

UNITED STATES DISTRICT COURT
DISTRICT OF PENNSYLVANIA

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| USA, et al., |) | 10-CV-04374-CFK |
| |) | |
| Plaintiff, |) | |
| vs. |) | UNDER SEAL |
| |) | |
| |) | |
| MERCK & CO., INC., |) | Philadelphia, PA |
| |) | January 24, 2023 |
| Defendant. |) | 10:11 a.m. |
| |) | |

UNDER SEAL TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE CHAD F. KENNEY
UNITED STATES DISTRICT JUDGE

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Proceedings recorded by electronic sound recording, transcript produced by transcription service.

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I N D E X

ARGUMENT:

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1 (The following was held in open court at 10:11
2 a.m.):

3 COURTROOM DEPUTY: All rise, please. The United
4 States District Court is now in session, the Honorable Chad F.
5 Kenney presiding.

6 THE COURT: Good morning, everyone.

7 ALL COUNSEL: Good morning, Your Honor.

8 THE COURT: All right. This is Merck -- in re:
9 Merck and U.S., ex rel, Krahling and, what is it, Wlochowski
10 vs. Merck, and we're going to start with that one, 4374-10.
11 And then we'll follow right up with 355 of 12, and that's in
12 re: Merck, the antitrust litigation.

13 So in 43, the 10:00 argument, 4374-10, counsel for
14 the record?

15 MR. SCHNELL: Gordon Schnell from Constantine,
16 Cannon for Relators.

17 MR. VITELLI: Good morning, Your Honor. Daniel
18 Vitelli, also of Constantine, Cannon, counsel for the
19 Relators.

20 MS. SCANLAN: Good morning, Your Honor. Kathleen
21 Scanlan, also for the Relators.

22 MS. ELLSWORTH: Good morning, Your Honor. Jessica
23 Ellsworth of Hogan, Lovells, for Merck.

24 MS. DYKSTRA: Good morning, Your Honor. Lisa
25 Dykstra, Morgan, Lewis, for Merck.

Colloquy

1 MR. SANGIAMO: Good morning, Your Honor. Dino
2 Sangiamo of Venable for Merck.

3 MR. FEE: Good morning, Your Honor. Brendan Fee
4 from Morgan, Lewis, also for Merck.

5 THE COURT: All right. Everybody can have seat.

6 MR. SWEET: Your Honor, Joel Sweet, for the United
7 States.

8 THE COURT: Okay. Good morning. And there was
9 somebody here from GSK, I was told?

10 MR. COLVIN: Good morning, Your Honor. David
11 Colvin, on behalf of the non-party, GSK.

12 THE COURT: And you're asking for certain parts of
13 the transcript to be restricted?

14 MR. COLVIN: I am, Your Honor. Would it be helpful
15 if I approach the microphone for the record?

16 THE COURT: No, it wouldn't be.

17 MR. COLVIN: Okay.

18 THE COURT: We can hear you from there.

19 MR. COLVIN: Okay. Yes, Your Honor. As I
20 understand it, GSK figures to play a central role in one or
21 both hearings today, based on documents and deposition
22 testimony that GSK provided in response to subpoenas served by
23 the parties in these matters.

24 THE COURT: All right. So, this is what we're going
25 to do, we're going to -- we will seal the transcript

1 initially. All right. After you get the transcript, you will
2 have 30 days to redact what will be made -- redact from the
3 transcript what you claim is confidential. So there will be a
4 sealed full version of the transcript. And then the public
5 transcript will have your redactions in it as to confidential
6 information. You do want to read the Third Circuit -- which
7 I'm sure you have -- the Third Circuit rulings on what is
8 confidential information.

9 MR. COLVIN: Of course, Your Honor.

10 THE COURT: Okay. That's how we'll handle it.

11 MR. COLVIN: Of course, Your Honor. And with
12 respect to the courtroom, today, Judge, it's my understanding
13 that one or more parties may be publishing on the screen
14 documents that contain sensitive and proprietary information
15 that belongs to GSK. It was designated under the protective
16 order, in place, entered by the Court, as confidential and
17 having confidential, and so we would object to that, unless
18 the Court were to close the courtroom for purposes of this
19 hearing.

20 THE COURT: I'm not closing the courtroom, so I
21 don't know how you want to handle it.

22 Is there anybody in here taking confidential
23 information that they're going to use for producing something,
24 some vaccine?

25 MR. MACORETTA: Your Honor, John Macoretta, here,

1 for the private plaintiffs. We will talk about some things,
2 GSK. We have -- their motion is that we have no basis for GSK
3 doing what they did. To defend that, we have to show some GSK
4 documents and testimony. We can avoid putting it on the
5 screen, but it's kind of hard to defend the motion without
6 talking about it.

7 THE COURT: All right. You can talk about it. We
8 won't put it on the screen.

9 MR. COLVIN: Thank you.

10 THE COURT: All right. So here we are. We're ready
11 to go, a motion for summary judgment, right, and it's rather
12 lengthy.

13 MR. SCHNELL: Your Honor, we had moved for summary
14 judgment, as well. There are cross-motions.

15 THE COURT: You have cross-motions for summary
16 judgment. Yes, I saw that. All right.

17 So, are you ready to begin? You can sit at your
18 chair. You don't have to come up here.

19 MS. ELLSWORTH: Okay.

20 THE COURT: Are you comfortable doing that?

21 MS. ELLSWORTH: It's unusual to address the Judge
22 seated, but I'm happy to do so if Your Honor is --

23 THE COURT: Well, welcome to my courtroom. You
24 stood -- everybody stood. We got the standing part over. I
25 need the substance part. So, if you're comfortable,

1 sometimes, it makes it easier, and you have your co-counsel
2 there. So that's helpful, too. So, go ahead, you can give me
3 the preliminaries.

4 THE COURT: Thank you.

5 Good morning, Your Honor, may it please the Court,
6 Jessica Ellsworth, for Merck, and I would like to reserve a
7 small bit of time to respond to what the Government may say
8 and also what the Relators may say in this case.

9 As I'm sure the Court is aware, everything was filed
10 under seal for the summary judgment briefs, and our view is
11 that the Court does not need to conduct this hearing under
12 seal. It's a summary judgment hearing. Most of the evidence
13 is quite dated, at this point, and FDA has approved GSK's
14 Mumps vaccine. So, I think we're all on the same page about
15 that.

16 If I could, Your Honor, I'd like to hand up to you a
17 set of slides that I'll walk through with the Court. May I
18 approach?

19 (Pause in proceedings.)

20 THE COURT: Sure.

21 MS. ELLSWORTH: Your Honor, the briefs cover a lot
22 of ground in this case, but we believe the summary judgment
23 can and should be granted on a number of grounds, including
24 the evidence created -- does not create a triable fact as to
25 falsity and materiality and scienter.

1 But given the shortness of time, I'd like to focus,
2 today, on the argument we think is most obvious and
3 undisputable as a reason to grant summary judgment for Merck,
4 and that is materiality.

5 So if you open the slides to page two, you see a
6 graph --

7 THE COURT: You want to start, where, with what?

8 MS. ELLSWORTH: Materiality.

9 THE COURT: That's where I wanted you to start, and
10 that's, really, what I want you to address, so go ahead.

11 MS. ELLSWORTH: Thank you, Your Honor.

12 Slide two is a graphical depiction of what has
13 happened with reported cases of Mumps in this country since
14 Merck's Mumps vaccine was approved by FDA in 1967, and I think
15 that's important context to have in mind as we go through the
16 argument this morning.

17 The False Claims Act has a number of elements,
18 falsity and materiality, causation and scienter. They are set
19 out on page three. But materiality is what I really want to
20 focus on. What is materiality? Materiality is what polices
21 the line between matters of regulatory compliance or breach of
22 contract and actionable False Claims Act cases.

23 So if we turn to slide five -- excuse me -- turn to
24 slide four, you will see why this line is important. The FCA
25 exists to protect the Government from paying fraudulent

1 claims, not to allow Relators to second guess Agency judgment
2 or ask lay jurors to do so. And so materiality looks at what
3 the Supreme Court described as the likely or actual behavior
4 of the recipient of any alleged misrepresentation.

5 In other words, it asks whether the Agency would
6 have actually or likely done anything differently as a result
7 of a compliance issue that the Relators are alleging. Escobar
8 emphasizes it's a demanding standard. It's a rigorous
9 standard. It should be strictly enforced, and that it is not
10 too fact-intensive to address at summary judgment.

11 So as the Court looks at the summary judgment
12 record, the Court should ask a straightforward question, and
13 that is whether there is any non-speculative evidence. And
14 the non-speculative part of that is important, because to
15 avoid summary judgment, the Relators need more than
16 speculation or innuendo.

17 Is there any non-speculated evidence that CDC would
18 have made different purchasing choices in the Vaccine for
19 Children Program, based on Relators' opinions about a research
20 study known as Protocol-7 or based on Relators' opinions about
21 the meaning of a single, internal, unverified potency loss
22 model that conflicted with actual stability data? The answer
23 is, no, there is no non-speculative evidence that CDC would
24 have made any different purchasing choices related to M-M-R II
25 or ProQuad. Those are Merck's two combination vaccines that

1 have the Mumps vaccine as a component.

2 If we turn to slide six, I want to briefly pause to
3 make clear that there are two agencies discussed in the
4 briefing, the FDA and the CDC. The FDA's mission is to
5 protect public health by insuring the safety and efficacy of
6 drugs, including Merck's Mumps vaccine. FDA oversees drug
7 approval, licensing, labeling, stability testing and
8 manufacturing practices. And it has an array of enforcement
9 authority.

10 CDC's mission is to fight and track diseases and
11 protect people from health threats. For decades, the CDC has
12 bought Merck's Mumps vaccine, and the Vaccine for Children
13 Program, based on recommendations from its internal advisory
14 committee on immunizations practices, a group of medical and
15 public health experts that study using vaccines to control
16 diseases.

17 During the summary judgment briefing, to try to save
18 their case, the Relators repeatedly and expressly disclaimed
19 that they are pursuing a fraud on the FDA theory. You can see
20 that in their response to our motions and in the reply on
21 their own motion. That disclaimer makes this Court's job
22 easier. Every time the Relators stand up -- or sitting down
23 this morning -- and point you to a piece of evidence, you
24 should ask yourself if it relates to communications or
25 obligations between Merck and the CDC.

1 If it, instead, relates to whether FDA should or
2 would have done something differently, it falls within the
3 theory that Relators have disclaimed, and it cannot save their
4 case.

5 If we move to slide seven, this is relevant timeline
6 for the materiality question. 22 years ago, which, to give
7 you a sense of time, is the year George W. Bush was sworn in
8 as President, FDA issued a warning letter to Merck involving
9 some lots of Mumps vaccine that predated a formulation change
10 and had dropped below the labeled potency, which was a potency
11 level Merck had always understood to be the release potency
12 and not the potency at expiration.

13 Before this warning letter issued, Merck had already
14 raised its release potency to a level that FDA had requested,
15 which is the potency used today. Also, in 2001, one of the
16 Relators called FDA to raise concerns that Merck was
17 committing fraud in the lab he worked in, which was conducting
18 Protocol-7.

19 FDA investigated those claims for months and reached
20 an agreement with Merck on what data from Protocol-7 could be
21 used in connection with labeling changes for M-M-R II and a
22 later approval of ProQuad, Merck's new quadrivalent vaccine.
23 You fast-forward to 2010, and the Relators filed this suit,
24 alleging that Protocol-7 showed the Mumps vaccine was not as
25 efficacious as it had been back in 1967, when Dr. Hilleman

1 conducted his pathbreaking studies that led to FDA's approval.

2 The Government invested those allegations, and it
3 declined. What followed was years of fact and expert
4 discovery, during which the Government had access to all of
5 the materials in this case, attended, participated in
6 depositions, authorized CDC witnesses to be deposed, and even
7 authorized former CDC employees to be experts for Merck.

8 Then, in 2019, the Court authorized Relators expert,
9 a former FDA Commissioner named Dr. Kessler, to go directly to
10 public health officials at FDA and CDC and offer his opinions
11 and conclusions about why the discovery record here showed
12 concerns about the Mumps vaccine that the agencies didn't know
13 about. This submission went directly to the Director of the
14 CDC and the Commissioner of the FDA, among others.

15 It attached and discussed dozens of exhibits from
16 the discovery record and Dr. Kessler's analysis of those
17 issues. Today, it's 2023. I checked the CDC's website this
18 morning. After more than two decades of hearing these
19 Relators and their experts' complaints, the CDC's very public
20 position is that the Mumps component of M-M-R II and ProQuad
21 is "very effective", with an average effectiveness of 88
22 percent when administered as recommended.

23 In other words, two decades later, the CDC has not
24 changed its views about the vaccine one whit as a result of
25 the complaint filed by these Relators.

1 If we move to slide eight, I want to emphasize the
2 Court's order authorizing this submission to the CDC and FDA
3 for two reasons. One is, it's fairly unique. And two, it's
4 very important to the materiality question before the Court.
5 At the hearing that led to this order, which had to do with
6 whether Dr. Kessler could take certain opinions public, the
7 Court took the position that it was the expert agencies who
8 should look at Dr. Kessler's professed concerns about the
9 vaccine, based on what he saw in discovery.

10 By going to public health officials at these expert
11 agencies, the Court said that the agencies could evaluate his
12 concerns, decide whether they are valid, and decide whether
13 they warrant any action by the agencies. On October 23rd,
14 2019, this submission went directly to public health officials
15 at CDC and FDA, including, as I mentioned, the CDC Director
16 and the FDA Commissioner.

17 We are now three years and three months later. The
18 CDC and FDA have taken no action in response to Dr. Kessler's
19 professed opinions, concerns and conclusions.

20 If we look at slide nine, this tells us a lot about
21 why. It is a reflection of the undisputed real world impact
22 of this vaccine. Before the vaccine was approved, there was
23 an average of 186,000 cases of Mumps every year. If you
24 multiply 186,000 times 23 years, the time period between 2000
25 and 2022, that would equal almost 4.3 million cases of Mumps.

1 But with the vaccine, how many cases of Mumps have
2 there been? In actuality, there have been just over 37,000
3 cases reported. And so the undisputed real world impact is
4 that there has been a 99.1 percent reduction in cases of Mumps
5 from the pre-vaccine era. The timeline we were discussing and
6 this data on impact point in the same direction.

7 Despite everything that Relators and their experts
8 have said, FDA and CDC stand squarely behind this vaccine and
9 for a very good reason. In fact, for more than 4.2 million
10 reasons, just counting the individuals who avoided Mumps in
11 the years since Relators started their campaign against this
12 vaccine.

13 If you move to slide 11 to 13, I want to make clear
14 that CDC has had full knowledge of the record in this case,
15 and yet, it's public statement of support on its website,
16 including that the vaccine is 88 percent effective, when
17 administered as recommended, has not changed, and we quote
18 those websites on those slides so you can see that for
19 yourself.

20 The FDA's public statements of support haven't
21 changed either, and you can see that on slides 14 and 15. In
22 fact, the person who made the statement from FDA -- it's
23 listed on slide 14 -- was also a recipient of Dr. Kessler's
24 submission, Peter Marks, from FDA.

25 So after Peter Marks said that he could not state

1 strongly enough the overwhelming scientific evidence shows the
2 vaccines are among the most effective and safest inventions to
3 prevent illness and protect public health, that the vaccine
4 was very effective at protecting against Mumps, and that the
5 FDA had 50 years of experience and evidence supporting that
6 fact. He received the Kessler submission, and he didn't take
7 that statement back. He didn't say anything in response.

8 In reality, the CDC's purchasing patterns have not
9 changed on bit. The FDA approved a new Mumps vaccine last
10 year, manufactured by GSK, after concluding that that vaccine
11 was non-inferior to Merck's vaccine. No one at either agency
12 asked Merck to reprove the bonafides of its vaccine. No one
13 sent a "dear doctor" letter to providers. No one rescinded
14 the FDA approval. No one asked Merck to conduct additional
15 research trials. No one asked for a recall. No one asked for
16 more stability testing. No one asked for even a single batch
17 of vaccine to be traced because of some concern about potency
18 or efficacy.

19 All of this matters a great deal. We're here more
20 than three years after Relators laid out their best case for
21 their truly bold claim that Merck lacks any data its Mumps
22 vaccine works.

23 Back at the motion to dismiss stage, the Relators
24 could get away with telling Judge Jones that he didn't know
25 what he didn't know, and they needed a chance to develop the

1 facts. Well, here we are more than a decade older and wiser,
2 after a newly coined theory of the case during discovery, with
3 millions and millions of pages that Merck produced, dozens of
4 fact and expert witnesses deposed, including from the CDC,
5 itself, and quite literally, nothing left to be discovered
6 with regard to the complaint's allegations.

7 The Government has followed all of it. They know
8 everything the Relators have discovered. They have seen
9 everything the Relators have to offer, and yet, nothing has
10 changed about the agencies' opinion of the Mumps vaccine.
11 Both FDA and CDC still fully embrace this vaccine.

12 Despite all of this discovery, Relators have no
13 evidence that CDC would have stopped buying M-M-R II or
14 ProQuad based on their complaints about Protocol-7 or the
15 internal potency loss model. On Protocol-7, the CDC witnesses
16 pointed to FDA as the agency that evaluates manufacturer
17 clinical research data as part of licensing and made clear
18 that CDC's own evaluation of effectiveness data is what is
19 most important to the agency, not clinical research trials
20 relating to licensing, which is in FDA's bailiwick of
21 responsibility.

22 On potency, certain losses of M-M-R II did actually
23 dip below the labeled potency in the late 1990s, when Merck
24 understood the label's potency to be a release potency, just
25 as it had going back to 1967. But when that happened, FDA did

1 not ask Merck to recall those lots. It issued a warning
2 letter. That warning letter says that it would be shared with
3 contracting agencies, like the CDC, and the CDC paid for and
4 continued buying the vaccine at the statutorily capped price.

5 The Relators have no evidence, no testimony from a
6 single CDC witness that would allow them to show materiality.
7 I invite the Court to ask them to identify for you any CDC
8 witness testimony that says CDC would have stopped paying for
9 the Mumps vaccine based on a single immunogenicity study,
10 Protocol-7, or based on a single potency model that Merck had
11 already told the FDA about. They didn't identify it in their
12 papers, and they won't be able to today.

13 We turn to slide 18. This underscores why all of
14 this is significant. The Relators cannot show a triable issue
15 of fact on materiality. How on Earth can they go to a jury
16 and say CDC would have made different purchasing decisions,
17 despite all the real world effectiveness and impact data,
18 based on Protocol-7, which FDA oversaw, or an internal potency
19 loss model, which Merck told FDA about and turned out to be
20 inconsistent with real world stability data? The answer is
21 that there is no evidence creating a dispute of fact on
22 materiality.

23 Under the Supreme Court's decision in Escobar and
24 materiality decisions from around the country, this is exactly
25 the sort of fact pattern on which summary judgment must be

1 granted. And I want to just talk about the holistic analysis
2 that Escobar says this Court should conduct.

3 One of the things to look at are continued
4 purchases, which we have been discussing this morning.
5 Continued purchases can be strong evidence that the
6 materiality standard is not met, when those purchases are made
7 with knowledge. We think there is such evidence of knowledge
8 here, based on the record in this case, the submission that
9 Dr. Kessler made directly to public health officials at the
10 CDC and the FDA, going all the way back to the warning letter
11 in 2001. It discussed actual lots of vaccine falling below
12 the labeled potency, and Protocol-7, which the FDA interacted
13 with Merck about every aspect of.

14 The reality is, the CDC has negotiated 22 annual
15 contracts with Merck since Relator Krahlung called the FDA to
16 report his concerns about Protocol-7. CDC has negotiated 12
17 of those since the complaint was filed, five of those since
18 fact discovery ended and three of those since Relators sought
19 summary judgement, presented their best version of their story
20 to the Court, to the CDC, to FDA, and the CDC's purchases have
21 continued.

22 This kind of unwavering position renders it
23 implausible, in the words of the First Circuit in its Nagle
24 decision. It renders -- it substantially increases the burden
25 on Relators, in the words of the Fifth Circuit, in its Harmon

1 decision, and it precludes Relators from pursuing these
2 claims, in the words of the D'Agostino decision.

3 To take the D.C. Circuit's view, when the Court had
4 the benefit of hindsight, which it does in this case, it
5 should not ignore what actually occurred. So that's the
6 continued purchases bucket. What else is there? Because
7 materiality is a holistic inquiry. And I would note, on
8 continued purchases, all of those cases that I just mentioned
9 are ones that the United States' statement of interest did not
10 discuss those holdings and did not discuss the outcome in
11 those cases.

12 That moves us to the other buckets of information
13 that could show materiality or could show there is a triable
14 fact. Here, there is no statute, no regulation and no
15 contract provision that expressly conditions the CDC's payment
16 on Mumps vaccine exceeding some specific efficacy rate or some
17 specific potency level.

18 This question about statutes, regulations and
19 contracts with such express conditions was an issue in Escobar
20 because the Circuits had split on whether courts should be
21 differentiating between conditions of payment and conditions
22 of participation. And what the Court said in Escobar is that,
23 even where we have an expressed condition of payment, that,
24 alone, is not enough to show materiality or trying to figure
25 out what the agency would actually have done.

1 In this case, there is not the kind of statute,
2 regulation or contract provision that contains the express
3 provision that Escobar was talking about. Efficacy, from what
4 the record shows, is not a procurement criteria. It was not
5 written into the contract as a criteria, and it never came up
6 in contract negotiations. Potency is, likewise, not a
7 condition of payment.

8 The Relators try to point to certain contract
9 provisions about CGMP regulations, which are manufacturing
10 requirements that FDA supervises, a shelf life requirement,
11 but that, really, is just about when the expiration date is,
12 and a warranty of merchantability, which just asks whether
13 there was, in fact, an FDA license, which there was, and the
14 Relators have disclaimed that they are trying to show that
15 that license was obtained fraudulently.

16 So that leaves us, in this case, in the same
17 situation that this Court identified in the Dr. Reddy's case,
18 where there is no statutory, regulatory or contractual
19 provision that makes statements about efficacy or potency a
20 condition of Government payment.

21 The next factor is whether this -- whether there is
22 any evidence that the CDC consistently refuses to pay claims
23 in the mine run of cases, based on non-compliance with the
24 particular statutory, regulatory or contractual requirement at
25 issue here.

1 First of all, there is not a mine run of cases about
2 these kinds of allegations. So the Relators have pointed to a
3 bunch of other types of enforcement action that DOJ and the
4 FDA sometimes take related to misbranded and adulterated
5 drugs, related to the Anti-Kickback Statute, related to a
6 whole bunch of other types of enforcement, but there is no
7 example of a case in which CDC has refused to pay for an FDA-
8 approved drug as insufficiently protected. They just don't
9 have one.

10 They have no example of a case in which any
11 relevant, regulatory agency was on notice of the basis of
12 Relators' allegations for more than two decades, while it
13 continued entering annual contracts to purchase the product,
14 all the while making public statements about the product's
15 effectiveness and impact and without making any comment or
16 raising any concern to the manufacturer. Simply, there is no
17 other record evidence that could create a triable fact as to
18 materiality.

19 Two brief final legal points. One is that courts
20 presume Executive Branch agencies and employees are
21 discharging their duties. That's the presumption of
22 regularity. Here, FDA and CDC's duties include analyzing the
23 validity of serious public health allegations levied by
24 Relators and their former FDA Commissioner paid expert and
25 adhering to the agencies' duties to inform the public of

1 vaccine safety concerns. That presumption of regularity
2 should lead this Court to grant summary judgment for Merck on
3 its materiality argument.

4 The second legal point I want to make is that, as a
5 legal matter, if FDA concluded that Dr. Kessler's 2019
6 submission or anything else in this record presented "new
7 information" that should be reflected on the label, FDA was
8 statutorily obligated to take action. That's 29 U.S.C.
9 Section 355(O)(iv)(a), and we cited that in our response to
10 the Government's statement of interest at page eight, footnote
11 five.

12 We are simply past the point where FDA's continued
13 purposeful inaction can mean nothing. In fact, it means
14 something, and it means something as a matter of law. The
15 indisputable record shows FDA has kept the label as it is,
16 knowing full well the specifics of the evidence in this case,
17 and CDC's purchasing patterns and related conducts have
18 remained steady, in spite of knowledge of all of the evidence
19 in this case.

20 For these reasons, we ask the Court to grant summary
21 judgment for Merck on materiality and end this case.

22 THE COURT: Thank you, Counsel.

23 Counsel?

24 MR. SCHNELL: Thank you, Your Honor.

25 The one thing missing from -- the one big thing

1 missing from Merck's counsel's presentation was any discussion
2 of the evidence. So, let's talk about the evidence, give you
3 a sense of what this case is really about, and then I can talk
4 about materiality, but I think that's an important backdrop.

5 so, it starts when Merck discovered pervasive
6 potency problems with its marquis vaccine for Mumps, M-M-R II.
7 And these were problems that were so serious that it raised
8 within Merck the alarm that they better fix it or they were
9 going to be subject to a product recall.

10 The first thing they tried was to double the Mumps
11 potency to address this problem, and they did that with the
12 FDA's knowledge. It was the FDA's suggestion, so they doubled
13 the Mumps potency. It didn't help. They still had Mumps
14 potency failures that they could not meet the minimum potency
15 specifications in the product label for the full 24-month
16 shelf life. This raised the alarm within Merck to the highest
17 levels, which they did not share with the FDA, the highest
18 level so much that the documents that we have presented on
19 summary judgment -- part of the reason why we're moving for
20 summary judgment -- is that Merck internally recognized in
21 their own words that the product was misbranded, Merck's
22 words, out of compliance, Merck's words, non-marketable,
23 Merck's words. All of those documents are in the record, but
24 Merck is not mentioning those.

25 So what do they need to do? They needed to lower

1 the Mumps potency specification to get it back into
2 compliance. Again, none of this was shared with the FDA, let
3 alone with the CDC. So Protocol-7, the clinical trial at
4 issue in this case, was the clinical trial Merck needed to
5 pass to get its product back into compliance and avoid a
6 product recall. The documents are clear, at the highest
7 levels of the company, they were concerned about a recall. It
8 was not shared with the FDA or the CDC.

9 So, Merck started on Protocol-7 with standard
10 regular testing. What they needed to show with Protocol-7 was
11 that the lower potency specification that they wanted to get
12 to to bring the product back into compliance, the Mumps
13 vaccine still afforded sufficient protection. Standard
14 testing showed they weren't even close.

15 So, what do they do? They engaged in a results-
16 oriented design of a test that would guarantee they reached
17 the result they needed. Dr. Krall (ph) was the Chief
18 Scientist at Merck who ran this study, who designed this
19 study, who ran the lab that did the study, and we deposed him.
20 He admitted that he created a results-oriented test to get the
21 results that we needed -- that Merck needed.

22 That didn't work either, and that's when they had to
23 resort to falsifying data, destroying unfavorable data. Our
24 Relators were there in the lab. They saw it firsthand. There
25 is no dispute that this did not happen, and the FDA inspection

1 that was prompted by one of our Relators was a result of that.
2 But what Merck is not saying is that even during this
3 inspection, Merck lied to the FDA to get out of it, to get out
4 of the problem. Our Relator was there. Both of them were
5 there. They overheard the lies. We have documents that show
6 the lies to the FDA to get out of this inspection.

7 So, they continue with Protocol-7, and what do you
8 have at the end of the day, because of the manipulation and
9 designing of the test and the falsification of data, you have
10 a completely inaccurate and unreliable test, a clinical trial,
11 that had nothing to do with measuring protection. And you
12 don't have to take our word. This whole presentation, our
13 whole summary judgment motion isn't based on our word. It's
14 based on Merck's documents, the witnesses' testimony and their
15 own experts. Their own experts support virtually everything
16 we're saying.

17 And so, I just want to walk through with you, just
18 take a minute, these are what Merck's witnesses and experts
19 have said about Protocol-7. We'll start with Joe Antonello.
20 He's the chief biostatistician involved in Protocol-7. What
21 he said is -- his words -- the precision of the test was "very
22 poor". The test had "no clinical history expectation or
23 meaning".

24 Florian Schodel, very high up in Merck vaccine
25 research, this is what he said, "could not overemphasize the

1 weakness of the test." Another one of his quotes, "very
2 unreliable".

3 Emilio Emini, another high up executive in Merck
4 research called the test "very artificial". David Krall,
5 again, the gentleman who designs the test and ran the test, we
6 asked him at his deposition whether the test was even
7 accurate. He said, "that's beyond my expertise to answer."
8 The guy who designed the test and ran the test couldn't even
9 answer whether it was accurate.

10 We asked the same question to Merck's 30(b)(6)
11 corporate representative, Barbara Kuter, another executive
12 high up in Merck's vaccine research. We asked if the testing
13 "had any relationship to protection from disease". That's
14 what the whole point of the test was. And her answer, "I
15 really can't answer that." This is Merck's corporate
16 representative. But it doesn't stop there.

17 We asked Marcela Pacetti, one of Merck's experts,
18 who specializes in this kind of testing, her words, "Protocol-
19 7 did not include a proper analysis of vaccine efficacy or
20 effectiveness." That was the whole point of the test.
21 William Atkinson, another one of Merck's experts said this,
22 the testing "would not have really anything to do with
23 effectiveness."

24 This is what their own people are saying about the
25 clinical trial that they were using to support licensure of

1 this Mumps vaccine. Our experts are in complete accord with
2 these opinions. David Kessler, who Merck's counsel
3 referenced, a former FDA Commissioner and who, until just last
4 week, was the Chief Science Officer for the Government's COVID
5 Task Force, said this about the test, his words, "a mess, with
6 no clinical relevance."

7 Peter Calcott, another one of our experts, who was
8 the head of quality for a major vaccine manufacturer said
9 this, "The test had no technical validity. It was
10 meaningless." There is undisputed evidence that Protocol-7
11 was essentially garbage, yet, Merck represented it to every
12 constituency in the opposite way, saying that it proved that
13 the vaccine at the lower potency was effective.

14 It's what they told the parents -- and this is all
15 in the record. I can stop at any point to show you a
16 document, but it's all in our papers, and that's why we're
17 moving for summary judgment here, Your Honor. It told the
18 parents of the children who were the subjects of the tests
19 that the test was going to show your child is protected.

20 It's what they told the doctors who were
21 administering the shots on these kids that the test is going
22 to show these kids are protected. It's what they told the DOJ
23 when they were trying to get DOJ to dismiss this case several
24 years ago, that the test measured protection. And it's what
25 they told the FDA in the clinical license applications, which

1 they were successful in getting because of these
2 misrepresentations. And these same misrepresentations are
3 reflected in the label.

4 So here's what we know, because there's a lot of
5 talk about how great this vaccine is, right? So here's what
6 we know about the Mumps vaccines that Merck has been selling
7 the CDC for the past 20 years. There is no clinical data, at
8 all, supporting the level of protection this vaccine affords.
9 The only clinical data is from Protocol-7, and we heard what
10 their witnesses and experts said about that test.

11 What you haven't, also, heard from Merck's counsel
12 is this unprecedented resurgence in Mumps that has occurred
13 since 2006. It is undisputed. Nowhere in Merck's
14 presentation do they mention this. All of these great figures
15 about the 99 percent reduction of disease are pegged to where
16 the disease was in 1995. But if you look at from 2006
17 forward, it paints a very, very different picture. And it's
18 own that the CDC, in its own words has said, "is of serious
19 public health concern."

20 In these public statements that Merck's counsel
21 represented about the FDA and the CDC trumpeting the vaccine,
22 those same public statements, as we pointed out in our summary
23 judgment papers, also raise the serious concern about the
24 Mumps resurgence that they're still trying to figure out what
25 the basis is for. This concern is so severe that some of the

1 world's leading experts have called for a new vaccine. One of
2 them is the FDA's Steven Rubin, perhaps, the FDA's leading
3 Mumps expert.

4 In writing a letter of support for NIH funding for
5 new vaccine research, this is what he said, the resurgence has
6 made "it quite clear that newer more immunogenic vaccines are
7 needed. Dr. Biao He from the University of Georgia, who
8 received NIH funding for a new vaccine, said this, in his
9 application for the grant, "The resurgence underscores the
10 urgency for new and effective Mumps vaccines to replace
11 Merck's vaccines." Stanley Plotkin, who is, I think, by all
12 accounts, the world's leading expert on Mumps, is calling for
13 a new vaccine.

14 So, yes, the vaccine, to a point, was doing a very,
15 very good job, but something happened, something, around the
16 same timeline as these potency failures happened, and now, we
17 have a very, very different product on the market. But we
18 even asked Merck's witnesses -- we asked them, how is your
19 vaccine? How effective is it? It's something you would think
20 the manufacturer of the vaccine would know.

21 Dr. Krall, again, the designer of Protocol-7 and the
22 one who ran the lab testing it, we asked him, with all of the
23 testing that you've done with Protocol-7, how well does the
24 vaccine protect against Mumps. We asked him that basic
25 question. His answer, "I don't have an opinion on that."

1 This is the guy that ran the test to demonstrate that it
2 provided sufficient protection. And we asked him the basic
3 question, does it work? "I don't have an opinion on that."

4 Again, we asked Merck's corporate 30(b)(6)
5 representative, Barbara Kuter, we asked her the same question.
6 She -- that was one of the subjects she was there to testify
7 to. She said she wasn't able to answer that. She said, well
8 -- we asked if anybody at Merck could answer that, and she
9 said, "I don't know."

10 Also, as we stated in the papers, Dr. Krall, during
11 this testing, admitted to one of our Relators that the vaccine
12 didn't work as well and was going to lead to the resurgence
13 that we now see has happened. There are also several internal
14 Merck documents that we've cited in our summary judgment
15 papers where Merck, itself, besides these witnesses who didn't
16 seem to have an opinion, they are internally questioning how
17 well the vaccine works. They are raising concerns about how
18 well the vaccine works, and they're wondering if the 96
19 percent figure on the label really needs to be lowered to
20 reflect the actual protection that's provided.

21 So why is this a False Claims Act? Where is the
22 fraud on the CDC? Merck's counsel is absolutely right. There
23 was a lot of fraud on the FDA, no question, but this is not a
24 fraud on the FDA case. Merck has independent duties to the
25 CDC of full disclosure of any issues with the vaccine. They

1 negotiated with the CDC under the -- it's all reflected in the
2 Third Circuit's Mazur decision.

3 But they negotiated with the CDC to protect
4 themselves from product liability lawsuits. They said, hey,
5 we're exposed. We need you to get out there if we're going to
6 continue making this vaccine. We can't be exposed to all of
7 these product liability suits. Vaccines are risky. And the
8 CDC agreed that it would take on that liability. It would
9 have the duty to warn the public about the benefits and risks
10 of vaccination.

11 But the CDC insisted on a reciprocal duty. But you
12 need to warn us, the CDC said, if you have any issues with
13 your vaccine that might impact the benefits or risks that we
14 are responsible for now providing. Merck negotiated that
15 duty. They're trying to walk away from it. They clearly have
16 a duty, but there are contractual duties, as well, and CGMP is
17 one of them. It's not about, just, manufacturing. It's about
18 assuring that your product has the potency and the protection
19 that you are claiming.

20 So, that's the essence of where the responsibilities
21 come. So, what did Merck share with the CDC about any of what
22 I just said? Absolutely nothing. They didn't share that they
23 had original potency failures. They didn't share that they
24 had to double the potency of the vaccine, something you'd
25 think the CDC would want to know. They didn't share that they

1 had to double the potency of the vaccine. They didn't share
2 that they continued to have pervasive potency problems after
3 they doubled the vaccine, so serious that internally for
4 years, they recognized they were out of compliance,
5 misbranded, non-marketable and potentially at risk of a recall
6 or not even being able to sell the product at all, all from
7 Merck's own mouth.

8 They didn't share the fraud they had to commit to
9 succeed with Protocol-7. They didn't share that they
10 misrepresented the results of those clinical trials. And I
11 want to focus on the clinical trials, because Merck's counsel
12 said, well, that's just between Merck and the FDA. Absolutely
13 not.

14 Merck's own experts testified that what is a
15 critical input to CDC decision-making on whether to recommend
16 and purchase vaccines are the clinical trials that support
17 licensure. That was Jonathan Temte, one of their main
18 experts, said their decisions on vaccine purchasing and
19 recommendations -- his words -- "largely depend" on the
20 clinical trials that the CDC is mandated to review as part of
21 that process.

22 William Atkinson, another one of Merck's experts,
23 said the same thing. "The trial results" -- in his words --
24 "are critical information the CDC would need to understand in
25 making vaccine purchase decisions."

1 Same thing with the label. The label isn't just
2 between Merck and the FDA. As one of the Merck's witnesses
3 said, and as reflected in the Mazur decision -- I'll start
4 with that because it's clear. In Mazur, the Third Circuit
5 says, that, because of this duty to warn, the main audience --
6 that's the Third Circuit speaking -- the intended audience of
7 the label is the CDC, not the FDA. It's the CDC because it
8 gives them an understanding of what they're supposed to be
9 able to explain to the public.

10 So, all of these omissions, all of these direct
11 misrepresentations, yeah, FDA, that was part of it -- that's
12 why it's in our briefs. It tells you the extent to which
13 Merck had to go. It shows their intent and their knowledge.
14 But this is about the CDC. So, all of the fraud cases on the
15 FDA, the Nargle case, which is one of their favorite cases,
16 and another -- I can't even remember the names -- all of these
17 fraud on the FDA cases are completely irrelevant here, because
18 you did not have the same kind of direct responsibility to the
19 purchasing agency.

20 You have to show, in those cases, that the FDA would
21 have done something differently but for the misconduct at
22 issue. That is not the case here. We're talking about an
23 independent relationship with the CDC, independent duties,
24 independent contractual requirements. These critical
25 omissions and misrepresentations that have gone on for years,

1 gone on for years, are the essence of why this is a False
2 Claims Act case.

3 The Third Circuit, in Wilkins, says that, False
4 Claims Act cases take many shapes, but what they all have in
5 common is either providing a product that the Government
6 didn't pay for or providing one that violates key contractual
7 regulatory or statutory obligations. You have both here. It
8 fits into the factual falsity rubric. It fits into the
9 implied certification rubric, and it falls into the fraudulent
10 inducement.

11 What the CDC paid for was a vaccine that was free of
12 potency and protection issues, that met the label
13 specifications and the contract specifications that was backed
14 by accurate and reliable clinical testing, and that worked, as
15 well as Merck claimed, and on top of all that, with full
16 disclosure -- full disclosure of any issues or concerns that
17 Merck had about its vaccine. The CDC got none of that. This
18 is exactly the type of case the False Claims Act was designed
19 to cover.

20 So, now, let's talk about materiality, because I
21 think with the full understanding of the gravity of the
22 misconduct here, we can understand materiality. We're not
23 just defending summary judgment on materiality. What Merck's
24 counsel skipped over was the overwhelming and undisputed
25 evidence of materiality, so much so that we believe

1 materiality should be granted in our favor on summary
2 judgment.

3 None of this was discussed by Merck, so let me run
4 it through, because there are so many different factors.
5 First of all, who is in a better position to assess
6 materiality than the agency which was the subject of fraud?
7 The CDC is. And the CDC has spoken in this case on several
8 occasions.

9 First off, twice, the CDC injected itself into this
10 case with a letter that had to do with discovery and
11 authorizing 30(b)(6) witnesses. And the letter from the
12 Director of the CDC, and then there was a follow-up by the
13 Deputy Director, said this, the CDC has a "clear interest" in
14 the outcome of this case, because it is "critical" that they
15 receive accurate information from vaccine manufacturers.

16 If that doesn't answer the materiality question by
17 itself, I'm not sure what will, but we have a lot more from
18 that. We have the United States, which, on numerous
19 occasions, has injected itself into this case. Yes, they
20 didn't intervene so many years ago. But when they didn't
21 intervene, they made a point of saying, it had nothing to do
22 with the merits. There are many reasons why the Government
23 doesn't intervene.

24 And in the statement of interest they filed,
25 challenging one of -- Merck was trying to get them to dismiss

1 the case. Instead, they filed a statement of interest
2 rejecting Merck's main argument for dismissal. And in that
3 statement, they said, the United States is the real party in
4 interest here, and we have a "strong interest" in the outcome
5 of this case.

6 As you know, they also filed a statement of interest
7 in summary judgment on the very issue of materiality, and Mr.
8 Sweet will likely speak to what their positions are on that.
9 But if I can encapsulate them, I would point out that, first
10 of all, they made it very clear, the United States, that Merck
11 is applying the wrong standard on materiality. And what they
12 also said is that, the Government's continuing purchases, in
13 this context, where there is no actual knowledge, you have
14 mere allegations. They know that. Maybe they even have a
15 strong suspicion of wrongdoing, but that's not the standard
16 under Escobar. It's actual knowledge. They don't have actual
17 knowledge, and that comes clear from the statement of
18 interest.

19 And, finally, in the statement of interest, the
20 Government made it clear that even if the CDC did have actual
21 knowledge, it doesn't undermine materiality in situations like
22 this, where there are serious public health and safety reasons
23 why you might want to continue purchasing here.

24 What are those reasons here? Mumps vaccines, until
25 just a few months ago, when GSK finally was able to get into

1 the market, but up until, for the last 50 years, Merck was the
2 only source for Mumps vaccine. So if the CDC stopped
3 purchasing Merck's vaccines, they would have no Mumps vaccines
4 at all. But even worse than that, you can't buy a Mumps
5 vaccine alone. It only comes in a combination vaccine with
6 Measles and Rubella.

7 So, if the CDC did what Merck said they should have
8 done, if they cared about this case, they would had to cut off
9 vaccinating millions of children a year for Measles, Mumps and
10 Rubella. That doesn't give us any indication that they
11 continued to buy it, even if they had actual knowledge, which
12 they clearly did not.

13 But the DOJ issue doesn't stop there. We have cited
14 numerous False Claims Act cases, which Merck's counsel
15 dismisses as irrelevant but they are entirely on point. You
16 know, the mine run of cases language from Escobar is exactly
17 this. There have been -- we cited a half a dozen in our brief
18 where the very facts at issue -- well, not the very facts.
19 This is a very unique case. But the same kind of misconduct
20 at issue was enough for the Government to bring False Claims
21 Act enforcement actions against these defendants.

22 And I just want to highlight two of them. One is
23 the McKesson case, which we cite in our papers. That involved
24 CDC vaccine contracts under the Vaccine for Children Program,
25 the same program here. It involved misconduct that impacted

1 the potency of the vaccine. And in successfully settling the
2 matter, this is what the DOJ said, "Insuring the integrity and
3 performance of Government contracts is paramount, especially
4 when it impacts programs intended to protect young children,"
5 the same program at issue here. How is that not relevant to
6 this case and the assessment of materiality? Merck does not
7 say.

8 The other case I want to highlight is the Shire
9 case. That was about a drug maker selling drugs that lacked
10 clinical data -- sounds familiar -- and overstating the
11 efficacy, exactly what's going on here. In successfully
12 settling that case, this is what DOJ said, "We will be
13 vigilant to hold accountable pharmaceutical companies that
14 provide misleading information regarding drug safety and
15 efficacy," exactly the issues on the table here.

16 But there is more, Your Honor. Escobar speaks to
17 the essence of the bargain. The essential inquiry in a
18 materiality assessment is the violations or the
19 misrepresentations, omissions, do they go to the essence of
20 the bargain? Effectiveness is the core essence of these
21 vaccine contracts.

22 Their own experts admit -- and, I mean, it's not a
23 far cry. You don't even need evidence, it's such a
24 commonsensical point. But if we needed evidence, we can just
25 look at their expert, Dr. Atkinson. This is his quote -- and

1 he was an expert who previously worked at the CDC -- "Vaccine
2 effectiveness is obviously kind of the most important thing we
3 deal with."

4 We can look at Merck's own papers. I don't know how
5 they make this argument, and then have this in their papers,
6 but they do. Their opposition papers at page 29, this is
7 their quote, "CDC considers vaccine effectiveness the most
8 important factor when evaluating vaccines."

9 This entire case is about effectiveness, potency and
10 protection -- effectiveness. They admit it. It's the essence
11 of the bargain, a clear indicia of materiality. But there's
12 one more, and that's that the contract's provisions that we're
13 talking about, the violations that we're talking about weren't
14 just conditions of payment, and we spell this out in our
15 brief. They were actual prerequisites for purchase.

16 Merck's counsel says we have no evidence. She's
17 ignoring all the testimony that we got from the CDC. The CDC
18 witnesses, both the ones that were the 30(b)(6) witnesses that
19 the CDC produced, and the Merck experts, who were former CDC
20 employees, they were uniform in saying that violations dealing
21 with potency and protection, which are covered under CGMP, are
22 prerequisites to purchase. Following CGMP is a requirement of
23 -- it's in the contract.

24 And these witnesses were clear that if you're not
25 violating -- if you are violating CGMP, we're not going to

1 contract with you. Even fraud, one of Merck's -- I'm sorry --
2 one of the CDC's 30(b)(6) -- oh, no, no, this was one of
3 Merck's experts, Mr. Nichols -- or Dr. Nichols -- I don't
4 remember -- he said that -- we asked, well, if one of your
5 vendors committed fraud, would the CDC deal with them? I
6 mean, let's just deal with common sense so stay that none of
7 this would matter. And he said, "I don't think CDC would have
8 wanted to contract with a vendor found guilty of committing
9 fraud." This is their own experts who are backing this up.

10 So, we have the CDC speaking. We have the
11 Department of Justice speaking. We have the prior FCA
12 actions. We have the essence of the bargain, and we have
13 prerequisites for purchase, which are way more material than
14 conditions for payment. All of them undisputed from the
15 documents -- Merck's own documents, Merck's own papers,
16 Merck's own experts and the CDC witnesses.

17 So, let's talk about what they do talk about.
18 They're real focused on materiality. They throw that out on
19 the side and give it short shrift. And what they focus on,
20 instead, is the decision of the CDC to continue purchasing.
21 Well, I already spoke about, it's the only vaccine available
22 up until a few months ago. You couldn't buy it unless they --
23 couldn't stop purchasing it unless they also got rid of
24 Measles and Rubella.

25 So, what they're really asking for, Your Honor, is a

1 standard by which, if the Government gets a sniff or a whiff
2 or even a suspicion of fraud, regardless of the product,
3 regardless of the underlying circumstances, regardless of the
4 availability of alternatives, they better stop purchasing or
5 do something or they're going to lose their rights under the
6 False Claims Act. Do you know what a dangerous precedent that
7 would set? No court has ever adopted that.

8 They cite a bunch of cases. Not one of them deals
9 with even a fraction of the facts at issue here with the type
10 of product, bundled with another product, with all of these
11 materiality evidence that we set forth. Virtually all of them
12 deal with situations where lack of materiality was conceded or
13 the Government came out and said that we don't care about this
14 case. Very, very, very different than here.

15 And I think one of Merck's documents really speaks
16 to this continued purchases argument the best. It was one of
17 their consultants. They called the CDC and all of the other
18 captive purchasers of Merck's Mumps vaccine, in their words,
19 Merck's consultant, customers by force, not by choice --
20 customers by force. And that tells you a lot about the
21 predicament the CDC has been in.

22 I want to talk -- because a lot of their focus is
23 on this submission that Dr. Kessler made. What they haven't
24 said is that they made their own submissions, two submissions
25 actually, to rebut Dr. Kessler's position. And in those

1 submissions, they, essentially -- I don't want to speak too
2 strongly, but I'm going to say it like I see it. They are
3 continuing to perpetuate the fraud on the CDC that has been
4 going on throughout this whole case, and I'll tell you why.

5 It's not just that they continued to say that their
6 vaccine is safe and effective, even though they have no
7 clinical data supporting that. And it's not just because they
8 urged the Government to not take any action, even though they
9 said that. It's this, in the very submission to the CDC and
10 the FDA to rebut Dr. Kessler, they relied on the very
11 falsified data that's at issue here.

12 And if you want to see it, it's Exhibit 205 -- Merck
13 Exhibit 205 at pages 47 and 48. The Protocol-7 data that we
14 have already seen was garbage and falsified, they relied on
15 that to make their point that there's no case, here, so this
16 is the fraud that's continuing.

17 They've also, I told you earlier, told the DOJ what
18 Protocol-7 was about and didn't tell the truth on that either.
19 So this is continuing. This is not something to put the
20 Government on actual notice. Not only did they provide the
21 falsified data, but they actually said that this demonstrates
22 that the Mumps vaccine still provides protection.

23 So that's the materiality story in its entirety,
24 filling in the major gaps that Merck left out. Let's talk
25 about the effectiveness part, now, because they bandy about --

1 I mean, they had this nice chart that you saw which shows this
2 precipitous drop. We've already talked about that. It's
3 pegged to 1995. They don't really -- and it's on a scale that
4 you don't really see what happens after 2006. In our reply
5 brief, we do our own chart, which shows what happened from
6 1995. We kind of continue it on. And you see, it goes in
7 the opposite direction with huge spikes.

8 So, let's forget about this 99 percent drop, because
9 that's meaningless, at this point, since 2006. But let's talk
10 about the 88 percent figure, because that's more current.
11 And, yes, the FDA and the CDC are quoting to that number. But
12 let's talk about what that number is.

13 That's not an average. It's a median. It's in the
14 middle. And even their own slide, at page 11, shows what it
15 is really is. It's a range. And the range that they have on
16 their slide is 32 to 95 percent. So it's a range with a
17 lower bound and an upper bound. And that lower bound, since
18 2006, keeps getting lower. It started at around 75 percent.
19 Then it dropped into the 60s, and now, it's in the 30s.

20 What does that tell you, Your Honor? It tells you
21 that, yeah, some of these vaccines may be 95 percent
22 effective. Maybe a lot of them are 88 percent effective.
23 Some of them are only 30 percent effective, and we don't know
24 which ones are which. We don't know which -- which vaccine
25 you give to this kid. We don't know if it's the one that's 30

1 percent -- and it's probably going to keep getting lower -- or
2 if it's the 95 percent.

3 You know, here, CDC, here's all these vaccines. Can
4 you imagine an auto supply company selling brakes to the
5 Government and saying, yeah, 90 percent of these brakes work,
6 but, you know, around ten percent, we're not so sure. We
7 don't know which ones. Is the Government going to buy those
8 from that supplier? No way. And that's what's going on here,
9 and that's why CGMP and adequate assurances and the
10 adulteration statutes are so critical, but Merck keeps
11 skipping over that.

12 The potency failures, and the record is full of it
13 -- we can show you a dozen documents -- Merck statistically
14 predicted that up to eight percent of their vaccines were not
15 going to comply with the potency specifications for the full
16 shelf life. That's what raised the alarm, their statistical
17 certainty.

18 And this wasn't some one-off statistician. This was
19 done over many years, covering many different lots. There was
20 a statistical certainty that up to eight percent of the lots
21 were going to fail, and that's why they were fearing a recall.
22 None of it shared with the FDA. That's why they were fearing
23 a recall. That's why they called their product non-marketable
24 and misbranded and out of compliance. And that's why this
25 Protocol-7 -- it's not just some clinical trial that means

1 nothing. It means everything. But for that clinical trial,
2 their market -- if anybody had found out about it, that
3 product would have been pulled.

4 So, how does this relate to the 88 percent
5 effective, some kids getting a 30 percent good shot, probably
6 lower; some getting a 95 percent, and we don't know which one,
7 Merck acknowledging, internally, at the highest level that
8 eight percent are going to fail? That's what adequate
9 assurances have, and they don't have that with this vaccine.

10 All of these other comments that are in their
11 briefs, the second-guessing of the agency, you know, the -- I
12 mean, there's so many that -- potency isn't part of the case.
13 Efficacy and effectiveness are different. It's all a
14 distraction from the key issues in this case.

15 There is a serious problem, a serious problem. If
16 you could read the 500-page expert report of Dr. Kessler, you
17 could see why he is so concerned. In his -- and if you listen
18 to his deposition, he's shouting from the rooftops that
19 something needs to be fixed here. This is a staple of the
20 American Vaccination Program, and no one has any idea what's
21 going on. And we have all the evidence to show what's behind
22 it, and they've shared none of it with CDC.

23 If there wasn't a stronger case under the False
24 Claims Act, I don't know what there would be.

25 THE COURT: Counsel?

1 MR. SWEET: Your Honor, I have some comments on
2 materiality, as well. It might be better if Merck can speak
3 after, and they can respond to anything I have to say? Thank
4 you.

5 Your Honor, I'm going to speak for a few moments
6 about the Government's position here. I am limiting my
7 comments to the subject in the Government's statement of
8 interest. And the Government takes no view on the sufficiency
9 of the evidence in this case, but we do have a lot to say
10 about the interpretation of materiality and the legal issues
11 that are raised in the parties' briefs.

12 First, I just want to point out, because I think
13 it's always good to start with the statute, itself. There's a
14 definition of materiality in the False Claims Act. And I am
15 citing to the Escobar case specifically has the definition as,
16 "having a natural tendency to influence or be capable of
17 influencing the payment or receipt of money or property."

18 That definition doesn't appear in Merck's
19 presentation, but I think it's important to start there. The
20 Government's knowledge is critical here. And, again, it's
21 been pointed out by the parties that Escobar, which is the
22 Supreme Court case, which really defines materiality and
23 addresses the materiality prong, Justice Thomas specifically
24 talks about where the Government has actual knowledge and what
25 the Government's conduct is after actual knowledge.

1 I have some examples, if the Judge wants later at
2 some point, about what actual knowledge could mean for the
3 Government. But, at this point -- and the Government has
4 knowledge of accusations, of allegations by Relators. The
5 Government does not have actual knowledge. And allegations,
6 alone, has little relevance to the materiality inquiry under
7 the False Claims Act.

8 Merck states, throughout its briefing, that the
9 Government must have concluded that Relators' allegations are
10 untrue or otherwise not material, because the Government has
11 actual knowledge of all of the facts and all of the evidence
12 relating to this matter. That's just not true.

13 Merck's effort to represent that the Government
14 knows, and to interject that conjecture into the materiality
15 analysis is incorrect as a matter of law. The Government has
16 knowledge of the allegations made by the Relators. The
17 Government has not made any determination or drawn any
18 conclusions --

19 THE COURT: Well, there's a big difference between
20 knowing allegations, and all I know is the allegations, and
21 the Government stopping there and saying, all I know is the
22 allegations, and absolute knowledge over here. You can't
23 stand up here -- or are you standing up here and saying, the
24 FDA and the CDC did not have any of this information, did not
25 explore it?

1 My understanding is the Government explored it for
2 two years. So that's knowledge. Now, you want to tell me,
3 actual knowledge versus allegations? Certainly, you knew more
4 than allegations. And the Government knowing allegations,
5 stepped in and did discovery, decided not to intervene, which
6 is fine. It's not the case -- it's not the end of the case.

7 But, certainly, they made a due diligent look at
8 what's going on, because they're protecting the people, the
9 very people that are going to get these shots.

10 MR. SWEET: Your Honor, I'm glad you raised this.
11 The Government --

12 THE COURT: So, I'm reading Escobar, too.

13 MR. SWEET: Yeah, Your Honor, the Government --

14 THE COURT: You're right, that's the case. They
15 don't mention the statute, but they mention Escobar, which
16 defines it. So I read it, and the definition of materiality
17 is right there.

18 MR. SWEET: That's correct, Your Honor.

19 Let me speak to Your Honor's comments about what the
20 Government knows and what the Government doesn't know.

21 THE COURT: Yeah, but more than allegations, though.

22 MR. SWEET: The Government knows allegations. The
23 Government knows --

24 THE COURT: And they can't say, like, Sergeant
25 Schultz, I know nothing now.

Sweet - Argument

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1 MR. SWEET: We didn't say we know nothing now.

2 THE COURT: That's what I was hearing you saying.

3 MR. SWEET: The declination, the Government's
4 decision -- the Government investigated. They --

5 THE COURT: When she said -- counsel says, they know
6 all this. They know all that -- we put it in front of them to
7 let them investigate.

8 MR. SWEET: I think that says a lot about --

9 THE COURT: And they continued to buy. So it says a
10 lot about, what?

11 MR. SWEET: Your Honor, if I can? If I may, there's
12 a lot to say about -- in response to Your Honor's comments,
13 and I appreciate Your Honor's comments. I think they're right
14 on the mark.

15 In 2012, the Government declined to intervene, based
16 on allegations in the original complaint. On the very same
17 day, in April of 2012, the Relators filed an amended
18 complaint. The amended complaint had new allegations. The
19 amended complaint, then, went into discovery. There was years
20 and years of discovery. The Government was aware of some of
21 what was happening. The Government participated in some of
22 what was happening.

23 But the Government did not take this case on.
24 Again, we did not intervene in the case. We were not counsel
25 to the case. We did not digest every bit of evidence. We

1 watched as the case progressed. And, under the False --

2 THE COURT: And the Government is, who?

3 MR. SWEET: -- Claims Act, Your Honor --

4 THE COURT: The Government is, who? The Government
5 is the FDA?

6 MR. SWEET: The Government, in this case --

7 THE COURT: Is the Government the CDC?

8 MR. SWEET: Well, Your Honor, that's the point. The
9 Government is a lot of things.

10 THE COURT: Right.

11 MR. SWEET: Right. The Government is the FDA. The
12 FDA may know certain things.

13 THE COURT: So, you're --

14 MR. SWEET: The CDC may know certain things.

15 THE COURT: So, are you representing what the FDA
16 knew? Are you representing what the CDC knew or followed
17 during that period of time?

18 MR. SWEET: Your Honor, I'm saying that the
19 Government's collective knowledge is expressed through the
20 Department of Justice, and the Department of Justice is the
21 party that speaks in court for the United States.

22 THE COURT: All right. And that's good, and I
23 understand that.

24 MR. SWEET: And -- and, Your Honor --

25 THE COURT: But I'm looking at Escobar, which looks

1 at a holistic approach of materiality.

2 MR. SWEET: Correct.

3 THE COURT: So I understand that you're saying,
4 look, take with a grain of salt when it's mentioned that the
5 Government knew something. So they knew something, but what
6 did they know? But the Government is coming up here and
7 saying, collectively, we know nothing?

8 MR. SWEET: No. No, Your Honor, I never said
9 nothing.

10 THE COURT: All right. So, what did you know?

11 MR. SWEET: Your Honor, we knew all sorts of -- we
12 followed the case.

13 THE COURT: So you followed the case, okay?

14 MR. SWEET: So, when Merck says, the CDC and FDA,
15 and I'm quoting here, "have all of the evidence to evaluate
16 it", and they say that, "the DOJ, CDC and FDA know the
17 entirety of Relators' falsity claims, including every
18 pertinent piece of evidence that Relators say was withheld
19 from the agency" -- that's at page two of their response to
20 our statement of interest -- that's just simply not true.

21 THE COURT: It's hyperbolic, they call it.

22 MR. SWEET: Well --

23 THE COURT: They know all, but in other words, they
24 have access to all. They were invited into all. What they
25 knew, the DOJ is not going to say, we knew all.

Sweet - Argument

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1 MR. SWEET: Your Honor, no agency is all knowing.

2 THE COURT: Exactly.

3 MR. SWEET: Okay. This case progressed --

4 THE COURT: Exactly. Welcome to a courtroom, where
5 there's hyperbolic statements.

6 MR. SWEET: Well, Judge, it's hyperbolic, but it's
7 also the basis for saying that there's no materiality.

8 THE COURT: It is one basis for saying that, but
9 it's not -- but you can't come up here and say, we know
10 nothing.

11 MR. SWEET: I didn't say that, Your Honor.

12 THE COURT: Well, I heard that allegation.

13 MR. SWEET: I said we know allegations.

14 THE COURT: What do you know? So you know some
15 things, but you don't know what those things are?

16 MR. SWEET: Your Honor, I can't -- I can't cite to
17 you, right now, every piece of evidence we know.

18 THE COURT: Right.

19 MR. SWEET: We have had a lot of information
20 available to us.

21 THE COURT: Right.

22 MR. SWEET: We've had -- we've had CDC witnesses
23 deposed.

24 THE COURT: Right.

25 MR. SWEET: We've had discussions with the FDA, and

1 I'm not going to get into everything that we have internally
2 discussed.

3 THE COURT: Right, because it would take us three
4 days to go through it.

5 MR. SWEET: That's right, Your Honor.

6 THE COURT: Right, okay.

7 MR. SWEET: But, on the other hand, to suggest that
8 the Government has full knowledge of every fact --

9 THE COURT: I agree with you. We're on the same
10 page.

11 MR. SWEET: Okay. Your Honor, let me just continue
12 on this issue, because this is where it goes from. I think
13 we're on the same page that there is a difference between
14 actual knowledge and knowledge of allegations, so I'll give
15 you some examples, Your Honor.

16 THE COURT: Wait a second. There is, and we agree,
17 but actual knowledge, you had actual knowledge to a lot of
18 things, and you're saying, Judge, I'm not going to spend three
19 days telling you what I have actual knowledge to.

20 MR. SWEET: Well, Your Honor, actual knowledge of
21 the falsity of the -- of the -- whether there is falsity.
22 That includes quite a lot of information. And, at no point
23 since -- I'm not going to get into the Government's internal
24 deliberations, but this case has been going on for years. The
25 evidence has been developed over years. Testimony has been

1 taken. Experts have come in. I cannot say -- I cannot
2 represent --

3 THE COURT: Right, right. Look, I understand. I
4 understand what you're saying.

5 MR. SWEET: -- that the Government has distilled and
6 synthesized everything, and said, all of the information has
7 come to the Government, and we take this position. We know
8 all. We are watching this case as it develops, and that is
9 how the False Claims Act is designed.

10 The False Claims Act is designed to allow the
11 Government to do an investigation. It doesn't require that we
12 make a decision on the merits, and then we can decide to -- we
13 can elect to intervene or decline.

14 We declined the original complaint in 2012. That's
15 the point where discovery took off, and we were -- the
16 Government is allowed to -- in fact, that is the design of the
17 False Claims Act, to allow the Government to rely on Relators
18 and their counsel to develop a case and try to put it on in
19 court.

20 THE COURT: I understand that. And I understand
21 what you are saying about actual knowledge. I don't know that
22 I agree with you. I am reading Escobar. The DOJ can read
23 whatever it wants. You can come here and say, look, we're out
24 of the case, but you know what, we let it go on for ten years
25 and follow it. So, therefore, actual knowledge, DOJ, under

1 those circumstances, we'd never have actual knowledge.

2 MR. SWEET: I can give you --

3 THE COURT: I'm assuming, if you have actual
4 knowledge that this was causing a disease in children, you
5 would have come in and said, look, we're stopping this --

6 MR. SWEET: Well, Your Honor --

7 THE COURT: -- right?

8 MR. SWEET: -- let me -- let me get to that, because
9 the FDA's issues, and I think there was kind of a hit at the
10 FDA about its obligation to inform the public about safety
11 issues. This case is not about safety issues. The FDA looks
12 at safety and effectiveness. This case is about
13 effectiveness.

14 So I think it would be wrong to suggest --

15 THE COURT: Thank you, that -- that's --

16 MR. SWEET: -- and Merck's counsel did suggest --

17 THE COURT: -- counsel for defendants, if you
18 listened carefully, said it was about safety and
19 effectiveness.

20 MR. SWEET: Well --

21 THE COURT: But you're saying it's about
22 effectiveness.

23 MR. SWEET: Well, yes, and I'm saying that --

24 THE COURT: Yes. But counsel was saying, look, if
25 they're saying about safety, you had a responsibility to tell

1 the public.

2 MR. SWEET: That's correct.

3 THE COURT: And you didn't tell the public, because,
4 Judge, it's about effectiveness.

5 MR. SWEET: That's correct.

6 THE COURT: Right, okay.

7 MR. SWEET: Okay. So the FDA is not falling on its
8 obligations, here, because there is no safety issue; it's an
9 effectiveness issue.

10 THE COURT: Okay, good.

11 MR. SWEET: Your Honor, if I can, I could give you a
12 few examples --

13 THE COURT: We're on the same page with that.

14 MR. SWEET: Because Your Honor is interested in this
15 knowledge issue, I'll give you a few examples of actual
16 knowledge, because there are plenty of cases in which the
17 Government, in a False Claims Act, after investigation, has
18 actual knowledge.

19 One example, self disclosure. We have a lot of
20 defendants who come in and self disclose. Then we have actual
21 knowledge. We have discrete cases --

22 THE COURT: Wait a second. Wait a second. We can
23 do all the generics you want about cases here and cases there,
24 all right? Counsel is saying, look, they had knowledge of
25 this Protocol-7 and the issues. The FDA came in, and they

1 worked with us with the issues.

2 They knew about the release potency versus the --
3 the discrepancy between the release potency and 24-month
4 potency. FDA had actual knowledge of that. They came in, and
5 they looked at it. The CDC, even though they were not dealing
6 directly, came in, had actual knowledge of that.

7 Are you saying that the DOJ, even though they had
8 actual knowledge of that, the DOJ had no actual knowledge of
9 that?

10 MR. SWEET: Your Honor, what I am trying to say is
11 that it's a matter of this argument on materiality --

12 THE COURT: Yes.

13 MR. SWEET: -- the suggestion that the Government
14 had actual knowledge of all of the evidence and all of the
15 pertinent records --

16 THE COURT: I agree with you. That's out the door.

17 MR. SWEET: Well, that's all I'm saying.

18 THE COURT: Okay, good.

19 MR. SWEET: That's what I'm -- so let me move
20 forward.

21 THE COURT: Then we're done. What else do you have
22 to say?

23 MR. SWEET: A few more things, Your Honor, if I may?
24 And I can give you more examples of actual knowledge, but I
25 think Your Honor has that issue, so --

1 THE COURT: I have the issue, and I am drilling down
2 on the issue.

3 MR. SWEET: Okay.

4 THE COURT: Actual knowledge, the FDA, what did they
5 have actual knowledge of? They had actual knowledge of the
6 problem.

7 MR. SWEET: Okay.

8 THE COURT: That's what the argument is.

9 MR. SWEET: So, Your Honor, all of the statements in
10 Merck's brief concerning -- and there were so many of them --
11 where materiality is based on continuing purchases, the
12 failure to -- of the CDC to negotiate --

13 THE COURT: Continuing purchases, that's Escobar.

14 MR. SWEET: That's Escobar.

15 THE COURT: Right.

16 MR. SWEET: But there are other similar Government
17 action and inaction that fall in the same category. For
18 example, they raised the issue of the CDC's failure to
19 negotiate the price of the vaccine once they became aware of
20 the issue. They raise other issues of the Government's action
21 and inaction. They raise out of state -- out of Court
22 statements by FDA officials concerning effectiveness.

23 All of that, Judge, is presumptuous. All of that
24 are conclusions. They do not have knowledge -- they do not
25 have a basis to know why the Government did what it did. And

1 our statement of interest specifically addresses that. The
2 FDA may act for all sorts of reasons.

3 THE COURT: They may, but, again, Escobar is saying,
4 strong evidence. It's not the end of the case. It's strong
5 evidence that, hey, the FDA comes in; they look at this. The
6 CDC comes in. Actual knowledge as to the testing problem.
7 The Whistle Blowers come in and say, look, there's a problem
8 here. Okay, we're going to come in and look at it, and then
9 the Government acts.

10 So, and then the Government acts, but then they say,
11 like, the FBI, we never make a determination.

12 MR. SWEET: Your Honor, we are on --

13 THE COURT: It's like the DOJ, we never make a
14 determination. We wait until the --

15 MR. SWEET: Your Honor --

16 THE COURT: -- the jury decides or the judge, but I
17 get that. We're on the same page.

18 MR. SWEET: We're on the same page with that, as
19 well, Your Honor.

20 THE COURT: Right.

21 MR. SWEET: All of this Government action can be --

22 THE COURT: Or inaction.

23 MR. SWEET: -- or inaction can be driven by
24 numerous --

25 THE COURT: Or whether they'll wait and see for 12

1 years.

2 MR. SWEET: Well, it could be driven by numerous
3 other factors.

4 THE COURT: But we'll continue to buy the product
5 while we wait and see.

6 MR. SWEET: But to conclude, and that's the -- look,
7 Merck brought a summary judgment --

8 THE COURT: To conclude, what? I like that word.

9 MR. SWEET: Merck brought a summary judgment motion
10 saying that all of this Government action should show the
11 Court that there is materiality. All we're saying is exactly
12 what Escobar and Your Honor says. It's evidence.

13 THE COURT: Right.

14 MR. SWEET: It's not conclusive.

15 THE COURT: It's not.

16 MR. SWEET: Okay. Your Honor, I think you've got
17 it, so I'm not going to belabor a lot of my argument here
18 other than to say -- well, one more thing. Declination, it's
19 come up over and over with respect to materiality.

20 The Government's decision to decline to intervene in
21 the case is completely irrelevant to materiality.

22 THE COURT: I absolutely agree.

23 MR. SWEET: Okay. And the Third Circuit's Chief
24 Judge Smith just spoke to this recently.

25 THE COURT: I always agree with the Third Circuit.

Sweet - Argument

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1 MR. SWEET: Okay, Judge.

2 THE COURT: Even when I disagree.

3 MR. SWEET: I understand, Your Honor.

4 THE COURT: I only let them know that in the
5 elevator.

6 MR. SWEET: I have the same practice. And I'd just
7 point out, Your Honor, that declined cases, the Government has
8 collected since 1986, I think, 3.5 billion dollars in declined
9 cases. The Government supports declined cases. The fact that
10 we decline is not a suggestion that we're commenting on the
11 merits of the case.

12 THE COURT: I whole-heartedly agree.

13 MR. SWEET: Okay. Judge, with the benefit of our
14 intern from Drexel Law School, Mary Rose Babcock, in the back
15 of the courtroom, we have a number of Circuit Court cases, and
16 we left them at Circuit Court cases --

17 THE COURT: So, let me say hello to Mary Rose
18 Babcock. Very good job. We love Drexel. Drexel sends some
19 very nice students down here, so.

20 MR. SWEET: And her first assignment working with us
21 this semester was to go back and look for Circuit Court cases
22 that address these issues, the materiality issue, since the
23 time we filed our statement of interest in 2000, right, a few
24 years have passed.

25 So there are a few cases, if -- Your Honor, I can

1 tell you what they are now or I can submit a submission, a
2 letter, but there are several Circuit Court cases, all of
3 which support -- they would seem to support the suggestion --
4 the issue here that Government action or inaction, continuing
5 sales, do not -- are evidence of materiality, and that
6 evidence, unless there is no evidence on the other side,
7 should go to a jury, and that there are many, many reasons
8 that the Government may act, despite having knowledge, actual
9 knowledge, even, of allegations.

10 THE COURT: So --

11 MR. SWEET: Yes?

12 THE COURT: -- I just feel like you're an advocate
13 on this side, for the other side, even though you don't know
14 nothing.

15 MR. SWEET: Your Honor, I'm an advocate --

16 THE COURT: It sounds like an advocacy position --

17 MR. SWEET: Your Honor --

18 THE COURT: -- for the plaintiffs, even though "I
19 know nothing".

20 MR. SWEET: Your Honor --

21 THE COURT: In other words, you're preserving, hey,
22 if they're going to get a few bucks, we get a few bucks, too.
23 I don't understand what's going on here.

24 MR. SWEET: Absolutely not, Your Honor. I'm an
25 advocate for the statute being interpreted properly.

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1 THE COURT: Yes, and so, I -- I agree.

2 MR. SWEET: Okay.

3 THE COURT: It should be interpreted properly.

4 MR. SWEET: And so, there are a few other cases,
5 Wolf Creek Federal Services, the Sixth Circuit Court of
6 Appeals, Yates vs. Pinellas Hematology and Oncology, the 11th
7 Circuit --

8 THE COURT: But materiality doesn't go to the jury
9 every time.

10 MR. SWEET: That's correct, Your Honor.

11 THE COURT: All right. So we're on the same page.

12 MR. SWEET: But it would seem to me that the issue
13 of materiality would go to the jury unless the Court were to
14 find that no reasonable juror could find for the non-movant in
15 this case.

16 THE COURT: Correct, I agree.

17 MR. SWEET: Your Honor, unless you have any
18 questions, finally, to conclude, the United States speaks
19 exclusively for the -- I'm sorry -- the Department of Justice
20 speaks exclusively for the United States in this case.

21 The Department of Justice has an established
22 statutory authority, an established criteria to -- when it
23 should intervene in a case and move for dismissal of the case,
24 when it's in the Government's best interest. That has not
25 happened here.

1 THE COURT: Well, listen, the Government could have
2 stayed in, and they could have been an Intervener, and the
3 question, still, of materiality is still on the table,
4 wouldn't you agree? Even if you stayed in, and you said,
5 Judge, it's material, I might say, it's not material.

6 MR. SWEET: Absolutely, Your Honor.

7 THE COURT: All right. So we're on the same page.

8 MR. SWEET: I think we are.

9 THE COURT: Yes.

10 MR. SWEET: Any further questions, Your Honor.

11 THE COURT: No, you did great. And thanks to the
12 Drexel student for putting all of those -- did you interview
13 for a new internship the day after you got the assignment?

14 (No audible response.)

15 THE COURT: I don't know how much further we can go
16 on this. I know that you have some rebuttal, and you saved
17 five minutes, but counsel took all 20 minutes of your five
18 minutes.

19 MS. ELLSWORTH: Could I have three minutes, Your
20 Honor?

21 THE COURT: I'll give you five minutes. Go ahead.
22 Because we have another argument after this, you know.

23 MS. ELLSWORTH: Well, let me start with what I think
24 was the most interesting thing that I heard today, which is
25 that all --

1 THE COURT: Something I said, I hope?

2 MS. ELLSWORTH: Hopefully, it's something you will
3 say.

4 I told you that effectiveness was the most important
5 factor for the CDC. Relators' counsel stood up and told you,
6 effectiveness data is the most important factor for the CDC,
7 and then the United States stood up and told you,
8 effectiveness is the most important factor to the CDC.

9 Well, if you want to talk about actual knowledge,
10 the CDC develops its own effectiveness data. Merck has
11 nothing to do with that. It is between the CDC, and the State
12 and local health officials, and the CDC has known that the
13 effectiveness data shows an 88 percent median effectiveness
14 rate, and it hasn't shifted.

15 The CDC has known the range the Relators counsel
16 told you has changed. The range has, but the median hasn't.
17 And so, on that point, alone, I think all of the parties agree
18 that, on this thing, on this element, there is actual
19 knowledge by the CDC, and it's the most important driver.

20 I'll also note, on actual knowledge --

21 THE COURT: They don't agree with that, I guarantee
22 it. So what's your next point? Go ahead.

23 MS. ELLSWORTH: The Relators and the United States
24 said, the U.S. didn't have actual knowledge here, but if you
25 look at Merck Exhibit 205, that is the Dr. Kessler

1 submissions. That is 30 pages of submissions from Dr. Kessler
2 laying out their best story. They absolutely -- the CDC and
3 the FDA, the Commissioner of the FDA and the Director of the
4 CDC and a whole bunch of other public health officials at HHS,
5 everyone who Dr. Kessler wanted to send this to, received it,
6 so that the FDA and the CDC have that knowledge to.

7 It's not a lack of knowledge here, that's the issue.
8 It's that that knowledge wasn't persuasive to the CDC in
9 changing any of its purchasing habits.

10 And the argument that because Merck defended itself
11 to the CDC, that meant the agency couldn't evaluate whether or
12 not this was valid concern really makes no sense, when you
13 think that the Relators are going to ask a lay jury to make
14 that assessment. That is what would be the absurd outcome
15 here, and that's why the Nargle and the D'Agostino case that
16 we cited in our papers, and I didn't hear the U.S. respond to,
17 I think are really important ones for the Court to look at.

18 The False Claims Act is not about second-guessing
19 agency judgment, and that is, really, what the Relators are
20 asking you to do today.

21 And I think I'll save the rest of what I have, Your
22 Honor.

23 MR. SCHNELL: Your Honor, may I have two minutes,
24 please?

25 THE COURT: Sure.

1 MR. SCHNELL: On the CDC knowledge, what I omitted
2 from, also, when I spoke, we deposed the 30(b)(6) witnesses.
3 We asked them, do you have any knowledge of any of the potency
4 issues in the complaint. This is years after the complaint.
5 Do you have any knowledge? They said, no.

6 They didn't even know that Merck had had to double
7 the Mumps' potency. They had no knowledge of the clinical
8 trial fraud. They had no knowledge of anything. This is
9 their own witnesses. That speaks directly to what the CDC
10 knows and doesn't know, not this conjecture about, well, they
11 must have done something; they must have gotten something.

12 And, again, with the exhibit that they're pointing
13 to, 205, I would point you to pages 47 and 48, where they
14 included the falsified information.

15 The most important point that we haven't touched is,
16 now, we finally have another Mumps vaccine. It's the GSK
17 vaccine. It's only been approved for a few months. The CDC
18 has already started to shift some of its purchases away from
19 Merck to CDC. That's one action that has changed.

20 Other actions, they said the CDC has done nothing.
21 The CDC has done a lot to investigate the resurgence. They've
22 set up investigatory panels, a working group exclusively
23 devoted to this. They changed their vaccine recommendations
24 in 2006 from -- first, they thought you only needed one shot.
25 They changed it to two shots. They changed it, again, in 2017

1 to three shots for outbreaks, and there are internal documents
2 from the CDC, which we have in our papers, referencing their
3 "vital need" for a second supplier.

4 So to say that the CDC has done nothing is just not
5 true. It's all about conjecture. The CDC has done stuff,
6 including shifting their purchases, starting to shift their
7 purchases, so you cannot say that is beyond dispute that that
8 is any indication of how the CDC feels about the allegations
9 in this case.

10 And I'll stop there.

11 THE COURT: All right.

12 Anything else, Counsel?

13 MS. ELLSWORTH: I would just note that on these
14 questions about the CDC witnesses who were deposed, it was
15 Relators' burden to put a document in front of the CDC and ask
16 that witness if it would have changed anything about CDC's
17 purchasing if the witness had known that. They didn't do
18 that, because they wouldn't have liked the answer.

19 THE COURT: All right. Anything else? A last word?

20 MR. SCHNELL: We did put those questions before
21 Merck's experts, who were CDC witnesses, and the CDC
22 witnesses, and they reaffirmed, these are prerequisites for
23 purchasing, so they absolutely did support materiality here.

24 THE COURT: All right, Counsel, thank you.

25 ALL COUNSEL: Thank you, Your Honor.

1 THE COURT: All right. Chris, we'll take ten
2 minutes. We'll take ten minutes.

3 COURTROOM DEPUTY: All rise.

4 (Proceedings concluded at 11:40 a.m.)

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C E R T I F I C A T I O N

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9 I, Jacqueline Mullica, court approved transcriber,
10 certify that the foregoing is a correct transcript from the
11 official electronic sound recording of the proceedings in the
12 above-entitled matter on January 24, 2023 from 10:11 a.m. to
13 11:40 a.m.

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18 /s/Jacqueline Mullica January 25, 2023

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JACQUELINE MULLICA

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