ruled on those motions to
13 dismiss. The Court felt that that would be very helpful
14 in that case. And I think that -- you know, I just want
15 the Court to be aware that that case has some very
16 particular facts.

17 You know, the *Carver* case is another one
18 that's interesting. And what happened in *Carver* -- the
19 relator got a default judgment against the defendant,
20 and then the Court, you know, apparently notified the
21 relator that they hadn't finalized the judgment. And
22 then the U.S. government and the relator were in a
23 negotiation over what that judgment would consist of,
24 what was within the scope of the False Claims Act, and
25 what was actually in the scope of a criminal case that

1 was going in parallel. Had the relator, again, worked
2 with the government, they would have had a default
3 judgment entry and had an award. Instead, that relator
4 behaved in such a way that that relator was
5 noncooperative with the federal government and was
6 disrupting the federal government's ability to collect
7 against the defendants.

8 So every case we've looked at where there is
9 a dismissal, we see things that, yeah, you know,
10 arguably -- even in *Wolf Creek* arguably -- are good
11 cause. And -- but good cause is not no cause. It's not
12 that, oh, the federal government wants to come in and
13 dismiss. That's not appropriate. That eliminates the
14 relator's role as a check, as the Senate sought. That
15 eliminates the Court's role to adjudicate what is or is
16 not good cause in this case. Those are the concerns
17 that we bring up.

18 Now, the other thing that I think is
19 critical -- you know, there's actually a lot that I
20 agree with in terms of the government's motion. And
21 I'll try to get into some of that, but what we're facing
22 right now is the decision that was made by the EPA based
23 on what we contend are lies. That's the problem. It's
24 not about safety --

25 THE COURT: Excuse me. The EPA?

1 MR. MENDENHALL: The FDA. Did I say EPA?
2 I'm sorry, your Honor.

3 THE COURT: That's what I thought you said,
4 yeah.

5 MR. MENDENHALL: Too many agencies that we're
6 suing, I guess. But the FDA -- we considered that what
7 was said to the FDA, and we've alleged, that they are
8 lies. Everything that they talk about in the JAMA
9 article, in their brief is based on the lies that we're
10 contesting. Clinical trials that put false data before
11 the decision-makers. Clinical trials that did not
12 reflect the all-cause mortality -- the reality of
13 all-cause mortality. Clinical trials that were designed
14 to obscure and call people unvaccinated even after they
15 had had one or two shots. They were unvaccinated until
16 after it got 14 days or whatever past the second shot.

17 So that's the way this was designed. So the
18 data is completely flawed by clinical trial design. Our
19 regulators made a decision based on that, and they're in
20 here defending saying they saved millions of lives for a
21 product that we know -- and I have submitted -- we have
22 submitted to the Court a bunch of scientific articles,
23 expert testimony, experts that would come here to this
24 court to testify. And I'll proffer that to the Court,
25 by the way, your Honor. I think that, you know, we

1 are -- we greatly appreciate you having the hearing and
2 hearing us out. That does not happen in every court.
3 So I just want to tell the Court how much we appreciate
4 that.

5 But we also would like to offer to the Court
6 that we will proffer every expert that is in -- in those
7 articles that we have submitted to the Court, we will
8 proffer that. They're -- they would be willing to come
9 here and talk about the injuries, the deaths, the
10 disabilities, and other problems that have occurred from
11 this vaccine. They would be willing to talk about how
12 the JAMA article is fundamentally flawed in its
13 analysis. There's a whole another analysis when you go
14 back and look at the clinical trial data that show
15 adverse events, deaths, and no overall effectiveness and
16 all kinds of safety signals that were obscured from the
17 FDA -- see, I almost did it again -- the FDA in its
18 decision-making. That's what we're concerned about.

19 The latest travesty that occurred is the --
20 is the release of the myocarditis report. I think I
21 have it down here. 148 pages that was issued by the
22 CDC. 148 pages all redacted. Where are we as a public,
23 as a people supposed to get our information in an
24 emergency? We are -- this is an emergency. The most
25 crucial thing in an emergency is to tell the truth, have

1 facts, and have our society make decisions about what
2 should be happening there. We don't --

3 THE COURT: Let me ask a question. You've
4 indicated various studies that vaccine -- the vaccine
5 has caused serious illness, perhaps death of
6 individuals. There is litigation against drug
7 manufacturers all the time regarding a problem with a
8 drug that causes death or injury. Why can't these
9 things be brought out by representing an injured
10 plaintiff or a deceased plaintiff and go against Pfizer
11 for having a bad drug essentially is what you're saying.
12 That's one group of facts and claims and what have you.
13 But here ours is not so much concern because Ms. Jackson
14 fortunately didn't become ill or didn't die.

15 She claimed she saw discrepancies in the
16 testing in some sites here in Texas. Therefore, she
17 reported that. She was fired. And she says those
18 discrepancies that she saw caused the -- had they been
19 considered, the FDA would not have approved the drug.
20 And since -- because that happened, the government was
21 duped into paying so much money per vial and that's a
22 huge sum of money. And that's money that was -- this is
23 really that the government has been defrauded. It's not
24 so much because of the testing protocol and what have
25 you.

1 Now, whether or not the drug itself is a bad
2 drug, hurts people, kills people -- I mean, that -- if
3 that's true, it may have its place in court, but
4 wouldn't it be more in terms of a pharmaceutical
5 liability case and those can be filed.

6 MR. MENDENHALL: Your Honor, my greatest wish
7 is that there would be a court that would consider those
8 claims. What we have now is the Countermeasures Injury
9 Program. It's called the CICP, Countermeasures
10 Compensation Program. That program has been the most
11 paltry response to major vaccine injury that I've ever
12 seen in my life. I think the average award at that
13 court has been \$3,000.

14 I can tell you that I have clients right now
15 that are injured. We're going after worker's
16 compensation, that's one possibility. We're looking at
17 disability claims in social security. We're looking at
18 disability claims in private insurance. Those are
19 paltry responses to the extent of the injury that's
20 occurring here. You know, we have people -- I have a
21 client with transverse myelitis, your Honor. She's in
22 her forties. She -- I have to help her stand up if she
23 wants to give a talk somewhere. In fact, her heart is
24 failing. You know, so, no -- the answer is no. There
25 is not an adequate compensation for them. There is not

1 adequate liability, and we need to make sure that the
2 PREP Act, which I believe is unconstitutional, is either
3 overturned or changed so that people can get
4 compensation against these companies.

5 THE COURT: But what I'm -- in this case, the
6 measure of damages sought is not the value of a human
7 life that's been lost because of an adverse reaction to
8 the vaccine or something like that. It's that -- it's
9 like \$20 a vial or some -- whatever the cost was --
10 times however many vials it was. And that's in the
11 document. That's -- that's what this lawsuit's about.

12 MR. MENDENHALL: That's right.

13 THE COURT: And whether or not -- this may
14 sound harsh to say, but whether or not the vaccine hurt
15 somebody or killed somebody or somebody had an adverse
16 reaction to it, is not really what this lawsuit is
17 about. It's about getting that \$20 a vial.

18 MR. MENDENHALL: Well, your Honor, that does
19 add up to a considerable sum in the hundreds of billions
20 of dollars.

21 THE COURT: It does.

22 MR. MENDENHALL: And, additionally, we
23 believe that penalties of over \$20,000 per -- per
24 administration of the shot and that adds up to
25 somewhere at this point I think over \$4 trillion, which

1 would bankrupt and cause -- cause Pfizer to be
2 bankrupted and sold off in bankruptcy court.

3 So the damages and the penalties are very,
4 very substantial here. And the damage to the
5 taxpayer -- that's what we're addressing here. The
6 damage to the taxpayer is in the hundreds of billions of
7 dollars because we have paid for essentially a bullet
8 that blows up in your face and injures some percentage
9 of the people who shoot it. And it's not an
10 insignificant number.

11 So the product that's been provided to the
12 Department of Defense is flawed, faulty, ineffective,
13 and unsafe and is injuring our troops and it's injuring
14 our citizens. And it is not providing effectively for
15 the national defense. So that's a serious problem. And
16 we think that this is literally in the mine-run of
17 qui tam False Claims Act cases dealing with military
18 procurement where we got faulty blankets and shoes with
19 cardboard soles and bullets that didn't work. You know,
20 so it's in the mine-run, but we have to change how we
21 think about it. We have to remember this is a defense
22 contract that gave us a product that's blowing up in our
23 faces. And we have got to hold those defense
24 contractors like Pfizer accountable for that. And
25 that's -- you know, that's our position on that.

1 THE COURT: But -- and back to the issue.
2 Without all of the scientific evidence that you want to
3 proffer about the ineffectiveness of the drug or even
4 the dangers of the drug, the real issue here is were
5 test protocols followed so that the FDA approval was
6 valid. That's really what this case is about. And also
7 she reported it and got fired and she has a retaliation
8 claim -- let's don't lose sight of that -- and that is
9 also a part of this lawsuit. That's really what this
10 lawsuit is all about.

11 MR. MENDENHALL: Again, it falls right down
12 the mine-run of defense department cases where the
13 improper testing of whatever military equipment went on
14 and then the military equipment failed in the field.
15 And they run it back to see what happened with the
16 testing. It was bad, faulty, inappropriate.

17 Did you have something --

18 I'm sorry, your Honor. I've got such
19 esteemed colleagues here.

20 THE COURT: Right. Everybody wants to get in
21 on that. Well, I'm sorry. I probably got you out of
22 your stride. I'm going to let you get back into your
23 argument. I'm going to listen more. You probably -- do
24 you have some more you want to argue?

25 MR. MENDENHALL: I just want to make sure I

1 go through a couple of other --

2 THE COURT: Go ahead. I'll listen.

3 MR. FRIEDMAN: Can I just respond to the
4 question that you asked?

5 THE COURT: Is this like a good wrestling
6 match? You tag-teaming here?

7 MR. FRIEDMAN: Is that okay?

8 THE COURT: Tag team.

9 MR. FRIEDMAN: Okay. Thank you, your Honor.
10 The proffer of proof about bringing in
11 experts to show that this thing is causing injuries and
12 it's ineffective, that's part of what we're saying the
13 evidence would be. But the Cureus article that was
14 authored in part by Peter McCullough doesn't just go to
15 the fact that it's caused all this harm. He goes into
16 all of the proof of what Brook Jackson and what our case
17 says, which is they committed clinical fraud because the
18 clinical trials are very well controlled, very adequate.
19 They're supposed to be. And if you have a drug that's
20 going to cause injury, the clinical trials will catch
21 it. You can't just lie about one little thing. The
22 clinical trials have cross-checks to make sure that if
23 this vaccine doesn't protect against infection and if
24 this vaccine causes injury, then the clinical trial will
25 show that.

1 So the only reason why people got injured by
2 taking this is because Pfizer was lying in their
3 clinical trials to get the emergency use authorization.
4 So that's where the connection is. We're not suing on
5 the injuries to the people. We're suing for the
6 clinical fraud that allowed those injuries to happen.
7 And if those clinical trials were conducted correctly,
8 this thing never would have happened. And that's why
9 they're trying to cover it up. That's why the
10 Department of Justice -- the Department of Justice is
11 not saying that there was some sort of reason why we
12 should allow clinical trial fraud. They're saying the
13 vaccine is safe and effective. What's their evidence?
14 The clinical trials. They're relying upon the clinical
15 trials to support their opinion that it's safe and
16 effective.

17 So we presented a lot of evidence about how
18 the vaccine is causing injury, but that wasn't to show
19 what our case is about. That's -- those injuries came
20 about because of the fraud in the clinical trials. And
21 even the Department of Justice's position before this
22 court right now that it's safe and effective and it has
23 saved millions of lives, that depends upon the integrity
24 of those clinical trials.

25 THE COURT: Okay. Thank you very much. I

1 appreciate that. And, by the way, I will, as is
2 customary, give the movant an opportunity to make a
3 response. But I do feel like Mr. Gillingham may want to
4 address that. At least I would ask him to address that.

5 Assume everything they say is true and I
6 know -- perhaps you just assume it's true -- bad test
7 protocol that ultimately led to a drug that is
8 dangerous. Just assume that's true. Given the
9 procedural case that we're in now, a qui tam action to
10 recover for fraud on these vials that were sold to the
11 Department of Defense, if the government can evaluate
12 all that evidence and still say we don't want to pursue
13 it, is that really under Supreme Court precedent? Is
14 that really what the law is? I'll give you a chance to
15 respond in a moment, but I think that -- maybe given
16 what we've heard, that is perhaps the question that we
17 need to hear a response to.

18 All right. Go ahead.

19 He's checking his notes. You've got him off
20 his tracks.

21 MR. MENDENHALL: No. No. No. Jeremy, I
22 always appreciate -- you can't imagine the hours we've
23 spent discussing these issues, your Honor.

24 You know, just in closing -- you know,
25 this -- this -- the FDA seems to be requesting, you

1 know, basically carte blanche to dismiss. You know,
2 that their own motion to dismiss is the reason to come
3 in. I just think that is not what *Polansky* was about.
4 *Polansky* didn't really get to good cause anyway. It's
5 just on the 41(a). But once -- and once they're in the
6 case, you know, I get the 41(a) and they're leading
7 it -- so once they're let in, you know, they do gain
8 control, your Honor.

9 THE COURT: Well, what is good cause in your
10 opinion under 31 U.S.C. § 3730(c)(3)?

11 MR. MENDENHALL: Well, it's not to make a
12 claim on health policy that goes right to the issue of
13 whether the data the health policy is based on is
14 fraudulent or not. That's certainly not it. It's not
15 to dismiss. I think there has to be some reason. They
16 have to show that the federal government has some
17 burdens that are beyond just the normal burdens of
18 observing a case go on, on its own. You know, the
19 burdens that we've seen in the other cases. And I think
20 maybe it is a case-by-case analysis. Every case we
21 looked at had a burden. It had a relator who wouldn't
22 agree to -- to what the penalties were. It had a
23 relator who messed up the discovery. It had a relator
24 who messed up the trial -- the court process. You know,
25 it had relators that the government also had tried to

1 work with. We haven't had any -- you know, any
2 involvement with the government. We've required nothing
3 of them.

4 And they're not having to work on discovery
5 or anything with us at this point. Furthermore, your
6 Honor, I want to point this out: We actually -- we
7 recognize that the United States has an important role.
8 They may want to intervene. This is just not the time.
9 And they may want to intervene later, but they haven't
10 shown any burdens right now. Maybe we do become
11 burdensome on the government later. I believe that's
12 possible. And if we do become burdensome and they have
13 good cause at that point because we've created a burden
14 or there's a real problem that we've created in our
15 litigation, I think that's -- I think it's perfectly
16 reasonable for them to come back to this Court and say,
17 hey, we have this problem with discovery, the relator
18 won't let up on us and they don't even need it and boom,
19 boom, boom. So there are things that I think could come
20 in later.

21 So a dismissal today, you know, I think,
22 anyway, would be a dismissal -- would be a dismissal
23 without prejudice. I think if they had evidence that
24 there was a burden and the judge would have to be the --
25 you know, your Honor would have to be the arbiter of

1 where that threshold is -- you know, they could come in
2 later actually and move to dismiss the case.

3 THE COURT: As you know, courts are not
4 political. Decisions by an agency, decision to -- by
5 the Department of Justice, Department of Defense to
6 pursue an action may be political in nature. How can a
7 court even interfere with what might have some -- a
8 political component to it? In fact, if there is
9 criticism of the government for its decision with regard
10 to the vaccine, isn't that really a political decision
11 and citizens are free to do whatever they do politically
12 to address that? But it's not in the purview of the
13 courts to get involved in that.

14 MR. MENDENHALL: Well, your Honor, I agree.
15 The Court should look at it as not political. And the
16 relator's --

17 THE COURT: I mean, I'm stuck with Supreme
18 Court decisions and rules of procedure and -- I mean,
19 that's what the law is, you know.

20 MR. MENDENHALL: But I'm going back to the
21 Senate report, and Senator Grassley has been very clear.
22 You know, he helped pass the statute when it originally
23 passed. You know, and they left flexibility for the
24 government to intervene later. They left flexibility
25 for the government to get involved in these cases later,

1 but they didn't leave it without a check and a balance.
2 And the first check is the relator, and the second check
3 is your Honor. And they have to have good cause before
4 they dismiss this case. And if they have good cause
5 later, they can come back in. But I tell you it's not
6 good cause today, your Honor.

7 THE COURT: Okay. All right. Mr. Barnes,
8 did you want to say anything?

9 Anybody else want to say something on this
10 side?

11 MR. BARNES: Just briefly, your Honor, to the
12 Court's question.

13 THE COURT: Yes.

14 MR. BARNES: I think the interest is where
15 could good cause come into play. The Seventh Circuit
16 talked about it in one case. It's what happens when the
17 government's reason to dismiss isn't in the interest of
18 the American people or the American taxpayer. And in
19 the Seventh Circuit, they raised what if the reason is
20 they want to protect the reputation of a particular
21 businessman? Well, here we have a situation where --

22 THE COURT: Do you know the specific case?

23 MR. FRIEDMAN: The spelling is
24 C-i-m-z-n-h-c-a.

25 THE COURT: It's in your brief?

1 MR. FRIEDMAN: It's in our brief, including
2 the sur-reply --

3 THE COURT: I'll look for it. Go ahead.

4 MR. BARNES: Thank you, your Honor.

5 The -- here we have a situation where there's
6 no -- because going to the Court's question about
7 politics. Unfortunately, I think politics may have
8 contaminated the decision here. I think the Court's
9 role is to keep politics out of it. The Court's role is
10 to look at this and say, okay, have you given me a
11 reason that has a nexus to the qui tam's public
12 policies, the policies it serves? In other words, okay,
13 you've identified a change of fact or law that makes it
14 unlikely that this case is going to succeed or you've
15 got a relator that's impossible to work with that's
16 going to make it more costly, more risky than reward to
17 get the benefit, but it needs to relate to the public
18 policy of the statute. As opposed to here we have a
19 situation where the fact -- for example, the government
20 hadn't submitted any declarations under penalty of
21 perjury.

22 There's nothing from the FDA saying we have
23 evaluated Brook Jackson's allegations and we have
24 concluded they're true but we don't care. Or we've
25 evaluated Brook Jackson's allegations and we've

1 concluded factually they didn't happen. We have none of
2 that. No evidentiary submission has been made at all by
3 the government. It also goes to the Court's question
4 about when might an evidentiary hearing be necessary. I
5 think when there is a question about the basis for which
6 the government is asserting good cause. The government
7 says they're entitled to it. I think their phrase is
8 "virtually entitled." That isn't what the Senate report
9 shows. That isn't what the statute itself says. That
10 isn't what the Federal Rules of Civil Procedure provide
11 for. Nor is it --

12 THE COURT: The statute is silent as to good
13 cause.

14 MR. BARNES: It is, your Honor.

15 THE COURT: Uh-huh.

16 MR. BARNES: So what does that mean? I think
17 if the intention of the Senate and the Congress was to
18 have no limitations, it would have had no limitations.
19 It wouldn't have had any role for the Court. It would
20 have said the government can intervene any time it wants
21 without any reason or basis given. That no -- like, for
22 example, when we see the phrases "notice and to hear it"
23 in the statute, well, that comes within the broader
24 context of procedural due process. And we look at
25 what -- what do we mean by that? Normally we mean

1 notice and a hearing on the merits and a hearing that
2 has evidence if, as the Court mentioned, what if there's
3 facts in dispute.

4 THE COURT: How much due process is due? A
5 full trial in front of a jury?

6 MR. BARNES: Only, I believe, if the
7 evidence -- if it there is a factual dispute. The Court
8 pointed out a very good question the government can
9 answer or address in a minute. But here it appears the
10 government is disputing the facts. In other words, the
11 government is saying we don't want anyone to believe
12 that the vaccine is not safe or not effective or a
13 vaccine. And the -- not because they fully have any
14 testimony that they've researched our allegations and
15 found them to be untrue or immaterial. Solely because
16 there's an official public policy of the current
17 administration that states that. That doesn't sound
18 like good cause. That doesn't have a nexus to the
19 underlying qui tam's public policy purposes. That
20 sounds like there's people with a lot of reputations
21 that would be damaged if the world found out they
22 vouched for and mandated even a vaccine that wasn't a
23 vaccine, wasn't safe, and wasn't effective. That's the
24 kind of thing the Seventh Circuit is talking about.
25 What if the motivation doesn't relate to the qui tam

1 motivation.

2 In other words, are they moving to dismiss
3 because it doesn't serve the American taxpayer's
4 interests for this case to move forward? That's what
5 every single case where any dismissal has ever happened
6 in the qui tam -- that's been the government's good
7 cause. This is not in the taxpayer's interests because
8 it's not worth the risk reward. And I -- I recognize
9 what the Court says that that decision is something that
10 the judicial branch defers to the executive branch for,
11 but that isn't what they've said here. What they've
12 said here is we have an official public policy that says
13 we can't have that public policy exposed as being based
14 on bad data, bad science. That's not what the qui tam
15 is about.

16 The qui tam isn't about protecting the
17 reputation of people in power or that they currently be
18 there or to help them or hurt them in an upcoming
19 election. It's what is the benefit to the American
20 taxpayer? And here, going to Mr. Mendenhall's last
21 point, the Court can deny their motion to intervene at
22 this point without prejudice. They can come in and give
23 a roadmap to the government because this is somewhat
24 unprecedented -- this kind of basis for a motion to
25 dismiss -- and say here's what good cause is, provide an

1 evidentiary foundation for it. And then I believe if
2 there's disputes between us on that evidence, then
3 evidentiary hearing on that limited question as to does
4 this serve the taxpayer's interests because here they
5 haven't even given any evidence at all that it does.
6 And that's why we say it doesn't meet good cause, your
7 Honor.

8 THE COURT: All right. Thank you very much.

9 MR. BARNES: Thank you, your Honor.

10 THE COURT: Anything further?

11 All right. Oh, yes. Okay. Come forward,
12 Mr. Friedman.

13 MR. FRIEDMAN: I'm sorry. It ties in with
14 what Mr. Barnes was saying. If you're going to look at
15 the question of good cause to intervene to dismiss in
16 this case, you need to see it in the context of what the
17 False Claims Act is trying to achieve. Nothing would
18 undermine the False Claims Act more than telling the
19 other future "Brook Jacksons" of the world, if you know
20 about fraud in the development of these drugs, don't
21 come to us, we don't want to hear about it because our
22 government stands behind vaccine manufacturers.

23 The dismissal here that the DOJ is asking for
24 is an attempt to try to send a signal to everybody else,
25 that despite the fact that you might have a meritorious

1 False Claims Act case, don't come forward. And what
2 Mr. Mendenhall said is that -- we refer to the letter
3 that Senator Grassley wrote to the Department of Justice
4 saying that your assertion of an unfettered right to
5 dismiss cases, which is very similar to this unfettered
6 right to intervene to dismiss any time we want, that is
7 the worst thing you could do for -- not you, your Honor,
8 what the Department of Justice would do, to hurt the
9 functioning of the False Claims Act.

10 When they made those changes in the
11 amendments in 1986, they transformed this law that had
12 remained dormant from 1944 to 1986 because there was a
13 government knowledge defense. If the government knew
14 about the information of the fraud, you couldn't bring a
15 lawsuit. And they said that's not good because there
16 are people who know about fraud and they don't want --
17 they'll never come forward if what they think is they'll
18 come forward and nothing will ever happen. So you'll
19 never encourage the relators to come forward with
20 knowledge of the fraud if you have a rule that says if
21 the government doesn't want to pursue it, don't come
22 forward. And so that's why the qui tam provisions make
23 an assignment directly from Congress to Brook Jackson.

24 It's not an assignment to the Department of
25 Justice to then hire Brook Jackson and her lawyers.

1 It's an assignment to Brook Jackson and other relators
2 to enforce this action on behalf of the United States.
3 The government has an amazingly important role in that;
4 that they can intervene to dismiss when good cause
5 exists, when there's a good reason. And even if they're
6 already part of it as part of the intervention as of
7 right, they still have to have a good reason. It can't
8 just be we want it dismissed because our politicians
9 have decided that we want to support this. So in terms
10 of the good cause standard and Mr. Barnes's argument
11 that it needs to be interpreted and consistent with the
12 False Claims Act, that would require a denial of this
13 motion.

14 THE COURT: I have a question for you. Under
15 313 U.S.C. § 3730(c)(1), it's still -- the statute says,
16 I think, that the primary responsibility for pursuing an
17 action is the government's, not the relator. Do you
18 agree with that?

19 MR. FRIEDMAN: I agree that once the
20 government is a party, they have primary responsibility.
21 So they first have to be able to get into the case and
22 then they have primary responsibility.

23 THE COURT: Okay. If they get into the
24 case --

25 MR. FRIEDMAN: If they get in the case, then

1 they have primary responsibility --

2 THE COURT: And then if they decide, hey,
3 these defendants over here haven't answered yet, they
4 have a motion to dismiss on file, we're going to cashier
5 this case.

6 MR. FRIEDMAN: In the mine-run of cases, yes,
7 your Honor. However, this is not the mine-run of cases.
8 And all of the courts, including *Polansky* in Footnote 4,
9 says that there is a constitutional floor. And, you
10 know, the Department of Justice lawyers say there's due
11 process and equal protection. But that's not the only
12 provisions of the constitution. In fact, the First
13 Amendment protects the right to petition, just like it
14 protects the right to free speech. In fact, they
15 correlate together. The same rules about free speech
16 apply to freedom of petition because your right to
17 petition is an exercise of speech rights in a court or
18 in some other adjudicatory process.

19 So in this case -- for example, I posit this
20 question: Could the government say, Brook Jackson,
21 don't go into the public square and say that Pfizer
22 committed fraud in the clinical trials because we think
23 the Pfizer vaccines are great and we're not going to
24 allow you in the public square to articulate your
25 opinion that these -- clinical trial fraud is

1 responsible for all this harm? And the answer is, no,
2 they can't do that. The First Amendment protects it.
3 How is this any different? They're going into this
4 court and saying we're not allowing Brook Jackson to
5 express her opinion in this case that Pfizer committed
6 clinical trial fraud to make this thing happen, make
7 this debacle happen, and the attempt to try to cut --
8 terminate her right to petition the government on this
9 theory because of the content of her, because of the
10 viewpoint of her, and because it's her. And we know the
11 government doesn't like what she has to say because it
12 undermines what they've done with this vaccine.

13 So, yes, your Honor, the government does have
14 a predominant interest once they are a party. However,
15 they first have to have good cause to come in at this
16 late stage to become that predominant interest. But
17 even if they had intervened early on, if they decided to
18 terminate it in violation of the First Amendment or the
19 separation of powers, which -- the Department of Justice
20 didn't even address the separation of powers. We -- we
21 put an opposition -- that's the Seventh Circuit with the
22 difficult name to pronounce -- that said you have to
23 consider the separation of powers. It should weigh
24 heavily in any good cause determination if what the
25 reason why they're trying to terminate a case is because

1 it's going to embarrass or expose some sort of financial
2 interest in some executives.

3 So this separation of powers argument is
4 extremely important even with the government having a
5 predominant interest. And the Department of Justice has
6 waived their argument in opposition at this stage. If
7 the motion is denied without prejudice, they can bring
8 it again, they can put in actual evidence, and we would
9 then petition for an evidentiary hearing to prove the
10 things that we've offered.

11 THE COURT: Okay. All right. Thank you very
12 much.

13 MR. FRIEDMAN: Thank you.

14 THE COURT: I'll give the government a chance
15 to respond.

16 MR. GILLINGHAM: Thank you, your Honor. I'll
17 try and respond to the tag team here. I mean, Eastern
18 District of Texas, as you know, one riot, one ranger, so
19 I'll -- you'll be stuck with me.

20 A few points, your Honor. The purpose of the
21 False Claims Act is to protect the government from
22 fraud. This is not a general purpose statute to
23 litigate any concerns outside of that. I think we heard
24 from Mr. Mendenhall of FOIA issues regarding the
25 myocarditis report. That's a FOIA issue. That can be

1 litigated in FOIA. That has no bearing on what's
2 happening here.

3 Whether or not he believes the PREP Act is
4 unconstitutional. Again, these are not issues that need
5 to be litigated here. The False Claims Act is not the
6 ultimate entry point for any litigant to address
7 concerns they have with the government's actions. And
8 that's exactly what's happening here. It seems like
9 there's an attempt to usurp the False Claims Act and
10 move it away from what it is, which is an effort for the
11 government to protect itself from fraud, from paying for
12 something it shouldn't have paid, into a general attack
13 on the COVID vaccine.

14 I think Mr. Mendenhall mentioned that there's
15 no burden on the government. They haven't imposed a
16 burden on us at this point. And that may be true. This
17 is early, but we have had to come in and file a
18 statement of interest, your Honor. And even in the
19 earlier hearing -- I believe it was back in March --
20 Mr. Mendenhall himself argued that we need discovery --
21 we also need discovery from the federal regulator and
22 the FDA and talk to them about what their standards are.
23 That's on Page 108, Line 18 through 109, 1, your Honor.

24 This isn't some, like, mere possibility in
25 the future. I could go through plenty of statements in

1 the briefing and -- you know, setting aside all of the
2 public -- the public statements on social media and
3 otherwise. The relators are coming after the government
4 here. They're arguing that we're corrupt, that we're in
5 bed with Pfizer, attacking our individual attorneys
6 saying they're going to need discovery to prove all
7 this. Again, your Honor, the False Claims Act is
8 designed to prevent our interests and that our interests
9 are predominant. And here we've done the kind of cost
10 benefit analysis that we -- I think Mr. Barnes said, you
11 know, that generally this is an issue where there's some
12 sort of cost benefit analysis in these cases that hasn't
13 been done here.

14 I think that the problem is, your Honor --
15 and I would invite you to look at Page 7 of our motion
16 to dismiss. Yes, the concluding line on that references
17 that the government shouldn't be forced under these
18 circumstances to pursue a case that's inconsistent with
19 its public health policy. And I agree with that. But
20 the preceding paragraph talks about the concerns about
21 the viability of the case given what the FDA knew and
22 what it's continued to see through things that happened
23 after the EUAs ended and also the burdens of litigation,
24 which are very clearly going to be coming. I guarantee
25 you that if this goes into litigation, we're going to

1 get buried by -- by not only the defendants, but now
2 apparently in addition to defending discovery from the
3 defendants, we have to prove that we're not corrupt?
4 No. For a case that we've evaluated has little chance
5 of success and these burdens coming, this is exactly the
6 sort of thing that does establish good cause for the
7 United States to say enough is enough.

8 I think -- you know, a couple of other
9 points, your Honor. We heard about the right to
10 petition. You know, the Footnote 4 in *Polansky* talked
11 about constitutional concerns. It identified due
12 process and equal protection. I work in the False
13 Claims Act space, and I have never heard of a court
14 concerning a First Amendment right to pursue a False
15 Claims Act case. And it really doesn't make sense, you
16 know. If you go back and look at *Blackstone* or *Stevens*
17 and talk about the limited assignment of rights to a qui
18 tam relator, they're -- those would have derived from
19 what the government's right as the real party in
20 interest were. And the government doesn't have a
21 First Amendment right to petition, and Ms. Jackson is
22 not prevented from petitioning.

23 THE COURT: Well, this is not the public
24 square. This is a courthouse.

25 MR. GILLINGHAM: It's not the public square.

1 It's not a courthouse. And from the -- from what we see
2 in the courthouse today, clearly Ms. Jackson has not
3 been prevented from putting her message out there. She
4 can pursue other avenues. As your Honor hinted at
5 before -- I mean, if she's concerned about the decision
6 on the EUAs, the proper procedure to challenge final
7 agency action is through the Administrative Procedures
8 Act. And, believe me, we have seen multiple APA cases
9 involving all aspects of COVID since -- since this has
10 taken place. If there's concerns about what the FDA is
11 doing, there are citizen petition rights.

12 But, again, the False Claims Act is not a
13 catchall for people who want to voice concerns about the
14 government policy. It simply doesn't apply here. As
15 for separation of powers, I'll mention it briefly. We
16 didn't spend a lot of time addressing this in the brief.
17 I think that the courts have considered separation of
18 powers issues. You know, this was not an issue for the
19 Supreme Court there. And some of these arguments --
20 both the right to petition and the separation of powers
21 issues, these would be exceptions that swallow the rule.

22 If -- if the government moving to dismiss,
23 which is provided for by Congress in the statute somehow
24 was violating the First Amendment or the separation of
25 powers in a way that it shouldn't be allowed to, then

1 that would read those out of the rule, your Honor. And
2 I haven't seen any cases, including the *Polansky* case,
3 where the Court found that the separation of powers
4 issue was something that prevented the government from
5 proceeding there. And also, your Honor, we have to keep
6 in the back of our mind that, you know, the executive
7 was assigned in the constitution, the take care clause,
8 to take care that the laws were enforced.

9 And, of course, cases like *Heckler v. Chaney*
10 say that the government's decisions in terms of whether
11 or not to prosecute or how its administrative priorities
12 are done are ill-equipped for the courts to handle, and
13 they should -- the Court shouldn't second-guess whether
14 or not something is prosecuted. And that's similar to
15 this. You know, we didn't choose for this case to be
16 filed. We investigated it, dealt with it, and now we've
17 decided to end it. Much like the courts can't step in
18 and tell the prosecutors down in the Beaumont office,
19 like, hey, you have to go prosecute this particular
20 person. It's a similar concern here, your Honor.

21 And, you know, I hear the concern that we --
22 that this dissuades relators, your Honor. I don't
23 really know how to -- exactly the way to respond to
24 that. You know, relators know what they're getting into
25 when they file the case. They're eventually going to

1 become public that they filed the case, and there is
2 always a chance the government steps in to dismiss.
3 It's not a surprise. It's in the statute. And, your
4 Honor, before assuming my current position, I was in a
5 firm as a civil enforcement attorney. It's all I did.
6 Relators were essentially my clients. Like, we love
7 relators. We want them to bring the cases because they
8 help afford the government the ability to do what it
9 does in protecting itself from fraud.

10 The last -- the last thing, I think, I -- you
11 know, I'll try to address your Honor's hypothetical.
12 This -- I want to be very clear. I think that the
13 government very much disagrees with the premise there.
14 But I believe your Honor asked us -- and maybe if you
15 restated it, it would help me just to make sure I'm
16 addressing it properly. I think the idea was if we
17 assume that everything is a lie, would the government do
18 something different? Is that close?

19 THE COURT: If all of the complaints that
20 Ms. Jackson has about the process and about the dangers
21 of the -- of the vaccine were true -- given all that --
22 just accept it as true -- could the government still
23 decide on their own we don't want to pursue this action
24 and we want -- it's our case and we want to dismiss it?

25 MR. GILLINGHAM: Yes, your Honor. And I

1 think that in this case actually Ms. Jackson did voice
2 her concerns to the FDA prior to the EUA. They had that
3 -- they were aware of that. They put out the EUA But I
4 think it's important to remember this case is not
5 limited to what Ms. Jackson learned in her two weeks at
6 one or two locations. The clinical trial was much
7 bigger than that. The Ventavia locations were a mere
8 small subset of the overall data that was considered by
9 FDA. They considered that data, and they actually
10 considered -- were able to consider what Ms. Jackson put
11 forth. But the clock doesn't stop there, your Honor.

12 The FDA continues to monitor these things. I
13 think if -- you know, even in the Danco oral argument
14 that counsel cited in their brief, the solicitor general
15 talked about how the FDA continues to monitor the
16 environment and look for adverse -- adverse events and
17 can always take -- make changes to the regulatory
18 landscape. This isn't some sort of switch that turned
19 off once the EUA was granted. And going back to the
20 JAMA article, which, again, you know, according to
21 relators, it's all false and based on lies. The FDA has
22 access to everything the relators have access to.
23 Ms. Jackson ended her tenure at Ventavia a long time
24 ago. There's no new information that she came out of
25 that was, like, a hidden source that she has provided to

1 the government.

2 Most of the data at issue came from FOIA
3 requests to the government. It's the government's data.
4 We have access to our databases and all of the studies
5 that are cited. These aren't hidden studies that they
6 just published for purposes of this litigation. These
7 are studies that are in the public domain. The FDA has
8 access to this. It simply doesn't have the same
9 conclusion. And I think that the case law is clear that
10 if the government has an argument -- a good argument for
11 why it should be dismissed, even if there is a vigorous
12 defense and even if the relator may have a different
13 position, the question is whether or not the government
14 should be able to dismiss because it's pursuing its
15 interests.

16 And here we think that the government has
17 established good cause because of the concerns about the
18 merits of this weighed against the burdens. And given
19 that, the government believes it's time to stop the
20 case from going forward, intervene pursuant to
21 31 U.S.C. § 3137(c)(3), and dismiss this case over
22 relator's objections pursuant to (c)(2)(A), your Honor.

23 THE COURT: Okay. All right. Thank you very
24 much. The Court is going to take this matter under
25 advisement. And we're going to take a brief ten-minute

1 break -- a comfort break for everyone. And then we will
2 pick up with the defendants' motions and -- I think -- I
3 would hope you can be very concise in your arguments.
4 And -- and then -- I don't know if you want to change
5 tables. That's -- it is a bit interesting to see the
6 visual here because in most qui tam actions the
7 government is sitting with the relators. And here
8 they're with the alleged defrauders. In any event, that
9 kind of speaks volumes.

10 All right. We're in recess.

11 (Recess taken.)

12 THE COURT: Thank you. And please be seated.

13 All right. And now we will hear from
14 Ventavia, correct?

15 MS. MCDONALD: Yes, your Honor. I think we
16 decided that -- whether to retread all the grounds
17 that's been discussed previously and fully briefed --
18 I'm going to discuss retaliation first because your
19 Honor referenced earlier that that claim would
20 potentially stand were the case dismissed by the
21 government.

22 THE COURT: Okay. Thank you.

23 MS. MCDONALD: So I'm going to go ahead and
24 discuss retaliation, which is a claim that only pertains
25 to Ventavia as Ms. Jackson's former employer, but which,

1 even as amended in the second amended complaint, fails
2 as a matter of law. And I will discuss the reasons why.

3 First, your Honor, as to Count Five, I'll
4 discuss the False Claims Act retaliation claim. And you
5 previously dismissed that claim on two independent
6 bases. One was that Ms. Jackson failed to allege she
7 engaged in protected activity within the meaning of the
8 statute, the False Claims Act; and, two, she failed to
9 allege that Ventavia knew she was engaged in protected
10 activity. And so those are the two bases on which you
11 previously dismissed this claim.

12 She then amended the claim in her second
13 amended complaint, but nothing has changed with respect
14 to those two independent bases on which this Court
15 dismissed her prior claims. And so they must be
16 dismissed again. I'm going to try to be brief. I know
17 we're short on time. So as we explained in our brief,
18 the Fifth Circuit has run a clear line between the kinds
19 of internal reports that give rise to a retaliation
20 claim under the False Claims Act and that are, quote,
21 protected activity under the statute. In order to be
22 protected activity, the relator must have actually
23 raised concerns about false claims for government
24 payment, not nearly criticize the company's business
25 practices or even discuss regulatory violations,

1 et cetera. And this Court previously dismissed her
2 retaliation claim on this bases.

3 Ms. Jackson did not cure this issue in her
4 second amended complaint. In fact, her factual
5 allegations have not really changed. She continues to
6 say, as you'll see in her second amended complaint, that
7 she engaged in protected activity through internal
8 complaints about participant safety and regulatory
9 protocol and HIPAA violations, just as she stated in her
10 first amended complaint. But these allegations, again,
11 fall short as a matter of law under Fifth Circuit
12 precedent of rising to what constitutes protected
13 activity under the False Claims Act.

14 Further, on the second basis that this --
15 these claims were previously dismissed, as before
16 Ms. Jackson fails to allege that Ventavia knew she was
17 engaged in protected activity, which is also required
18 under the False Claims Act retaliation provision. And
19 for both of these reasons, Ms. Jackson's FCA retaliation
20 claim must be dismissed on the same basis as the Court
21 previously dismissed it.

22 And now when Ms. Jackson amended her
23 complaint for a second time, she added a state law
24 retaliation claim. And that one is Count Six in the
25 second amended complaint, and that claim also fails as a

1 matter of law for reasons I'll briefly discuss. First,
2 your Honor -- I guess before I get to that, were you to
3 dismiss the entire complaint, either because -- grant
4 the government's motion or our motions, we would -- we
5 would first argue that you should decline to exercise
6 supplemental jurisdiction over the standalone state law
7 claim in that instance. So that would be our primary
8 argument.

9 But second and most importantly, the state
10 law retaliation claim also fails and must be dismissed
11 as well. And that is also on two independent bases.
12 First, the state law retaliation claim is based on
13 Section 161.134 of the Texas Health and Safety Code,
14 which does not apply to Ms. Jackson or to Ventavia as a
15 matter of law because Ventavia is not the type of
16 healthcare facility governed by that statute. And we
17 explained this in detail in our brief, and it is --
18 there is quite a bit written on that. But
19 Section 161.134, which is the provision under which she
20 brought her retaliation claim, appears in a narrow
21 subchapter related to, quote, abuse, negligent, and
22 unprofessional or unethical conduct in healthcare
23 facilities. That chapter defines abuse and negligent by
24 references to a Federal Protection and Advocacy for
25 Individuals With Mental Illness Act and addresses

1 misconduct against patients receiving chemical
2 dependency, mental health, or rehab services.

3 And so taking that in context, that section's
4 retaliation provision protects only the employees of
5 three types of healthcare facilities; hospitals, mental
6 health facilities, and treatment facilities. None of
7 these apply to Ventavia. Ms. Jackson alleged in her
8 opposition to our motion to dismiss that Ventavia is a
9 treatment facility under the statute, but it's not. The
10 term "treatment facility" is defined by reference to
11 Section 464.001, which lists facilities like hospitals,
12 outpatient facilities, halfway houses, end quote, and
13 any other facility that offers or purports to offer
14 treatment. And then treatment is defined as a planned,
15 structured, and organized program designed to initiate
16 and promote a person's chemical-free status or to
17 maintain the person free of illegal drugs.

18 And so under those definitions, Ventavia is
19 not a treatment facility because it undisputedly does
20 not provide programs that promote chemical or drug-free
21 status. And not only does the plain reading of that
22 statute defy her interpretation that it is a treatment
23 facility, but there is some case law interpreting the
24 statute that disagrees with her interpretation. There's
25 at least two cases we mentioned in our brief that have

1 held the term "treatment facility" in the statute is
2 plainly limited to those that provide some form of
3 chemical dependency or addiction treatment program.

4 And even if the statute did apply to
5 Ventavia, which we don't believe it does, Ms. Jackson
6 has not sufficiently alleged the type of violation of
7 law contemplated by that section. The statute lists
8 three types of violations; a violation of this chapter,
9 a rule adopted under this chapter, or a rule of another
10 agency. And relator's second amended complaint alleges
11 none of these. And so on those bases, your Honor, we
12 would respectfully request that you grant our motion to
13 dismiss and dismiss for retaliation claims both under
14 the False Claims Act and Count Six under the state law.

15 And then, your Honor, she does request leave
16 to amend yet again in order to plead a new common law
17 claim for wrongful termination and additionally to cure
18 any further deficiencies, and we would respectfully ask
19 that that request should be rejected with prejudice.
20 You know, she's had several opportunities to plead a
21 viable claim, if she has one. As you noted this
22 morning, you know, her original complaint has been
23 filed -- was filed three years ago, first amended in
24 February '22. After this Court's dismissal, she was
25 given another opportunity to amend. And she could have

1 alleged the wrongful termination claim at common law if
2 she had that claim at that point. And, in fact, her --
3 I think her -- her opposition actually states on Page 28
4 that it would be based on the same facts she's had, your
5 Honor. So we would ask that you dismiss her retaliation
6 claim, Count Five and Count Six, against Ventavia with
7 prejudice and deny her motion to file an amended
8 complaint.

9 THE COURT: All right. Thank you. Anything
10 else?

11 MS. MCDONALD: No, your Honor.

12 THE COURT: Thank you very much.

13 Yes. Come forward, please.

14 MR. DAVIS: Your Honor, Scott Davis on behalf
15 of Icon. Your Honor, despite the extraordinary breadth
16 of the discussion which you've had so far today, I
17 believe I can be brief, as the Court requested, because
18 the reality is the issue that brings us here today is
19 actually quite simple. The Court may recall you've
20 already dismissed this complaint once. Counts Two,
21 Three, and Four of the second amended complaint were
22 included simply to preserve them for appeal. They're
23 not at issue today. And, by the way, that determination
24 that the claim should be dismissed and lacked merit in
25 the Court's prior ruling is a fact which clearly

1 supports the United States's determination regarding the
2 likelihood of ultimate success here and is consistent
3 with their determination that the claim should be
4 dismissed.

5 But in the event you choose not to dismiss as
6 the United States has requested, you should still
7 dismiss Count One -- and that's the only count at issue
8 except with regard to Ventavia. For Pfizer and for
9 Icon, Count One is the only issue. It was a fraudulent
10 inducement claim. And the Court granted the relator
11 leave to file that claim to potentially cure some of the
12 deficiencies which led to the prior dismissal of the
13 other counts. And in response, the relator added 20
14 paragraphs relating to that count to the second amended
15 complaint. That's it. Those 20 paragraphs are all that
16 are at issue in this motion to dismiss.

17 Those 20 paragraphs do not meet the
18 particularity requirements of Rule 9(b). They don't
19 specify particular fraud by any of the defendants. They
20 certainly don't specify fraud as to my client Icon,
21 which I'll elaborate on in just a moment. But just as a
22 reminder, the United States attorney mentioned this,
23 there really can't be fraudulent inducement in this
24 particular scenario because all of the allegations which
25 Ms. Jackson makes today were allegations which she

1 provided to the FDA prior to the issuance of the EUA
2 They were aware of these allegations. There was no
3 concealment. There was no fraud. And, thus, there is
4 nothing that can be pled even theoretically that would
5 satisfy the requirements of the False Claims Act case.

6 And as you mentioned, Judge, this is not a
7 personal injury case. It's not a political discussion.
8 It's a fraud claim. It's a claim involving fraudulent
9 statements made with fraudulent intent for the purpose
10 of securing payment. And in regard to my client, that
11 standard can never be met. As a reminder, Icon did not
12 contract with the government. Icon was not paid by the
13 government. Icon did not make submissions requesting
14 payment from the government. Icon did not -- did not
15 act in concert with Pfizer for the purpose of its
16 submitting payments to the government. Icon was not
17 in a position that it could ever be subject to a
18 False Claims Act. And the relator apparently knows this
19 because they've never even tried to make specific
20 allegations that would satisfy the requirements of the
21 False Claims Act and the particularity requirements of
22 Rule 9(b) in regard to Icon.

23 At our previous hearing in March, I walked
24 you through in some great detail all of the allegations
25 that involved Icon. None of them involved statements at

1 all or representations. None of them involved falsity.
2 None of them involved sinister. When they amended their
3 complaint following that dismissal in Count One, they
4 added those 20 paragraphs I mentioned a minute ago.
5 They don't mention Icon. None of them are specific to
6 Icon. They just get lumped in together with the
7 defendants, but there are no specific allegations made
8 regarding Icon. In the entirety of the claim, if you
9 look at Pages 29 and 30 of their response, in their
10 effort to summarize their False Claims Act allegations
11 against Icon and, for that matter, Ventavia, again, none
12 of them involve actual representations. None of them
13 involve actual falsity. None of them involve actual
14 fraudulent intent and, thus -- and none of them, in
15 fact, involve request for payment. And, thus, none of
16 them, in regard to either Icon or Ventavia, could
17 possibly qualify for recovery under the False Claims
18 Act.

19 In essence, Judge, what the relator is asking
20 you to do today is to ignore your own prior ruling
21 regarding the merits of this claim, the DOJ's evaluation
22 of the merits of this claim, the clear Supreme Court
23 precedent in *Polansky*, and the determination that was
24 made by the FDA and continues to be made by the FDA with
25 full knowledge of the allegations that Ms. Jackson

1 brought to them at the time and today as a result of
2 this litigation. None of that is warranted. If we
3 focus on the issue, the simple question, did they
4 satisfy Rule 9(b) for pleading the necessary elements of
5 the False Claims Act in Count One of their complaint,
6 the answer is clearly, no, they didn't. They didn't
7 even come close. They didn't as to any of the
8 defendants, and they certainly didn't as to mine. And
9 that failure, together with this Court's prior
10 dismissal, is a clear demonstration of the merits of the
11 DOJ's determination that the costs of this litigation
12 will ultimately outweigh the benefits. And, therefore,
13 we would ask that the case be dismissed either by virtue
14 of the government's dismissal or by virtue of our own
15 motion to dismiss under 12(b)(6).

16 Thank you.

17 THE COURT: Thank you very much, Mr. Davis.
18 And Pfizer is next.

19 MR. WESSEL: Your Honor, I'll be very brief
20 because I know we spent quite a bit of time last year
21 talking about the motion to dismiss. And really,
22 your Honor, the issues are identical here. Your Honor
23 has allowed amendment to -- for the relator to add a --
24 bring a fraudulent inducement claim. The issues of
25 materiality are precisely the same as they were back

1 when we talked about this in March. And they -- the
2 governing precedent there is the Fifth Circuit's *Harman*
3 case.

4 The only thing that's changed, frankly, your
5 Honor, is the government's motion to dismiss. So I
6 think that the lack of materiality has become even
7 stronger since we filed our motion and since we talked
8 about this last year. I'm happy to answer any questions
9 you might have about that, but that's our position
10 there.

11 I'd like to just briefly address -- and I'm
12 not going to get into a lot of point-by-point rebuttal
13 of relator's allegations. Today is not the first time
14 they've made unsubstantiated allegations against my
15 client and they've made unsubstantiated allegations
16 against many people -- other people in this courtroom.
17 But, you know, this -- we talked about this is not the
18 place for a mini trial. But I do think it's important
19 to just put on the record that if this case does go
20 forward, Pfizer is prepared to rebut each and every one
21 of those allegations point by point. And it is very
22 confident it will be able to do so. The company is very
23 proud of having developed the lifesaving vaccine in
24 record time during a pandemic. That -- you know, as the
25 government talked about in its submission here, along

1 with other vaccines, saved tens of millions of lives.
2 So I just want to state that for the record. Again, I'm
3 not going to get into a tic for tac on all of that.

4 We -- I'll mention briefly -- we talked about
5 the materiality. Your Honor mentioned this issue of
6 standing, Justice Thomas's dissent, in the *Polansky*
7 case. I found it to be a very intriguing argument. We
8 briefed it in our brief. And, you know, we still take
9 the position that there's an Article II issue there with
10 even allowing qui tam actions. And, again -- but
11 that -- that you see in our brief and I don't need to
12 spend a lot of time on it unless your Honor has any
13 questions about that.

14 But in conclusion, we would ask the Court to
15 follow the Supreme Court precedent in *Polansky* and grant
16 the government's motion to dismiss. And if it declines
17 to do so, to follow the Fifth Circuit precedent in
18 *Harman* and grant our motion under 12(b)(6) and 12(b)(1)
19 and dismiss Counts One through Four of the complaint.

20 THE COURT: All right. Thank you.

21 Anything further from the defendants?

22 Okay. All right. From the relator?

23 MR. MENDENHALL: Thank you, your Honor. And
24 just to let the Court know, Attorney Barnes is going to
25 address the 3730(h) part of the argument.

1 THE COURT: All right.

2 MR. MENDENHALL: But I will -- I will attempt
3 to address some of the other issues that have arisen
4 here. You know, it is very interesting -- you know, the
5 statement of interest that was submitted by the
6 United States last year. And, in fact, the Court's
7 ruling on -- incorporating the ideas of the statement of
8 interest. And the fact that we had mentioned fraudulent
9 inducement, but this Court directed us that there was
10 a -- a better way to insert that into our complaint
11 and -- and we greatly appreciated the opportunity to add
12 the fraudulent inducement count to the complaint. And
13 we followed the roadmap laid out by the United States.
14 I think that may be what's happening here. Because, you
15 know, Pfizer and the defendants do not agree with that
16 roadmap. They do not believe there could be fraudulent
17 inducement when you lie and cheat the FDA. But the
18 United States does not want to give that -- that up.

19 They are -- they are backing that theory of
20 the case that there can be a fraudulent inducement to
21 the FDA if bad data is submitted. And we really have
22 seen -- you know, it's been such an interesting process
23 because this has gone on for years. And we've got the
24 most remarkable public effort by experts and citizens to
25 understand the data that keeps coming out day after day

1 after day showing the inefficiency and effectiveness and
2 harm that these, quote-unquote, vaccines are causing.
3 And every bit of data has been borne out and shows that
4 that clinical trial data is not being reflected in the
5 populations around the world. It is not being reflected
6 here in the United States.

7 And, in fact, the injuries that were covered
8 up, the deaths that were covered up, the effectiveness
9 that was obscured to show it was effective, all of that
10 has now been verified by public -- you know, by
11 scientists operating in the public interest, operating
12 independently, operating pro bono, and they verified all
13 of the -- all of what we knew because of the falsity in
14 the clinical trial. So it shows how important this
15 clinical trial data is, and it shows this remarkable
16 effort that I think that the United States unfortunately
17 has not -- is not respecting what has happened here.

18 So I want to go back up here. You know,
19 we've listed -- I'm not going to go through the listing
20 of failures. I think that's on Page 7 of the second
21 amended complaint. But, you know, there's about a page
22 of the failures including, you know, the unblinding, the
23 high adverse events in the control arm didn't look
24 right. And then we saw the data come out initially in
25 the first three months of these shots. There were

1 93,000 adverse events that occurred in the first three
2 months that these shots were, you know, issued into the
3 public.

4 There were over 300 strokes. One percent of
5 the population had facial paralysis. You know, over 500
6 people had neurological damage. We had 38 people that
7 had MS and 11 that had adverse myelitis. This is in the
8 public data that was supposed to part of the remainder
9 of the trial -- the phase three trial, which, as your
10 Honor knows, was truncated by vaccinating them way back
11 in December of 2020. So the design of this trial,
12 this -- this design was -- was set up in a way to show
13 an effectiveness that was never there and it was to
14 obscure the problems that were emerging among the trial
15 participants and it obscured the impact on the public.

16 They destroyed the control group in December,
17 like I said. They didn't report adverse events, and
18 they falsely counted the vax as unvax. And I've gone
19 over this a little bit before. But, you know, all I'm
20 trying to say is we amended the complaint based on the
21 federal government's guidance, based on this Court's
22 guidance, to go after fraud in the inducement. That's a
23 theory that the federal government actually backs. I
24 don't think they want a ruling on that. I think that's
25 why they've come in and have moved to dismiss at this

1 time.

2 And I'll let Bob follow up on the 3730(h)
3 retaliation part.

4 THE COURT: Yes. Okay. Thank you.

5 MR. BARNES: Thank you, your Honor. I
6 appreciate that the Court afforded this generous hearing
7 as it did before so that all parties could be heard.

8 It was interesting what the government said
9 earlier when it suggested that there were other places
10 and mechanisms of suit. But point in fact, if you're
11 injured or harm is caused from this drug because there
12 was -- Dr. Davis submitted to the government -- you
13 can't sue under the PREP Act. Everybody is immune. So
14 if you're injured, out of luck. If -- the government
15 suggested, well, they could always sue under the APA.
16 Well, I would know something about that because I filed
17 a suit against the FDA on behalf of Robert Kennedy and
18 Children's Health Defense. And what was the
19 government's position? Oh, no, actually, you can't. No
20 standing to sue and to challenge the FDA's ruling.

21 And now they say you can't sue even when you
22 found the fraud and were the first to find it like
23 Brook Jackson. This just leaves us with one little thin
24 effort at the petition of redress of grievance as
25 preserved under the First Amendment for Brook Jackson

1 and that is her retaliation claim against Ventavia.
2 There's -- we amended the facts of the complaint because
3 the Court originally noted there wasn't a connection --
4 there was no fraud inducement claim originally brought;
5 and, thus, there was no connection between her protected
6 activities and the fraud claim. That has been remedied
7 by the amendment.

8 Now, everything she was -- why did she get
9 fired? It's kind of obvious. She reports it to the
10 FDA. She tells them the day before she's going -- this
11 can't continue. That they can't continue to enroll
12 people. They've agreed not to enroll people. She goes
13 to the FDA. That afternoon she's fired after she
14 reports to the FDA. The connection to the false claim
15 is that they were falsifying information to the FDA for
16 the fraud and the inducement to get the money. The
17 Court's point was that that connection wasn't originally
18 in the complaint -- in the first amended complaint. It
19 now is in the second amended complaint.

20 So under the very liberal standard afforded
21 pleadings, we've alleged sufficient facts to at least
22 reach the discovery stage of the case as it concerns
23 3730(h). Secondly, as to the Texas Health and Safety
24 Code, I would note that the provisions --

25 THE COURT: Let me interrupt just a second.

1 MR. BARNES: Yes, your Honor.

2 THE COURT: I think in their motion, they --
3 they're saying that you didn't specify the fraudulent
4 acts as to each of the individual defendants. Do you
5 have a response to that complaint?

6 MR. BARNES: Yes, your Honor.

7 THE COURT: That issue they raise?

8 MR. BARNES: Yes, I do. I don't think that
9 would relate to the retaliation claim. I think that
10 would relate to the other --

11 THE COURT: Yeah. Well, it really does. But
12 when you said that, it made me think about that.

13 MR. BARNES: Yes, your Honor. Understood.
14 The -- there is specific allegations, but here you have
15 three parties working together to submit the emergency
16 use authorization information in order to get payment
17 under the contract. So our allegation is -- is specific
18 to individual -- individual defendants when it's
19 applicable, but in many cases they're acting jointly.
20 And they're acting for joint benefit and for joint
21 objective and they're involved in joint fraud. And
22 there are supervisory relationships between them. There
23 are other agency relationships between them that we
24 allege. But if the Court goes back to what this Court
25 discussed last time, which was what Justice Thomas said

1 in *Aguilar* -- said if you're trying to figure out if
2 there's a fraud, look at the essence of the bargain.
3 Don't worry too much about the formalities and
4 technicalities. What's the essence of the bargain? The
5 essence of the bargain is the defendants joined together
6 and promised to the defense department that they would
7 deliver something specific; a safe, effective vaccine
8 for the prevention of COVID-19. Not as a diagnostic,
9 not as a therapeutic, but as a true inoculation. And
10 that's what's repeated throughout the defense
11 department's statement of work. That's what's in the
12 defense department contract. And they are collectively
13 working to achieve that. They're making arguments
14 about, well, Pfizer is the one that technically asked
15 for the money and then we got paid from Pfizer. Or
16 Ventavia was actually doing the clinical trials and
17 Pfizer was just supervising. But they're acting
18 collectively for a joint effort, for a joint benefit
19 from the government.

20 And the problem is we look at the essence of
21 the bargain. Why is this fraud? If we're just -- we
22 get away from all the technicalities and formalities.
23 It's they promised to deliver a safe, effective vaccine
24 for the prevention of COVID-19. And what they
25 delivered, because they doctored the clinical trial data

1 to get the false emergency use authorization, is a
2 dangerous, ineffective drug that doesn't inoculate
3 against anything. So it's not even a vaccine, and it
4 doesn't prevent COVID-19.

5 The whole essence of the bargain -- the
6 reason why the defense department was offering this
7 incredibly lucrative billions of dollars project was for
8 this extraordinary delivery at speed and scale of a
9 vaccine that most people thought couldn't be delivered
10 and still be safe and still be effective and still be a
11 vaccine and prevent COVID-19. Coronavirus is notorious
12 for evading vaccines. What Brook Jackson figured out
13 was that they knew they couldn't deliver that. That's
14 what she was witnessing. She didn't realize that. She
15 spent almost 20 years trying to make sure we had safe,
16 effective medicine; safe, effective vaccines.

17 She gets there and all of the rules are being
18 thrown out. You have bags with needles sticking out of
19 them. You have people's private medical information
20 plastered on the walls for anybody to read. You have
21 people being rolled out in the hallways and not even
22 being monitored. You have people being completely
23 unblinded. The whole basis of all clinical trial
24 success is protection of blinding at all costs. Here
25 you have everybody being unblinded. Anybody can see

1 what's happening. You have people bringing in their
2 friends and their family members and other people and
3 paying them under the table. Why? Because they
4 couldn't deliver at speed and scale what they were
5 promising the government they could. But there were
6 billions of dollars on the line. And that's a mighty
7 temptation.

8 And when she brought up -- Brook Jackson
9 said: We've got to fix this. Let's just stop
10 enrollment. Let's just fix this. She wasn't trying to
11 undermine it, trying to prevent it, trying to preclude
12 it. She just said: Let's make sure we can fix it so we
13 do the clinical trial data right so the world can have
14 confidence that this will be safe, that this will be
15 effective, that this will work. And as she kept
16 documenting it, you know, with photographs, texts, and
17 other information -- when she brought it in, they were
18 shocked at how much documentation she had. They had
19 been slow rolling her for weeks. And then they were
20 like: What have you done? How in the world did you
21 take photos? Like, we've just got to focus on
22 delivering what we've promised everyone we're going to
23 deliver. And that's when they said: Well, maybe you
24 need to go home, but didn't terminate her or anything
25 else.

1 So she reaches out to FDA and says, you know,
2 here's the problem, basically we can't deliver a safe,
3 effective vaccine at speed and scale because we can't
4 even honor the very basic limits of honest clinical
5 trial data. We can't deliver it, details it. That
6 afternoon she's fired. That afternoon she's terminated.
7 And then she risks her entire future and career to bring
8 this to the attention of the United States Government.
9 Who for more than a year told this Court that they were
10 seriously and sincerely investigating the allegations,
11 that they were doing a thorough review of it. We still
12 never seen what the product of that thorough review is.

13 But now when they come in and step in late
14 and ask for it all to be dismissed and for the very last
15 case -- the very only case that can ever get any remedy,
16 any truth for the American people is this case. Because
17 of all the immunities, because of all the standing
18 limitations, because of all the special provisions
19 applicable to this very unique public health
20 controversy, this is the only case the American people
21 have a chance for the judicial branch to have a role.
22 Because without it, we are stuck in a situation where
23 the American people are left in the dark. The American
24 people are left out. The American people, who the
25 qui tam law is supposed to be there to protect and

1 enforce, is the very law used to abandon them in the end
2 if the government is to have its way.

3 She provided under the same Texas Health and
4 Safety Code, your Honor -- it's very broad. It talks
5 about treatment facilities. It talks about any facility
6 where medical treatment takes place. That is the
7 definition of a clinical trial location. That's why
8 there are doctors there. For example, one of the issues
9 she raised was what about people that could have an
10 allergic reaction to something in the vaccine. They
11 have to have special protocols to treat those people on
12 the scene -- to diagnosis it and treat it. That sounds
13 like a treatment facility. They attempt to borrow from
14 other statutes and suggest that maybe this is a very
15 narrow statute.

16 If you have any doubt about what the Texas
17 state position is on whether or not what's been
18 happening here is relevant under Texas state law, the
19 attorney general of the State of Texas is currently
20 suing Pfizer over the falsification of information and
21 false public marketing of the vaccine as safe and
22 effective when it was neither. So that's the official
23 position of the state government. This law is here to
24 protect anybody in the healthcare context. If you see
25 something wrong, you can report it without being fired.

1 It's an exception to the at will provision by statute.

2 Now, if this Court concludes that that
3 statute is narrow and not as broad as we suggest, that
4 is the only reason we request the -- a move to amend to
5 add the general public policy exception to termination.
6 It says wrongful termination, violation of public
7 policy, if they're trying to force you to do something
8 illegal, that is outside the at will doctrine. We
9 believe the Texas Health and Safety Code statute already
10 specifically addresses this. But if the Court doesn't
11 believe it does so, we're only asking for leave to
12 amend. Not to change any facts, but simply to change
13 the legal theory by which remedy can be afforded because
14 the Texas courts do allow that remedy.

15 It is not a case where federal law and Texas
16 law completely shuts out the ordinary American from
17 getting relief and remedy when they expose one of the
18 biggest frauds and scandals in the history of American
19 public health.

20 Thank you, your Honor.

21 THE COURT: All right. Thank you very much.

22 All right. Nothing like teamwork.

23 MR. FRIEDMAN: And not only that, I hope that
24 we can keep in mind what Mr. Barnes said as the final
25 statement because that's a closing. That's a closing.

1 I just wanted to point out two issues just to make sure
2 to complete the record.

3 THE COURT: Yes.

4 MR. FRIEDMAN: One of your questions was how
5 are the allegations specific to the other defendants
6 including, I imagine, Icon. In this case we definitely
7 alleged a lot of very specific issues about what Icon in
8 its role in this -- and they're summarized -- I won't go
9 over them, but they're summarized on Page 29 and 30 of
10 our opposition to the brief. But Icon was responsible
11 for data management. And the data manipulation is
12 exactly what this case is about. So not only is Pfizer
13 responsible and Ventavia was the one that was performing
14 the work, but Icon was the one that was responsible for
15 making sure the data integrity and they were responsible
16 for looking for the red flags and they failed.

17 The other issue I wanted to talk about is
18 materiality. And that is -- their argument is if the
19 FDA decided that it was -- met the EUA standards, then
20 that's the end of it. And it -- and they can still look
21 at it. So it doesn't matter what she has to say. If
22 they listen to what Brook Jackson had to say and they
23 made a decision that it is -- that it meets the EUA
24 standards, that's enough. As if one single lawyer at
25 the FDA gets to make the decision as to whether or not

1 Congress's standards have been met. And that is
2 incorrect.

3 In the EUA statute, it sets forth not a
4 subjective standard, but an objective standard. And I
5 think a lot of the people in the -- in America that's
6 following this case and following the problems with
7 the -- with the -- and with Pfizer's defenses, which is,
8 no, it only takes approval from one person and that's
9 good enough. They don't understand the way the law
10 works the way some lawyers do. And lawyers see the
11 statute. And the statute says that the decision to
12 issue the EUA has to be based on a totality of
13 scientific evidence available to the secretary,
14 including data from an adequate and well-controlled
15 clinical trial, if available. It is reasonable to
16 believe that the product may be effective in preventing
17 the disease and that the known and potential benefits of
18 the product when used to prevent outweigh the known and
19 potential risks.

20 That is reason to believe. It's not enough
21 that some bureaucrat says I believe it. There has to be
22 a reasonable basis. That's Congress's way of telling
23 lawyers and judges that we are looking for objective
24 basis. Not subjective basis. And so the falsities that
25 Brook Jackson has revealed and that when we filed the

1 statement of interest roadmap that led us to this
2 lectern today, it's because those evidence is the
3 objective basis for the EUA. And that's what they lied
4 about. So even if they could convince the FDA even
5 today to want to have this case dismissed, that's not
6 consistent. Congress wanted objective standards to be
7 applied in this circumstance.

8 But, please, keep in mind, Judge,
9 Mr. Barnes's concluding because he's the closer.

10 THE COURT: I understand.

11 MR. FRIEDMAN: Thank you. Very good.

12 Any further response?

13 MS. MCDONALD: Your Honor, just briefly I
14 wanted to address Mr. Barnes's comments about the
15 retaliation claims. Mr. Barnes argues that essentially
16 because they believe they've cured the pleading
17 deficiencies as to the fraud claims under the FCA that
18 similarly the deficiencies as to the retaliation claim
19 have been cured. But that's just simply not the case.
20 The retaliation provision isn't concerned with the
21 validity of a False Claims Act theory. The question is
22 really, as you pointed out in your original order
23 dismissing, whether relator internally reported concerns
24 about false claims to the government for payment. And
25 in the Fifth Circuit, it makes no difference what the

1 relator believed. It's whether she reported it to her
2 employer, and they do not allege such a report.

3 Similarly, as to -- Mr. Barnes discussed her
4 report to the FDA, but they never allege in their second
5 amended complaint that Ventavia knew about her FDA
6 report before she was fired. And, in fact, it did not.
7 And as to the state statute, you know, any position the
8 State of Texas has with respect to the COVID vaccine and
9 any of the defendants is not relevant to this
10 retaliation provision in the state statute. It is not a
11 broad statute. It's a very narrow statute as you'll see
12 by reading the cases referenced in our brief, which
13 specifically addresses this issue. And, your Honor,
14 they could have included the common law claim as an
15 alternative legal theory had they wanted to when they
16 filed the second amended complaint and they did not.

17 So with that, your Honor, I respectfully
18 request that you grant our motion.

19 THE COURT: All right. Thank you very much.

20 Any further comments from the defendants?

21 Okay. Is there anything else at this
22 juncture that needs to be brought to the Court's
23 attention?

24 MR. BARNES: Not from the relator, your
25 Honor.

1 THE COURT: Not from the defendants,
2 Mr. Carroll; is that correct?

3 MR. CARROLL: No, your Honor.

4 THE COURT: The government?

5 MR. GILLINGHAM: Nothing from the government,
6 your Honor.

7 THE COURT: All right. Well, I want to thank
8 you all for coming. Everyone has done an outstanding
9 job as always. The lawyers in this case are always very
10 well prepared, and the Court appreciates that. And I
11 also notice there are a number of folks here who have
12 been listening very intently. I would love to invite
13 you to come back to be jurors some day because you're
14 good listeners and we always need good listeners in the
15 jury box.

16 But with that, with no further business, we
17 are now adjourned.

18 (Proceedings adjourned at 4:42 p.m.)

19 * * *

20

21

22

23

24

25

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

COURT REPORTER'S CERTIFICATION.

I hereby certify that on this date,
June 6, 2024, the foregoing is a correct transcript of
the record of proceedings in the above-entitled case.

April Hargett

APRIL D. HARGETT
Certified Realtime Reporter
Eastern District of Texas
Beaumont, Texas