

TextMap_FCA_Penelow_Trial_Tr_Transcripts

***2024.05.30 Penelow - Grooms
Direct-X-Redirect, Patel
Direct-X-Redirect, Hsu Direct-X***

5/30/2024

Full-size Transcript

Prepared by:

Jordan Einstein
Skadden

Monday, June 3, 2024

NYC1663022.01 PJC

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 UNITED STATES OF AMERICA, ET AL.,
4 Plaintiffs,

CIVIL ACTION NUMBER:

5 v.

3:12-CV-7758-ZNQ-JBD

6 JOHNSON & JOHNSON, JANSSEN
7 PRODUCTS, L.P.
8 Defendants

JURY TRIAL VOLUME 13

9 CLARKSON S. FISHER BUILDING & U.S. COURTHOUSE
402 East State Street
Trenton, New Jersey 08608
May 30, 2024
Commencing at 8:26 a.m.

11 B E F O R E: THE HONORABLE ZAHID N. QURAISHI
12 UNITED STATES DISTRICT JUDGE

13 A P P E A R A N C E S:

14 REESE MARKETOS

BY: PETE MARKETOS, ESQUIRE

JOSH RUSS, ESQUIRE

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W I T N E S S I N D E X

RELATORS' EVIDENCE

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
Matthew S. Grooms	4662	4688	4718	
Amit Patel	4736	4834	4885	

DEFENDANTS' EVIDENCE

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
Ricky Hsu	4906	4925		

E X H I B I T S

EXHIBIT	MARKED	ADMITTED
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1 (PROCEEDINGS held in open court before the Honorable Zahid
2 N. Quraishi, United States District Judge, at 8:26 a.m.)

3 THE DEPUTY CLERK: All rise.

4 THE COURT: Let's have appearances from counsel,
5 beginning with Relators.

6 MR. MARKETOS: Good morning, Your Honor.

7 THE COURT: Good morning.

8 MR. MARKETOS: Pete Marketos for Relators.

9 MR. WIRMANI: Good morning, Your Honor. Andrew
10 Wirmani for Relators.

11 MR. RUSS: Good morning, Your Honor. Josh Russ for
12 Relators.

13 MS. WENDEL: Good morning, Your Honor. Whitney
14 Wendel for Relators.

15 THE COURT: Good morning, everybody.

16 MS. BROWN: Good morning, Your Honor. Alli Brown for
17 Janssen.

18 MR. WYATT: Good morning, Your Honor, Jeff Wyatt for
19 Janssen.

20 MR. KLEIN: Good morning, Your Honor, Brad Klein for
21 Janssen.

22 THE COURT: Good morning to you folks as well.

23 Ms. Brown, what did we learn?

24 MR. WYATT: I can speak to this, Your Honor.

25 THE COURT: Or Mr. Wyatt, what did we learn?

1 MR. WYATT: Yes. So Your Honor had four questions at
2 the end of court today. I'm going to address those first
3 thing, and then we can talk about some other things that came
4 out of this.

5 So number one was, what did Ms. Kaucher actually do
6 relative to what the lawyers did? We confirmed that there were
7 two separate investigations, separate in time, so not occurring
8 at the same time, not intertwined with one another.

9 In early 2011, there was an investigation conducted
10 by HCC at the company. Ms. Kaucher was part of that
11 investigation. She did interview people, she testified
12 yesterday. And so relative to what the lawyers did, those were
13 two separate things. There was a second investigation that
14 began at the end of 2011 at the behest of Ms. Cesario, in which
15 Ropes & Gray was brought in and Ropes & Gray did its own thing.
16 So there's two separate investigations.

17 THE COURT: Wait. Sorry. You got to go slower.

18 The first investigation is in 2011?

19 MR. WYATT: Early 2011.

20 THE COURT: And that was done by Ms. Kaucher.

21 MR. WYATT: Health care compliance. She was
22 involved. There was others involved as well.

23 THE COURT: And that allegation from that employee
24 was related to Prezista and Intelence?

25 MR. WYATT: It was a list of things, but one of the

1 things was an accusation that there had been off-label
2 marketing by one member of the sales force.

3 THE COURT: And then the second investigation by
4 Ropes & Gray was when?

5 MR. WYATT: Starts late 2011 and it wraps up early
6 2012.

7 THE COURT: Those were separate allegations?

8 MR. WYATT: Ms. Cesario had reasserted the same
9 concerns. She felt that the first investigation needed to be
10 conducted again. So my understanding is the Ropes & Gray
11 investigation was prompted by that request.

12 THE COURT: All right. And so the allegations that
13 Ropes & Gray investigated subsequently, were those allegations
14 including allegations involving Prezista and Intelence?

15 MR. WYATT: It's the same -- yes.

16 THE COURT: Very similar allegations to the first
17 time; they did a second investigation.

18 MR. WYATT: Correct.

19 THE COURT: Okay. I may have more questions, but
20 what else?

21 MR. WYATT: Yes, Your Honor. Number two was where
22 are the documents that Ms. Kaucher was involved in the
23 investigation --

24 THE COURT: Well, even before we get to that, what
25 was disclosed to Relators' counsel through discovery? Only

1 information regarding the initial investigation by your
2 clients?

3 MR. WYATT: A couple things. So there were four
4 documents that we identified last night that were produced, not
5 redacted, that contained the substance of Ms. Cesario's
6 complaints, including the fact that there had been -- that she
7 had complained about off-label promotion, and I can show some
8 of those documents --

9 THE COURT: Of these drugs?

10 MR. WYATT: Sitting here, I can't remember if they're
11 called out in this, but it was in the -- it was under Frank
12 Murphy. It was the same sort of collection of folks, so yes, I
13 believe it's clear from the documents those are the drugs at
14 issue, but I'd have to double-check to be sure.

15 So certainly there are documents that were produced
16 and that put Relators on notice that these complaints had been
17 raised internally and had been brought to the attention of the
18 company. So I know that was an issue that was raised
19 yesterday. There was a question about that. I think the
20 question's answered, yes, they know that the company knew that
21 this complaint had been raised, and specifically that it had
22 been raised to and dealt with by HCC. That's part of this
23 email correspondence.

24 THE COURT: When compliance did the initial
25 investigation, were there any documents related to that

1 investigation? Are you telling me these four documents that
2 were produced related to that investigation?

3 MR. WYATT: Those four documents were email
4 correspondence that referred to the complaints and the
5 investigation but were not part -- they were not documents from
6 the investigation.

7 THE COURT: So when compliance did that
8 investigation, they didn't paper trail any of it? They didn't
9 write down anything regarding interviews or findings?

10 MR. WYATT: Let me address that, Your Honor. So in
11 the course of reviewing what was withheld, because there was a
12 Ropes & Gray file that was reviewed in response to discovery
13 requests around this question, those documents were
14 privileged -- were marked as privileged on the privilege log.
15 There was one document in there that was a draft HCC
16 investigation report, which we reviewed last night. It had a
17 comment to a lawyer in it saying that further changes were
18 coming. But in our review, there did not appear to be a
19 request for advice. It was merely communication that happened
20 to be to a lawyer. So we felt that that should be produced,
21 and we produced it to Relators this morning.

22 We also took a look to see if there was a final
23 version of this report. We did find a final version of the
24 report that was not produced. It was in the file of an
25 individual who was not an agreed-upon custodian to be searched.

1 That's all I know about it. I know it's not produced, but we
2 gave that to them as well this morning. It's substantively
3 identical to the draft.

4 THE COURT: So those documents relate to the
5 compliance investigation?

6 MR. WYATT: That's correct. They report the results
7 and findings of the compliance investigation. We also
8 inquired, not from Ms. Kaucher because we didn't want to
9 communicate with her, from others in the company, how does this
10 work, right? In answer to Your Honor's question, where is
11 the -- where would the documentation live for something like
12 this?

13 Our understanding is that in general, the way HCC
14 would conduct an investigation like this is there would be
15 teams of interviewers in which one person would be asking the
16 questions and another person would be taking the notes, and the
17 results would be input into a compliance investigation portal,
18 and the notes collectively would become the final report that
19 we've now given to Relators.

20 It's possible -- and Ms. Kaucher didn't work alone.
21 She worked with a Mr. Grimes on this investigation. It's
22 possible they would be in his file, and his file wasn't
23 searched. But we don't know that. I mean, I don't know if
24 there are additional notes or not, but what we do know is that
25 in a second search last night, we didn't find any other

1 documents reflecting notes, reflecting further drafts. What we
2 have are the two documents we gave to Relators.

3 THE COURT: So the two that you turned over this
4 morning are -- one is a draft report of this compliance
5 investigation; the other one's the final report of the
6 investigation?

7 MR. WYATT: Yes, Your Honor.

8 THE COURT: And it's your understanding, at least at
9 this time, that if there were any notes taken with respect to
10 interviews, those basically got molded into the final report.
11 There are no separate documents related to each separate
12 interview or anything of that nature?

13 MR. WYATT: That's my best understanding of how this
14 is typically done. We have not talked to Ms. Kaucher about
15 whether that happened in this case, so I can't say for sure
16 whether that is what happened. But my understanding, based on
17 these discussions, is it would not be unusual if that was how
18 this was conducted.

19 THE COURT: All right. And you would agree, though,
20 that those reports should have been produced much earlier than
21 this morning?

22 MR. WYATT: They appear to be responsive, but I do
23 want to address sort of the way the discovery process worked
24 here so we can have a little more context.

25 I don't know when this document was found, if it was

1 discovered in connection with this request or something else.
2 There were, as counsel pointed out yesterday, more than 50
3 requests for production in just the first set of RFPs in this
4 case.

5 There were a number of topics that were searched.
6 There was negotiations about who would be the custodians that
7 were searched, what the search terms would be. There was
8 separate back and forth on this request for production as well
9 as a number of others, and there was some discussion about what
10 additional searches would be done, where they were going to
11 look, et cetera.

12 I wasn't privy to those discussions, so I don't know
13 what else was discussed. I'm not exactly sure how it was
14 conducted. But I do know that there was attention paid to
15 this. There were documents that were produced in response to
16 it. There was the privilege log that we discussed. And there
17 were no, as far as I know, further discussions or at least no,
18 certainly, formal motions to compel or anything of that nature.

19 THE COURT: Well, I don't think they need to compel a
20 report that they don't know exists.

21 MR. WYATT: Understood, Your Honor.

22 THE COURT: So, I mean, again, don't shift the
23 responsibility to the Relators on this.

24 MR. WYATT: I'm not --

25 THE COURT: So far everything I've heard, Mr. Wyatt,

1 is you had a draft and final report of the HR or the compliance
2 investigation that you all failed to turn over in discovery
3 that should have been discoverable well in advance of this
4 morning. So I don't think the Relators have to figure out is
5 there a report that doesn't exist, and if so, how would they
6 find the report that doesn't exist when it's the responsibility
7 of the defense to produce it.

8 MR. WYATT: That's not my argument, Your Honor. I'm
9 not trying to say that. I'm merely trying to offer my
10 speculation as to how a document could be missed. There's a
11 lot going on --

12 THE COURT: Look, by the way, I want to be very
13 clear. Whether I determine that this should have been produced
14 well in advance of this morning, that doesn't necessarily mean
15 it was intentionally withheld from Relators with some malicious
16 intent or anything like that. I'm not insinuating that. I
17 don't have any facts before me to do that. That doesn't mean,
18 though, that the Relators may not have been prejudiced by not
19 having this report well in advance of trial, but I'll hear from
20 Relators' counsel on that issue later.

21 All right. So that's where we are there, Mr. Wyatt.

22 Is there more on that issue, or are we going to the
23 next question?

24 MR. WYATT: I was going to go to the next question,
25 Your Honor, which was did she review the outside counsel

1 investigation. My understanding is that she did not. And so
2 she was interviewed in connection with the outside counsel
3 investigation, but my understanding from speaking with -- from
4 others on our team, speaking with the witness before she
5 testified, she had not seen that report. So she was not at any
6 point yesterday conveying communications from outside counsel
7 with respect to this issue.

8 THE COURT: Let me ask you this. I failed to print
9 it this morning. Kim, the transcript portion that I reviewed
10 yesterday, do you have a printout of that, or can you print
11 that for me?

12 MS. BROWN: Your Honor, do you want me to approach?
13 I have it on my desk.

14 THE COURT: I'll take it, yeah.

15 MR. WYATT: Your Honor, it's page...

16 THE COURT: I'm trying to look at prior to the
17 sidebar. Bear with me then.

18 So, Mr. Wyatt, this is confusing to me, right. So
19 Ms. Kaucher was questioned. Did your investigation, right, the
20 one that she conducted into Ms. Cesario, that included reps, it
21 included doctors. Were there any folks outside of the company
22 involved in that investigation? Meaning the one that she's
23 determining is her investigation, and she says yes.

24 MR. WYATT: My reading of that, Your Honor, would be
25 that she may have viewed it as a continuation of the same

1 investigation but it was not contemporaneous. She was involved
2 in something related to this investigation before outside
3 counsel was ever involved.

4 THE COURT: And you're saying that it's your
5 understanding that Ms. Kaucher never reviewed anything with
6 respect to the outside law firm's internal investigation,
7 including their findings?

8 MR. WYATT: Yes, sir. That's my understanding, is
9 she did not review their findings. And here, she's simply
10 acknowledging that counsel became involved at some point and
11 that she was comforted by that, by the fact that they're
12 involved. I don't read her here as conveying anything about
13 their conclusions.

14 THE COURT: But she connected them to her conclusion.

15 MR. WYATT: I think it's fair for somebody to say a
16 lawyer became involved. We've heard that a number of times in
17 this case about people reporting to the DOJ. I talked to a
18 lawyer, et cetera. That doesn't sort of bolster or convey or
19 pierce the privilege with respect to any communications that
20 happened with that counsel.

21 The other thing I'll say about this is the Court
22 struck this testimony. So it's not a situation where the jury
23 is in a position to consider the fact or relevance of the fact
24 that a firm became involved at some point.

25 THE COURT: Let me ask you this. So with respect to

1 the -- let's talk about the outside counsel investigation,
2 those documents. There were, I presume, facts identified in
3 those documents which Ms. Brown yesterday even said, well, the
4 facts are not privileged. That's why I'm able to elicit this
5 testimony.

6 So was that information produced to the defense with
7 redactions but at least providing them any facts that were
8 identified in those papers?

9 MR. WYATT: No, Your Honor. So there's 16 documents
10 that are at issue here, and one of them is the firm's final
11 report. The others are interview memos, and these are all
12 either work product or attorney-client privilege or both. So,
13 typically, like if you have correspondence between a client and
14 a lawyer or an internal correspondence from a lawyer, you
15 wouldn't be producing those with redactions. They would just
16 be entirely withheld.

17 THE COURT: And the factual allegations that
18 Ms. Cesario made were produced to Relators' counsel through
19 some other document?

20 MR. WYATT: Yes, Your Honor. They're set forth in
21 three or four emails that we identified for counsel this
22 morning but have been previously been produced.

23 THE COURT: All right. What's the next question? I
24 know Relators' counsel is patient. They're waiting to speak,
25 so I'll give them that opportunity, but I want to make sure I

1 at least get some of the information now.

2 MR. WYATT: I just want to make sure I'm answering
3 all the Court's questions.

4 The last question I have from yesterday is what was
5 redacted. So there were a number of documents that were
6 produced that were redacted. It turns out they're all
7 essentially the same document that are different parts of the
8 same email thread, and the reason that was withheld is because
9 it was a communication to a lawyer within the company.

10 I will say that the documents that were produced are
11 roughly contemporaneous. They cover the allegations that
12 Ms. Cesario raised, and this thread, although it's sent to a
13 lawyer, is sort of -- I just want to phrase it so I'm not
14 piercing the privilege. But it doesn't add incrementally
15 really even to what has been produced in the non-redacted
16 documents.

17 THE COURT: Do you have those documents, both --
18 whether compliance-related documents or Ropes & Gray documents
19 unredacted for me to review?

20 MR. WYATT: I do.

21 THE COURT: How many is the total?

22 MR. WYATT: It's 16 from the Ropes & Gray file, Your
23 Honor. Actually 15 because -- I think it's 15 now, maybe 16, I
24 don't know, without the draft document. And then there's one
25 email that's been redacted, and I've got that as well. So it's

1 16, 17 documents.

2 THE COURT: But they're all related to the Ropes &
3 Gray investigation?

4 MR. WYATT: All but one. So the one that is redacted
5 was around the time frame of the initial investigation. It's
6 an internal J&J email --

7 THE COURT: But it was sent to attorneys on --

8 MR. WYATT: To an internal J&J email.

9 THE COURT: So one compliance document. The rest
10 are -- how many pages are we talking about?

11 MR. WYATT: It's a thin binder, Your Honor.

12 THE COURT: All right. What else do you want to say
13 about this before I switch sides to hear from Relators'
14 counsel?

15 MR. WYATT: I will just say that this one document --
16 really, effectively, it's two, but it's two versions of the
17 same document that has come out -- we view as not helpful to
18 us. I don't think it changes the game in terms of what are the
19 issues in this lawsuit. This issue with Ms. Cesario has come
20 up a couple of times. That's why we tried to address it in the
21 first place, but it has not been the centerpiece of the
22 litigation by a long shot. In fact, it wasn't really the
23 centerpiece of discovery.

24 THE COURT: Well, it can't be the centerpiece of the
25 case in any sort of way if Relators' counsel didn't even have

1 the reports until this morning. We don't know what they could
2 have done with that information in advance of the trial with
3 respect to witnesses, with respect to cross-examination of
4 Mr. Mattes and others. And now they're getting it halfway
5 through the trial.

6 MR. WYATT: What we do know, Your Honor, is they had
7 emails showing that Ms. Cesario raised these issues internally
8 and there was no follow-up. They deposed 20 fact witnesses and
9 didn't ask a single one of them about Ms. Cesario in discovery.

10 THE COURT: Let me ask this before I hand it to
11 Mr. Marketos or whoever is going to speak for Relators.

12 The documents that were produced that you're
13 referencing say, look, we did disclose at least the allegations
14 and what Ms. Cesario was saying, do you also have those
15 documents isolated, those few documents that were produced?

16 MR. WYATT: Yes, I do, Your Honor.

17 THE COURT: Can I also have -- I'm going to also want
18 those as well. How many of those documents are there?

19 MR. WYATT: I believe there's four.

20 THE COURT: Okay. Because I want to get a better
21 sense of what was provided and what wasn't to get a better
22 sense of your position of, hey, Judge, we produced these this
23 morning, but a lot of this was at least informed to Relators'
24 counsel in advance through these other documents. I need to
25 know what they are.

1 MR. WYATT: Do you want me to put one up right now
2 just to sort of walk us through?

3 THE COURT: Let me hear from Relators' counsel
4 because I think this is going to be something that -- I want to
5 hear from you all this morning, but I'm also going to need to
6 put eyes on the document, which can't happen this morning
7 because we're going to continue with witness testimony. So
8 it's an issue that we're going to have to continue to discuss.

9 Is there -- Mr. Wyatt, anything more before I hear
10 from Relators' counsel?

11 MR. WYATT: No, Your Honor. I'll reserve to respond.

12 THE COURT: Let me hear -- who is speaking for
13 Relators? Mr. Marketos?

14 MR. MARKETOS: Yes, Your Honor.

15 THE COURT: What say you about all this now that
16 you've got at least some of the narrative here and also these
17 documents this morning?

18 MR. MARKETOS: Your Honor, I want to try to be as
19 articulate as I can having just received an email from
20 Mr. Wyatt about an hour ago, if I get my timing right,
21 attaching some of these documents. I think we have a waiver
22 issue that we can address later, Your Honor, for obvious
23 reasons.

24 THE COURT: That's a second issue, right? You're
25 talking about whether me striking the testimony somehow shields

1 Janssen from having a waiver of their privilege in that they at
2 least reference the investigation by outside counsel?

3 MR. MARKETOS: Yeah. They talked about this
4 investigation. This is the investigation. They had outside
5 counsel. They haven't produced the document that is the
6 investigation that this witness is purportedly referring to.
7 They attest to the investigation, and then, you know, striking
8 doesn't matter.

9 At the end of the day, if you're at trial in this
10 circuit and you try to use selective waiver of the privilege so
11 that you can adduce evidence from or elicit evidence from a
12 witness in your client's favor, you waive the privilege
13 entirely, as the entire subject matter, particularly when
14 you're at trial. That, I will, Your Honor, for the time being,
15 put over to the side.

16 THE COURT: All right. That's fair. I understand
17 the argument, and we can always address that in further detail
18 outside of this morning. But let's talk about -- let's go
19 before that. Forget about the waiver of privilege for now,
20 although I know that's an issue that's outstanding.

21 MR. MARKETOS: Second, Your Honor, this is as bad as
22 it gets when it comes to not having produced documents. No, it
23 is not inadvertent. I'm sorry. It's not. This specific
24 document that they didn't produce that we're now getting a copy
25 of five years later was specifically requested in a request for

1 production, number 50, and followed up on by letter by
2 Ms. Clairmont and by Berger Montague, specifically asking about
3 investigations relating to health care compliance, not
4 custodians, not 46 people, every document relating to an
5 investigation into health care compliance involving Joanne
6 Cesario specifically. The document they don't produce is the
7 investigation report, which has substantiated allegations of
8 violations in it, the part they left out.

9 Mr. Murphy, the boss of Ms. Penelow and
10 Ms. Brancaccio, handing out off-label studies to the sales
11 force substantiated. Ms. Nancy Peterson falsifying records
12 because she was calling on doctors and not recording her calls.
13 Substantiated. She testified -- Ms. Kaucher took the stand
14 yesterday and testified that all of this was unsubstantiated.

15 THE COURT: I remember that testimony. So you're
16 saying that the report you received this morning refutes that
17 testimony by Ms. Kaucher?

18 MR. MARKETOS: They have three unsubstantiated
19 allegations, which is -- one of them was that Mr. Murphy was
20 engaged in off-label sales of these drugs to a bunch of
21 physicians. And they say, well, that was unsubstantiated
22 because we asked everyone else and we went to X, Y, and Z
23 doctors, and so that's unsubstantiated, right. So they're
24 saying you know what we could have done with that at the end of
25 the day.

1 So that's the unsubstantiated part. And they left
2 out the part that was substantiated, exactly what the witnesses
3 have been saying: They're distributing off-label studies.

4 THE COURT: This is all based on your review of the
5 documents that you received this morning?

6 MR. MARKETOS: Yes, Your Honor. I'll give it to you.
7 I mean, ERLR specialist group Johnson & Johnson investigation
8 summary report does not include Ms. Kaucher because the
9 investigation started in September of 2010, the month before
10 she even started at the company.

11 THE COURT: And there was a written discovery request
12 along with a filed letter for this specific information?

13 MR. MARKETOS: Your Honor, can I use the ELMO?
14 Ms. Johnson, can you give me the ELMO? All documents
15 concerning employee complaints regarding the unlawful practices
16 involving Prezista and/or Intelence alleged in the complaint,
17 including the complaints of New Jersey sales representative
18 Joanne Cesario and any other employees, as well as all company
19 meetings, decisions, and actions taken by the company in
20 response.

21 A follow-up letter from -- this is from Ms. Joy
22 Clairmont. This is February 19, 2019, more than five years
23 ago. Specifically talking about this request and how their
24 response had improperly narrowed the response to that request.

25 THE COURT: Was there a response that you received

1 from Janssen regarding that follow-up letter?

2 MR. MARKETOS: Yes.

3 THE COURT: What did they say with respect to that
4 request?

5 MR. MARKETOS: This is from Pepper Hamilton. They
6 said that they were going to do a further search. Relators'
7 counsel seeks -- requests that Janssen confirm they did search
8 for and produce all documents responsive to document production
9 request number 50, et cetera, et cetera.

10 They made a reasonable search for formal health care
11 compliance investigations into reports of misleading promotion
12 of Prezista with respect to its lipid profile as well as
13 reports of off-label promotion of Intelence for once-daily
14 dosing, et cetera.

15 So they went and did an investigation. The only
16 thing they missed was the report of the investigation. This is
17 what we got this morning, Your Honor, and it's lengthy. This
18 was followed up on.

19 THE COURT: How long is the report?

20 MR. MARKETOS: The report is -- this report is five
21 pages that we've got, no documents underlying it. And it's
22 just a Johnson & Johnson ERLR specialist group investigation
23 summary report. There are a number of allegations that are
24 made. I think this one is the draft. There's a final. I
25 can't tell yet.

1 THE COURT: By the way, Mr. Wyatt, I just want to be
2 clear, you confirmed that there are no underlying documents to
3 this five-page report?

4 MR. WYATT: We did another search last night, that's
5 how we found this report. We didn't find any other documents.

6 THE COURT: How did you go about finding this report?
7 What led you to this now that didn't lead you all to this
8 document years ago?

9 MR. WYATT: I'd have to get the details on that, Your
10 Honor, but my understanding is that we have a database of all
11 the documents.

12 THE COURT: But you admit it's a breach of the
13 request. You admit it's a discovery breach, right? How can
14 you see this as not being absolutely responsive to that
15 request? And how do you not see that as relevant and important
16 for the Relators to have received years ago? Is that the
17 position of Janssen? Or are you saying, look, Judge, we made a
18 mistake, we turned it over this morning? Or are you telling me
19 no mistake was made? I want to understand your position.

20 MR. WYATT: I believe it's responsive, that's why we
21 gave it to them this morning. So I don't know what happened
22 when this was done. Clearly, a search was performed. I don't
23 believe the person who wrote the letter is misrepresenting
24 that.

25 THE COURT: There are parts of this report that

1 substantiate some of the allegations?

2 MR. WYATT: No, I disagree with that characterization
3 of the document. And I can talk about it now, if you like.

4 THE COURT: I can read a document, so I'll find out
5 how I read it, and that will be the interpretation we go with.

6 MR. WYATT: Specifically, Ms. Kaucher was talking
7 about the off-label allegations and those allegations were not
8 substantiated, it says it right there under allegation
9 number 2. There is a part about Mr. Murphy, but it concludes
10 at the end that all the sales reps knew what they were supposed
11 to be doing.

12 THE COURT: How is it unsubstantiated? It's
13 unsubstantiated because she went out and talked to a bunch of
14 doctors and they said, I don't want to lose my medical license
15 so of course that never happened. Is that what he ended up
16 doing? Because even if that were the way it was
17 unsubstantiated, you don't see how that's something that
18 Relators' counsel should have been aware of? That the reason
19 why Janssen determined that these allegations were
20 unsubstantiated is because an HR compliance employee decided to
21 speak to some physicians and say: Did you commit illegal
22 conduct? And they said: No. And then they said it was
23 unsubstantiated?

24 MR. WYATT: No. So there's two questions in Your
25 Honor's question. I think number one is, is it responsive?

1 Would they want to have seen the document?

2 THE COURT: That answer is absolutely yes, you agree
3 with me there?

4 MR. WYATT: I do.

5 THE COURT: And you also agree with me that there is
6 arguably some prejudice to Relators' counsel getting it this
7 morning halfway through a trial?

8 MR. WYATT: I don't think it is substantial
9 prejudice. I believe that they would like to use this
10 document. I don't believe it changes their case. What this
11 allegation's finding says -- keep in mind, doctor's license
12 isn't on the line, right? The doctor's being asked did
13 somebody from my company go to you and say something off-label.
14 Doctor's got no skin in that game. The doctor could say yes,
15 they sure did. And they shouldn't have done that. None of
16 these doctors said that. That's number one. Number two is,
17 they also asked all the sales reps, and every single one of
18 them -- one of whom is Ms. Graham --

19 THE COURT: I'm sorry, the allegations in this, does
20 it have to also do with speaking programs?

21 MR. WYATT: Well, in this sense, yes, there was one
22 speaker that Ms. Cesario complains about in one of the emails,
23 but it's about this off-label issue. It's not about alleged
24 kickbacks.

25 What is said in this allegation finding is not only

1 that the physicians deny that Murphy had done this, but also
2 all the sales reps interviewed, one of whom was Donna Graham.

3 So I view this document as more helpful to us than to
4 them. It doesn't benefit us not to have produced this. And
5 quite apart from our obligations to produce it from a
6 standpoint of how it affects the overall merits of the case, it
7 was not to our benefit to not produce this document.

8 THE COURT: All right. I'll hear from Mr. Marketos.
9 But it sounds like Janssen's position is, an error was made in
10 not producing the document in advance, but you're saying
11 there's no prejudice to the Relators because you think the
12 document is helpful to you and not to them?

13 MR. WYATT: That is my position.

14 THE COURT: Let me hear from Mr. Marketos now.
15 Sorry, Mr. Marketos, I know I interrupted you, but I wanted to
16 get some more information from Janssen.

17 MR. MARKETOS: No problem, Your Honor.

18 THE COURT: Look, I think it's pretty clear that
19 there's a breach in Janssen's discovery obligations. The issue
20 I'm trying to get to now -- look, part of me getting to this is
21 going to have to review some of this documentation, right? I
22 mean, I can't assess this just based on the representations and
23 arguments, I have to put eyes on the document. So that will --
24 probably I'll need today to do that. I don't think this issue,
25 though, whether it's resolved today or tomorrow, I don't think

1 that puts you in any different bind that you're arguing you're
2 in. Is that fair to say? If you're in this bind, you're in
3 this bind this morning or tomorrow morning?

4 MR. MARKETOS: That's right, Your Honor. That's why
5 I think it's going to lead to the remedy we're going to ask
6 for.

7 THE COURT: Let me ask you this first. Let me hear
8 from you briefly, and I may have to hear from you more, but
9 give me a sense of what's in the paperwork that has now been
10 produced to you this morning and how you believe you were
11 prejudiced by not having that information years in advance of
12 the trial.

13 MR. MARKETOS: So, Your Honor, two ways. First of
14 all, the allegations that are made by Ms. Cesario are
15 identical. They are encompassed in the allegations that were
16 brought in the complaint that was filed in 2012 by
17 Ms. Brancaccio and Ms. Penelow.

18 It's all the same conduct. It's Mr. Murphy. By the
19 way, Your Honor, this is the gentleman with the comparing of
20 the MIRs, the 146, comparing them to Florida. He was over this
21 district, New Jersey and New York. He was the boss of
22 Ms. Brancaccio, okay? This is exactly -- and the allegations
23 were that he engaged in off-label discussions with several
24 physicians while on sales calls. And what they're saying is,
25 no, we went to all the sales reps, we went to the doctors, and

1 they said nope, didn't happen. That's exactly what Ms. Penelow
2 testified about, that that happened.

3 Second, they're handing out off-label studies, and
4 they're handing them to the sales force clearly for use in the
5 field. Substantiated. They're falsifying calls with doctors
6 that they're not making. Falsifying those records,
7 substantiated. Over and over again we could have taken this
8 information, we could have called Frank Murphy, we could have
9 called HCC to find out the results of this investigation. Your
10 Honor's going to find out when you review all these documents
11 that after Ms. Cesario continued to complain, human resources
12 told her that next time she wants to complain she needs to go
13 to sales.

14 So this whole nonsense this entire trial about you
15 should have called health care compliance, in this case they
16 told her to go back to sales and stop complaining to HR.

17 THE COURT: Wait, where does it say? It's somewhere
18 in the report? I don't need it verbatim, but you're saying in
19 the report it indicates that?

20 MR. MARKETOS: No, it's after her follow-up. So the
21 report, we don't know what's contained in it. They're talking
22 about these four documents where the allegations were revealed
23 in unredacted form, no, no. These allegations and what was
24 substantiated, what Ms. Cesario was specifically saying that
25 was investigated, no, they are not disclosed.

1 THE COURT: What was disclosed to you, in your
2 opinion, with respect to the documents that you did receive in
3 advance of trial that talk about Ms. Cesario's allegations?
4 What do those documents inform you of?

5 MR. MARKETOS: Your Honor, I'll give you an example.
6 It was -- the only documents that we received were documents
7 relating to a Mr. Slim, which is not the substance of her
8 allegations that were made in the investigation. And I know
9 that Your Honor needs to set eyes on these documents, I
10 apologize for slapping them down.

11 THE COURT: No, I get it.

12 MR. MARKETOS: They're so important. But look, Your
13 Honor, at the end of the day, this is Ms. Cusik, this is OMPUS,
14 HR, she basically says: Regarding the speaker program, moving
15 forward it is our expectation that when you have questions
16 regarding programs or other activities that are considered to
17 be part of your job responsibilities, you raise these concerns
18 through sales management, who will provide you with the
19 appropriate direction.

20 This is the opposite, right, of what they've been
21 saying in this trial. So Ms. Cesario made these complaints.
22 She goes to HCC, she goes to HR. She's still complaining about
23 it after the investigation is over, after the whitewash is
24 done.

25 THE COURT: What happened to Ms. Cesario? Why is she

1 not a part of this case?

2 MR. MARKETOS: Your Honor, because I think they
3 settled with her and she has a nondisclosure agreement, but I
4 don't know.

5 THE COURT: But either way --

6 MR. MARKETOS: She says we can't -- they couldn't get
7 ahold of her.

8 THE COURT: What relief are you requesting now that
9 you've received additional information regarding this
10 compliance investigation?

11 MR. MARKETOS: Your Honor, we're in the middle of
12 trial, I can't lose the jury, right? We're four weeks now into
13 a trial. Ordinarily I would say, if it were a bench trial I
14 would say, Your Honor, can we suspend. And we need to go get
15 all of the documents. And we need to be able to take our
16 discovery on these allegations. And I would ask for all the
17 other sanctions associated.

18 THE COURT: But we're not on a bench trial. We have
19 jurors here that have been patiently sitting through this trial
20 for the past four weeks and still have another week and a half
21 or so left, right?

22 MR. MARKETOS: The only remedy for this situation,
23 when it appears and it happens at trial -- and Your Honor will
24 see that it's not just the substance of what's contained in
25 this report. Your Honor, you can tell from the face it's a

1 whitewash. You don't have any other documents? And the
2 investigation started before Ms. Kaucher even got to the
3 company, tell me how she did the investigation.

4 So ordinarily -- Your Honor asked about the remedy.
5 It's going to have to be an adverse instruction that is
6 literally these documents were withheld, don't think it was by
7 accident. Nobody misses the investigation report when the
8 request is --

9 THE COURT: Is it relevant, though?

10 MR. MARKETOS: When Your Honor gets a chance to look
11 at it --

12 THE COURT: What I'm saying is, whether it was
13 intentional or accidental, it's still a significant breach, no?

14 MR. MARKETOS: Look, the standard is either reckless,
15 whether it was mistaken or not, it's prejudice to the Relators.
16 If it is relevant to the claims in the case, which it clearly
17 is, an adverse instruction is the only remedy for the reason
18 that we have a jury in the box.

19 THE COURT: I will tell you this. On that issue you
20 guys are going to put pen to paper. Because I don't know how
21 much argument we're going to have on it, but I definitely want
22 to see some legal support for it. I'm trying to figure out
23 time frame here because it's an issue that I want to resolve
24 well before the end of the trial so that everybody kind of
25 knows what's going to happen here. And in the interim that

1 gives me time to review the documents.

2 What I'm going to ask you all to do is put pen to
3 paper. I don't need a formal brief, but I need some letter
4 correspondence, some reasonable amount of pages, nothing too
5 lengthy that, one, I presume from Relators' counsel, you're
6 going to argue in that submission that whether there was a
7 breach of Janssen's discovery obligations, you can argue
8 whether it was intentional, reckless, or negligent, or whatever
9 you may want to put there, whether that's material to whatever
10 I would have to decide, and also the relief you're requesting
11 and the support for it. If you're requesting an adverse jury
12 instruction or a negative inference instruction on behalf of
13 Janssen for the violation, I'm also going to ask you to propose
14 language of what that instruction is going to look like.

15 Janssen, you're going to do the exact opposite.
16 Mr. Wyatt, you're going to put pen to paper -- I presume you
17 agree there was a breach, whether there is prejudice to the
18 Relators, whether a negative inference instruction should be
19 given, I assume you're going to oppose that. But I'm going to
20 have to have something more than just argument and documents.
21 In the interim, I can at least review what was produced this
22 morning, what was produced before this morning, and what was
23 not produced.

24 I also think separately you're going to have to
25 address the waiver of privilege issue. Because depending on

1 how I rule on that, there may be additional documents that will
2 be required to be produced to Relators' counsel. Because right
3 now those documents are still withheld, correct?

4 MR. WYATT: Yes, Your Honor.

5 THE COURT: So I think that's a secondary issue,
6 unless it's moot. Mr. Marketos, is that something that
7 Relators are still seeking, these additional documents of the
8 outside counsel's investigation based on a waiver of the
9 privilege?

10 MR. MARKETOS: Absolutely, Your Honor.

11 THE COURT: All right. So then that's a second issue
12 that you're going to have to address. So one is on the
13 compliance issue and the breach of discovery obligations by
14 defense and the remedy. And the other will be whether
15 privilege was waived or not here.

16 And I will tell you, sitting here today, just talking
17 about it this morning, I don't know whether striking the
18 testimony moots that issue or it doesn't. I really don't have
19 the answer to that because I'd have to look at some of the
20 relevant case law. But I'm going to allow you guys to educate
21 me on that so I don't have to do the homework independently.
22 So I think with the waiver I think I'm going to need to see
23 some legal support for your position from Relators' side and
24 also support from Janssen to support your position on the
25 defense.

1 Because that's something I want to resolve sooner
2 rather than later, how much time is needed to put that before
3 me so I can put eyes on your submissions? In the interim I'll
4 do the homework in advance on reviewing the documents. I won't
5 wait to do that. But I'm going to want to see your argument.

6 Mr. Marketos, since this is really more an issue that
7 you've raised, what time do you need to do that?

8 MR. MARKETOS: Well, Your Honor, I'm trying to think
9 of, you know -- I think we could file something by Friday -- by
10 Monday. The reason we're a bit hamstrung is we'll be doing our
11 briefing, and of course we'll be doing it without the benefit
12 of the in-camera documents that Your Honor has, we haven't seen
13 them, the Ropes & Gray material, for obvious reasons. But I do
14 think -- I'm sorry, I've lost track of what day it is.

15 THE COURT: I think it's Thursday.

16 MR. MARKETOS: Thank you.

17 THE COURT: Monday?

18 MR. MARKETOS: Monday, if that's acceptable to Your
19 Honor?

20 THE COURT: It's acceptable to me. I don't want to
21 put you guys on too tight of a timeline, but I also think this
22 issue has to be resolved one way or the other for both parties
23 so that you all know how we're going to be proceeding, because
24 it does impact the case depending on what I decide.

25 Mr. Wyatt, Monday works for defense?

1 MR. WYATT: Yes, Your Honor, you want simultaneous
2 submissions on that?

3 THE COURT: I do. We all know what the issues are.

4 MR. WYATT: We do.

5 THE COURT: I don't think there's a real surprise
6 here, we've been talking through them. But I need to spend a
7 little more time on the legal support for your positions
8 outside of just factually what may have occurred.

9 MR. MARKETOS: Your Honor, I think it would be
10 fruitless, before we get an October surprise so to speak, I
11 think it would behoove us and we would respectfully request if
12 Your Honor direct Janssen that this is not these lawyers,
13 right, who -- they weren't even around during this --

14 THE COURT: I'm well aware of that. By the way, when
15 I say Janssen has an issue with this discovery, as far as I'm
16 concerned, and you guys have breached an obligation, I don't
17 mean Ms. Brown, Mr. Wyatt, Mr. Klein. I mean attorneys that
18 represented your client. But you're all in the same boat,
19 you're standing here representing them, so you guys are the
20 messenger.

21 MR. WYATT: I am. If I may speak about this briefly
22 -- and I don't mean to cut you off, Mr. Marketos.

23 THE COURT: Finish your point, Mr. Marketos. Then
24 I'll give Mr. Wyatt a chance.

25 MR. MARKETOS: On the discovery front, that's true.

1 But it was their witness who they elicited this testimony from
2 to help themselves during the trial in the case, okay. So now
3 you've got the implications associated with the investigation
4 we never got because you tried to draw that out through a
5 witness who we don't even believe participated in the
6 investigation. And by the way, Your Honor, after you struck
7 the testimony relating to the outside counsel, then proceeded
8 to testify all about her independent investigation.

9 It would behoove I believe all of us, including would
10 be beneficial to the Court, to direct Janssen, the company, to
11 make sure that they have turned over every single health care
12 compliance, human resources, Johnson & Johnson document that
13 relates to this investigation. Before we find out on Monday,
14 simultaneously with the filing, there are 12 more attachments
15 and, yes, it turns out -- there's no way an investigation like
16 this takes place without another scrap of paper except for the
17 document.

18 THE COURT: Yeah, Mr. Wyatt, I will say this. By
19 Monday, I want a very clear representation from you all that
20 this is the end of the documentation on that. I understand
21 that you're looking to see if there's any other custodians,
22 where something else could be, but I want some confirmation by
23 Monday morning that you guys have done your due diligence and
24 that this is everything. Because it still appears a little
25 light for an investigation like that. I'm not saying that

1 that's not the only document, one draft report, one final
2 report, but you're talking about how many interviews? And
3 you're telling me now that the notes for those interviews were
4 somehow included in this very brief report. I want to make
5 sure that you tack that down. Does that make sense?

6 MR. WYATT: We will do that, Your Honor.

7 THE COURT: What did you want to say to put on the
8 record, Mr. Wyatt?

9 MR. WYATT: I just want to say we, our co-counsel,
10 have been accused of intentional misconduct by Mr. Marketos as
11 though it was just another argument to make in Court. And I
12 don't take that lightly. I think it's inappropriate. I don't
13 think he has any basis to say that other than his subjective
14 belief that the discovery here was not done correctly. And I
15 stand by our co-counsel and our client that they did the best
16 that they could do here. Mistakes do get made in big
17 litigation where there are a billion documents that are
18 collected and half a million that are produced. And he better
19 back it up in his brief if that's the position he's going to
20 take, that this is intentional, because I dispute that.

21 THE COURT: Look, I'm not saying it's undisputed, I
22 haven't made my findings. Look, my finding, at least for now
23 because we're going to proceed in this manner, is that this was
24 discoverable, it should have been produced before trial.
25 Outside of that, I made no findings whether it's intentional,

1 negligent, reckless. I'm going to have to hear from you folks.
2 And also, I don't even know whether that matters. If you fail
3 to provide what I find to be highly relevant discovery to
4 Relators' counsel, whether it's by mistake, whether it was
5 reckless, whether it was intentional, I don't even know if that
6 has any bearing under the law for purposes of whether that's
7 prejudice to Relators or not.

8 So I'll hear from you all in your written
9 submissions. But I understand your position, is that you're
10 holding strong that this was, if anything, it was a mistake,
11 but it was not something intentionally withheld from the
12 Relators in order to prejudice their case in any sort of way.

13 MR. WYATT: Thank you, Your Honor.

14 THE COURT: Mr. Marketos, I understand you have a
15 different position, but if you're going to articulate that,
16 you're going to have to do more than just say we had a request
17 and they failed to provide the documents that were responsive
18 to it. Because that, in and of itself, is not a per se
19 intentional violation of a discovery obligation.

20 MR. MARKETOS: Your Honor, I just got whipsawed by
21 trying to make sure that I told the Court that we're not
22 accusing specifically these lawyers who are standing to my
23 left.

24 THE COURT: I think what he's saying is that he's
25 representing Janssen, and so any lawyer that worked on the

1 case, I think he's going to stand up and say, look, we're going
2 to take the position that this was not intentional, there's no
3 evidence to support that, if you're going to make the
4 allegation, you have to back it up.

5 And that's fine. You guys have written submissions.
6 I'm going to permit you all to address these issues. Again, I
7 don't know yet without having the law before me whether I need
8 to make that type of determination at all.

9 I don't know if that changes the analysis. If it
10 does, then I'm going to have to make findings. But for now,
11 you can submit, Mr. Marketos, your position on that. I think
12 Mr. Wyatt just wanted to have a record that they strongly
13 oppose that discovery violation that I'm addressing was
14 intentional.

15 MR. MARKETOS: Yes, Your Honor. This matters to me
16 about professionalism. Saying -- making a point to say that
17 these lawyers that are trying the case were not involved in the
18 discovery process itself is not a reverse implication that the
19 lawyers who were involved in the discovery are at fault. That
20 is not what we just said, all right. I'm trying to make sure
21 it's Janssen that it was obligated to turn these documents
22 over. I don't cast aspersions on opposing counsel ever, unless
23 there's evidence that there's a specific reason for that.

24 THE COURT: I understand. You believe -- it's your
25 belief and it's your position that Janssen, the company,

1 withheld these documents, not some tactic by an attorney.

2 MR. MARKETOS: We know how this works.

3 THE COURT: I got it.

4 MR. MARKETOS: So to make sure that I was not casting
5 aspersions on trial counsel, does not mean to cast aspersions
6 on the other counsel.

7 THE COURT: I appreciate that clarification.

8 MR. WYATT: I'm sorry, Your Honor, but I have to say,
9 on behalf of my client, I strongly, strongly dispute that
10 accusation. Whoever it's thrown at, I don't believe it's well
11 founded.

12 THE COURT: I appreciate that. I understand that.

13 All right, folks, the jurors are here.

14 So let me ask you this, the binder of documents,
15 Mr. Wyatt, you have that for me?

16 MR. WYATT: I do.

17 THE COURT: And that binder is not just -- is
18 everything, including the documents that were disclosed,
19 correct?

20 MR. WYATT: I'll give you a package of materials that
21 includes that. They're not all in this binder.

22 THE COURT: When you give it to me, I need to know,
23 here are the few documents we did provide before trial, here
24 are the compliance documents that were produced this morning,
25 and here are the documents that are privileged under the Ropes

1 & Gray investigation that we have not disclosed. I mean, I
2 need to have an understanding, unless you're telling me, look,
3 Judge, it's self-explanatory when you see it.

4 MR. WYATT: We'll mark it very clearly.

5 THE COURT: I just need to know those are three
6 separate batches of documents, at least with respect to the
7 first batch which is, here's what was disclosed to Relators. I
8 would ask that you confer with Relators' counsel to say this is
9 what we're providing to the Judge as what we disclosed to you.
10 I'm not asking you to provide any privileged documents or
11 anything in advance to Relators' counsel, but at least that
12 first batch where you're saying, look, we're representing to
13 the Court that this is what we provided you and that's part of
14 this packet.

15 MR. WYATT: We'll show it to them before we hand it
16 to Your Honor.

17 THE COURT: Because I don't know if there was
18 anything additional or not. I prefer you guys to
19 meet-and-confer on that. When do I get that little group of
20 documents, sometime during lunch?

21 MR. WYATT: Or at the next break.

22 THE COURT: What else, folks?

23 Mr. Marketos, what else do we need to talk about
24 because the jurors are here?

25 MR. MARKETOS: Yes, Your Honor, I'll make this brief.

1 I really will. I want to make sure that the documents that are
2 being provided to you also include the documents showing the
3 redactions as Relators saw them so Your Honor understands what
4 was produced to us in redacted form.

5 THE COURT: Of course. And what I also need is a
6 clean form so I know what the information was that was
7 redacted.

8 MR. WYATT: It's both, the native document and the
9 document with redactions.

10 THE COURT: Perfect.

11 MR. MARKETOS: Your Honor, the RFP, the responsive
12 letter from Berger Montague to Pepper Hamilton asking for this
13 investigation these investigation documents --

14 THE COURT: And the follow-up letter.

15 MR. MARKETOS: And the follow-up letter. I want to
16 make sure Your Honor has it.

17 THE COURT: Yeah, I want that as well. All right.
18 So just make sure -- those are the only two written discovery
19 requests -- I shouldn't say only. I want to make sure that
20 anything written as far as discovery request that is on point
21 for these documents is provided. So those are the two at least
22 in writing.

23 MR. MARKETOS: Yes, Your Honor. It's just so on
24 point. There are other requests for production that would
25 encompass these.

1 THE COURT: What about the responses? Are you going
2 to give me that as well?

3 MR. MARKETOS: Yes. I actually am holding those,
4 yes.

5 THE COURT: All right. So I just want those two
6 discovery requests and the two responses from Janssen. I think
7 that's sufficient just so I have a little more context outside
8 of what was shown to me today and what was represented in court
9 about the request yesterday and today.

10 MR. WYATT: We can put together a package that
11 includes that, we'll share it with Relators, and the privileged
12 documents before we give them to the Court.

13 THE COURT: All right. And then I get your
14 submissions Monday?

15 MR. MARKETOS: Yes, Your Honor.

16 THE COURT: All right. So now we're tabling this
17 until then, but I will at least have reviewed the documents
18 before your submissions on Monday so I can get ahead of this a
19 little bit.

20 All right, folks. Anything further or can we get the
21 jurors in?

22 MR. WYATT: Your Honor, can we have two minutes to
23 use the restroom before the jurors come in?

24 THE COURT: Yes. Let's take a few minutes' recess.
25 You can all remain seated in the back and then we'll get the

1 jurors.

2 MS. BROWN: Thank you.

3 (Recess taken from 9:13 a.m. to 9:21 a.m.)

4 THE DEPUTY CLERK: Please remain seated.

5 THE COURT: Ms. Brown, do you want this back?

6 Actually, I marked it. Can I keep it?

7 MS. BROWN: Sure.

8 THE DEPUTY CLERK: All rise.

9 (The jury enters the courtroom at 9:22 a.m.)

10 THE COURT: All right, folks. Everybody have a seat.

11 Jurors, I appreciate your patience this morning. I
12 know we're starting a little late. There were some additional
13 legal issues that I needed to resolve, but with that, we're
14 going to proceed with continued testimony and evidence being
15 presented.

16 With that, Mr. Russ, are you ready to proceed?

17 MR. RUSS: I am, Your Honor.

18 THE COURT: All right. And, sir, just as a reminder,
19 you're still under oath from yesterday.

20 THE WITNESS: Yes.

21 THE COURT: You may proceed.

22 MR. RUSS: Thank you, Your Honor.

23 DIRECT EXAMINATION

24 BY MR. RUSS:

25 Q. Good morning, Mr. Grooms.

1 A. Good morning.

2 Q. Just to kind of reorient ourselves. I know were going
3 pretty quickly at the end of yesterday.

4 You were a sales representative in Kansas City for Janssen
5 from 2006 to 2010?

6 A. Yes, sir.

7 Q. Okay. We talked about some of the individuals that you
8 reported to. Just a reminder on some of those names.

9 Denise Levere?

10 A. Correct.

11 Q. Doyletta Minix was a KAM at some point?

12 A. Yes, sir.

13 Q. Mark Wilhelm was a boss of yours at one point?

14 A. Yes, sir.

15 Q. Scott Libby?

16 A. Regional director.

17 Q. So he was?

18 A. Two levels up.

19 Q. Two levels up?

20 A. Yes, sir.

21 Q. Okay. When we left off talking yesterday, we were talking
22 a little bit about some speaker programs.

23 Do you recall that?

24 A. Yes, sir.

25 Q. We talked about a Dr. Bellos, and then you were talking

1 about a gentleman named Dr. Verstraete?

2 A. Yes, sir.

3 Q. Remind the jury who Dr. Verstraete was.

4 A. He was one of my larger-targeted customers in the Kansas
5 City area for HIV patients.

6 Q. Again, if you could just get a little closer to the
7 microphone.

8 A. Sure.

9 Q. Thank you, sir.

10 When you say one of your larger-targeted doctors, what
11 does that mean?

12 A. For potential -- for potential patients. So he saw
13 between, like, five and 700 HIV patients. So it was like
14 decile rating of 1 to 10, he would have been a 7.

15 Q. Is this your first time testifying in court?

16 A. Absolutely.

17 Q. I know I was going fast yesterday. We only had 20
18 minutes. So we'll go a little bit slower for the court
19 reporter.

20 A. I'll take a breath.

21 Q. Okay. Was one of the ways that you and Ms. Levere
22 determined who was going to be a large target was the
23 prescription potential of a doctor?

24 A. That is correct.

25 Q. Were these doctors, were their prescriptions tracked?

1 A. Yes, sir.

2 Q. And we talked a little bit yesterday about some of the
3 speakers who you believe also were tracked as far as their
4 prescriptions; is that right?

5 A. That's correct.

6 Q. One of the doctors that you told us about was Dr. Dietz?

7 A. Yes, Dr. Craig Dietz.

8 Q. Is he the doctor that you provided these off-label lipid
9 messages about Prezista in order to get him to switch to
10 Prezista?

11 A. Yes. I would have the messaging myself, and then Doyletta
12 Minix would come in before Denise Levere, and then I had to
13 produce MIR forms. So Tiffany Surles was my medical science
14 liaison. She would come in -- she came in twice to cover I
15 believe it was a MONET study, which showed a correlation of
16 starting Prezista with the NNRTIs and then dropping them, and
17 then you looked at the difference between the cholesterol on
18 both arms.

19 Q. Was that an off-label study?

20 A. Yes.

21 Q. So is it fair to say that there was a sort of targeted
22 approach by multiple Janssen employees to Dr. Dietz on the
23 lipid profile for Prezista?

24 A. Yes, because he would have been a decile 10. He had about
25 a thousand patients. He was my largest target.

1 Q. What is a decile 10?

2 A. Decile 1 to 10, so it's a ranking, 10 being the highest of
3 potential for patients, for HIV patients.

4 Q. Decile 10 is the --

5 A. The highest, yes.

6 Q. So the company and some of your coworkers were targeting
7 him to get him to switch to Prezista?

8 A. Correct.

9 Q. That included using off-label lipid messages?

10 A. Correct.

11 Q. Did Dr. Dietz at some point tell you he switched because
12 of those messages?

13 A. Yes.

14 Q. Explain that to the jury. How did that conversation
15 occur?

16 A. It would be -- would boil it down to a particular patient,
17 like if a patient was -- could be a hairdresser, somebody
18 that's a bus driver, somebody that's in the community more.
19 Because Reyataz would cause some jaundice, so if we could say
20 we have the same lipid profile, which we showed, and not the
21 jaundice, it would be a better option for that patient. And
22 then we would also draw a correlation of dosing symmetry again.
23 So that's where the MONET study comes in, that you potentially
24 would draw the conclusion you could potentially use Prezista
25 monotherapy.

1 Q. What is monotherapy?

2 A. On its own with no other regimen behind it.

3 Q. Without ritonavir?

4 A. It would still have ritonavir, but you wouldn't have any
5 non-nucleosides or nucleosides with it.

6 Q. Okay. Was that another off-label message?

7 A. Yes, to my knowledge. I don't know of anything that was
8 at the time -- I don't know if there is now -- but that was
9 approved for monotherapy.

10 Q. Did Dr. Dietz tell you that those messages caused him to
11 switch to Prezista?

12 A. Yes.

13 Q. Tell us about that conversation.

14 A. I would go back in, and he would say have you checked my
15 numbers lately. So he was always wanting to know if I saw what
16 his numbers had done, if he had moved. Did you see how many
17 I've written? And it was specific again to patients that I
18 targeted for Reyataz as far as lipid-neutral and the jaundice
19 issue.

20 Q. You were able to target particular patients?

21 A. A patient type. Not a name, but a patient type.

22 Q. So you would work with Dr. Dietz on a patient type?

23 A. Correct.

24 Q. Give him, with your coworkers, the off-label lipid
25 message, and then he would say have you seen my numbers?

1 A. Correct.

2 Q. Were they going up?

3 A. Yes.

4 Q. Did you have similar conversations with Dr. Verstraete as
5 to either Prezista or Intelence?

6 A. Yes.

7 Q. Tell the jury about that.

8 A. Dr. Verstraete was a lot more of a -- I'd say amiable
9 doctor. He's a lot more open-minded to try different things
10 and more, I guess, off-label, if you will. He was not as
11 structured as some of the other physicians. So I'd call him a
12 maverick. He would just try out anything you kind of recommend
13 to him.

14 Q. Did he ever tell you that he tried Intelence once-a-day or
15 Prezista because of the messages that you were providing to
16 him?

17 A. Yes. He'd use Intelence once-a-day especially in the
18 slurry where you'd just drop the pill in, because it would be
19 no pills at that point. So it was very convenient for some of
20 his patients.

21 Q. So explain to the jury what the slurry is.

22 A. So you can take Intelence and actually dissolve it in
23 water and then drink it, so you would get the medication just
24 as a liquid as opposed to swallowing a pill.

25 Q. On a package insert, is there a method of how you're

1 supposed to take the medication, like dosage for instance?

2 A. Yeah. The dosage is on the pack insert, correct.

3 Q. Is there anything on the package insert for Intelence that
4 you should dissolve it in water and take it once a day?

5 A. Not to my knowledge.

6 Q. But you and your coworkers were providing QD dosing for
7 Intelence messages to doctors like Dr. Verstraete?

8 A. Correct.

9 Q. He told you he was trying it?

10 A. Yes.

11 Q. How did that conversation happen? Was it similar to
12 Dr. Dietz where he would say have you seen my numbers, or would
13 he just flat out tell you I'm trying this?

14 A. It was over lunch. He would just tell me, hey, that
15 really works well for some of my patients.

16 Q. Okay. Again, that was based off of off-label information
17 that you and your coworkers were providing to these doctors?

18 A. Yes.

19 Q. And that message was coming from Ms. Levere?

20 A. As far as directed down to me?

21 Q. Yes, sir.

22 A. Yes.

23 Q. And then I think you talked a little bit about this
24 yesterday, but you had reason to believe that it didn't start
25 with Ms. Levere?

1 A. No, I don't believe any of the marketing messages started
2 with her.

3 Q. Why do you believe that?

4 A. Because she would always say we just got off a call, like
5 a regional call with Scott Libby, or we had a managers call,
6 and this is the direction that we're given. It would change
7 quite often, very targeted.

8 Q. Is the Dr. Verstraete that you and I just discussed the
9 same doctor that we ended the day yesterday where you told the
10 jury he frequently went to -- attended speaker programs?

11 A. Yes, sir.

12 Q. Was that a common occurrence for some of the same doctors
13 to attend multiple speaker programs?

14 A. Yeah, I would say so.

15 Q. Remind us about how many speaker programs you attended
16 personally.

17 A. During my whole time at Tibotec?

18 Q. Yes, sir.

19 A. I know I was required to do three to four per quarter, so
20 about 12 a year times however many times I was there or how
21 many years I was there, five. And then also if Doyletta Minix
22 would do a program in my area, because she would do programs
23 too, I would go to hers as well. So maybe 30ish, I'm guessing,
24 something like that or more than that.

25 Q. You were there for four years?

1 A. 2005 through 2010, I think, or 2006 through 2010. Yeah.

2 Q. At those programs, do you recall off-label information
3 being discussed?

4 A. Yes.

5 Q. Okay. Describe how that would generally work for the
6 jury.

7 A. Usually I would prep somebody in the audience, a Pharm.D,
8 a pharmacist, Dr. Verstraete, Dr. Dietz, Dr. Ha Ta, to ask the
9 question to get to the information that we wanted to get out.

10 Q. We've heard some other testimony in this case about plants
11 in the audience?

12 A. Correct.

13 Q. Is that the similar concept that you would ask an attendee
14 to ask an off-label question?

15 A. Absolutely, yeah. That's what we were directed to do.
16 That's what I was directed to do.

17 Q. By who?

18 A. Denise and Doyletta.

19 Q. How would that process work? Walk us through step by step
20 how would you get somebody in the audience to ask a specific
21 question.

22 A. I would meet with Dr. Verstraete or maybe the Pharm.D from
23 Walgreen's the day of or day before, go over a couple of the
24 questions that I wanted them to ask to lead the speaker to the
25 information we wanted to get out.

1 Q. Mr. Grooms, you never worked as a sales representative
2 with Ms. Brancaccio or Ms. Penelow, did you?

3 A. Same company but not in the same area, no.

4 Q. You didn't work in the New York district?

5 A. No, no, sir.

6 Q. Would it surprise you to learn that there were similar
7 tactics being used in other districts within Janssen?

8 A. No, because I talked to people around the country. We all
9 talked as reps, and we all had the same direction.

10 Q. Give us an idea of some of the names of representatives
11 that you would talk to about these types of tactics.

12 A. Bob Foote was in Michigan. Russ Moyer was in the Boston
13 area. Kim Betty was in the Tennessee area. Brendan Snyder was
14 in Houston. Melissa Wade was in St. Louis, which was close.
15 So yeah, everybody that was around me I would talk to.

16 Q. What were they telling you was happening in their
17 districts across the country?

18 A. It was the same message, the same concern as far as the
19 message goes, and same thing as far as plants on speaker
20 programs. We wanted to get to a certain -- get certain
21 information out if we could.

22 Q. Did other sales representatives from different districts
23 tell you that they were selling Prezista as lipid-neutral or
24 lipid-friendly?

25 A. Absolutely.

1 Q. Did other sales representatives from across the country
2 tell you they were selling Prezista as appropriate for
3 treatment-naïve patients before 2008?

4 A. I don't recall that one specifically.

5 Q. Okay. But we do recall the lipid message?

6 A. Yes, that was a big message, yes.

7 Q. Did other representatives across the country tell you how
8 they were selling Intelence off label?

9 A. Yes, the slurry, and then once-a-day -- leading to
10 once-a-day dosing because of half-life, absolutely.

11 Q. Were there concerns being shared in these phone calls with
12 other sales reps?

13 A. Yes.

14 Q. Give the jury a sense of some of the concerns that were
15 being raised and how frequently those concerns were being
16 raised.

17 A. Well, we would speak daily, because for me, for instance,
18 I'd drive to Wichita or Omaha, which is a three-hour drive, so
19 you had time to talk. And we would talk daily about the
20 concerns of is this the right direction that we're going here,
21 is this correct, is this accurate, should we be doing this.

22 There's a really big amount of pressure and fear for
23 everybody for their role, so we would just go along with it,
24 but we definitely discussed it.

25 Q. Was there a general concern at the company at that time of

1 people being put on performance improvement plans or fired?

2 A. Yes.

3 Q. Give the jury a sense for what your day-to-day pressure
4 was like to make these sales and what would happen if you
5 didn't.

6 A. If my recollection is right, the first six months, there
7 was it seems like at least 10 or 12 people out of only 70 that
8 were on a performance plan for not hitting numbers or not using
9 messaging correctly. So it was -- every day was a check-in or
10 get checked on by your manager. What are you doing? What
11 messages are you delivering? Are you delivering all pieces of
12 the sales aid?

13 There would be a check-in on how many MIRs were being
14 submitted, how much stuff was being ordered, like I said
15 before, from the hub. Everything in general like that.

16 Q. So let's talk about some of those metrics. We talked
17 about the hub and some of the off-label studies yesterday.

18 A. Uh-huh.

19 Q. This was a hub that sales reps could go on and actually
20 have off-label studies delivered to their homes?

21 A. Go on and order marketing materials, off-label studies.
22 Sometimes they were just drop-shipped directly to you.

23 Q. This was, I believe you testified yesterday, one of the
24 metrics that Ms. Levere was calling you to check in on whether
25 or not you were ordering enough of these?

1 A. Correct.

2 Q. Was that happening with other sales representatives?

3 A. Yes, everybody in my district.

4 Q. And you mentioned MIRs, and I know this jury has heard a
5 ton about MIRs.

6 What was the company doing as to your medical information
7 requests as a metric for your sales performance?

8 A. We had, like, a contest where we had to have 12 -- I think
9 it was 12 MIRs per district per week, so about threeish per
10 person per week for MIRs. Then if we didn't hit that, we had a
11 call about it, why we weren't asking the right questions to
12 generate an MIR.

13 Q. Is there something that struck you as curious or
14 inappropriate of how you were supposed to actually obtain
15 something that was supposed to be unsolicited?

16 A. Yeah, because it's supposed to be unsolicited, exactly.

17 Q. Did you push back on that practice?

18 A. Yes.

19 Q. Tell the jury about that.

20 A. That was one of the real big reasons that Kim Betty, for
21 instance, in Tennessee got reprimanded, because she pushed back
22 really hard to Denise about unsolicited MIRs, and she wasn't
23 producing and going to produce three to four a week.

24 Q. Okay. Let's focus on that instance because I think it's
25 important.

1 How do you know Ms. Betty pushed back?

2 A. It was on a conference call.

3 Q. So you were on a conference call.

4 Who was on it?

5 A. My whole district, the seven of us and Denise.

6 Q. Seven sales representatives and Ms. Levere?

7 A. Yes.

8 Q. Were MIRs being discussed as a metric on that call?

9 A. Yes.

10 Q. What did Ms. Betty -- is it Betty?

11 A. Yes, B-E-T-T-Y.

12 Q. What did she say?

13 A. It was inappropriate to unsolicit MIRs -- or go get
14 unsolicited MIRs -- solicit MIRs, excuse me, for unsolicited
15 reasons. It's supposed to be the doctor is supposed to ask you
16 and then you respond to it, not you ask the question leading
17 the doctor to the information and say, oh, that's an MIR.

18 Q. How did Ms. Levere respond to that pushback?

19 A. Not well. That was the direction we were given as far as
20 how many we need to get. We're behind the Florida district.
21 We're behind the Chicago district. We need to up our game.

22 Q. Was Ms. Betty reprimanded on that call?

23 A. Yes, on the call.

24 Q. How?

25 A. Just scolded. This is our direction. You need to hit it.

1 If you don't like it, you need to change things you're doing.

2 Q. Did Ms. Levere -- I think we talked yesterday about some
3 of these off-label studies.

4 She directed you to leave some of those studies behind
5 without your business card?

6 A. Correct.

7 Q. Did Ms. Levere ever direct you not to put things in
8 writing?

9 A. Yes.

10 Q. Tell the jury about that.

11 A. Just everything. Any kind of emails or anything,
12 handwritten notes, nothing to be left behind in writing.

13 That's why we didn't leave our business card, anything in
14 handwriting left on a provider's desk.

15 Q. Did you have a discussion with some other individuals at
16 the company at some point about the importance of not putting
17 things in writing? In particular, I'm asking about a gentleman
18 named Ron Martin and Jeff Sowers?

19 A. I don't recall specific example of that offhand.

20 Q. Okay. Did you have discussions with other sales
21 representatives in your district about keeping things out of
22 writing?

23 A. Yes.

24 Q. Tell the jury about that.

25 A. It's just kind of common practice to be careful what you

1 put in writing because it could be misconstrued, especially if
2 it's something you shouldn't be putting in writing. So emails,
3 any kind of handwritten notes, do not mark on sales aids or
4 clinical studies. You're not supposed to highlight, anything
5 like that.

6 Q. As to -- going back because I jumped from that topic on
7 the use of plants at these speaker events.

8 Of the speaker events that you attended, can you estimate
9 for us how many times there was a plant asking off-label
10 information in the audience?

11 A. From my events, would be every single one.

12 Q. That's not a tactic that you came up with on your own?

13 A. No.

14 Q. As far as you recall, it was Ms. Levere?

15 A. Yes.

16 Q. As far as the doctors that were being paid to speak -- as
17 far as the doctors that were being paid to speak, based on your
18 experience in your conversations with other sales
19 representatives, was one of the purposes of paying them to get
20 them to prescribe Janssen's drugs?

21 A. We definitely had discussion on return on investment, ROI,
22 so yeah. The more doctors spoke about the drug, the more
23 likely they were to write more.

24 Q. Of all the doctors that you called on during your time at
25 Janssen, did they hear the off-label messages that you've

1 discussed for Prezista and Intelence?

2 A. Of all 35, it would be hard to say all, but I would say
3 everybody -- at least 90, 95 percent, if I got a chance to get
4 in front of them, yes, I would cover the message.

5 Q. You would cover the message with anybody you got in front
6 of?

7 A. Correct.

8 Q. So if you were able to get in front of your doctors, they
9 heard that message?

10 A. Yes.

11 Q. Multiple times often?

12 A. As often as possible, because my fear would be that if
13 Denise or Doyletta would ride with me and they'd ask the
14 questions that the physician didn't have the answer to or
15 didn't know that message, that would be -- I would fear that
16 they didn't think I was relaying the message. So I did that as
17 often as possible.

18 Q. So Ms. Minix or Ms. Doyletta would actually quality check,
19 so to speak, whether or not your doctors were getting these
20 off-label messages?

21 A. Yeah, that's a good way to say it. Quality check, yeah.

22 Q. Now, Mr. Grooms, we talked a little bit yesterday about
23 this event at the selling dome.

24 A. Uh-huh.

25 Q. Describe for us -- I think you briefly described it as

1 sort of an inflatable dome in a hotel. I mean, set the stage
2 for us.

3 A. Yeah. From what I recall, that's what it was. It was a
4 large hotel. I think it was a Portofino in Orlando, hotel, and
5 it was like this big blowup dome that we went and sat across
6 from a doctor, detailed the physician, and then there was a
7 trainer that was checking off the boxes of stuff we hit.
8 Certification, I guess, is what they call it.

9 Q. Now, Mr. Grooms, were there some sales representatives at
10 that meeting or maybe soon thereafter that pushed back on
11 Ms. Levere about the tactics?

12 A. Yes.

13 Q. Who pushed back?

14 A. Melissa Wade, Kim Betty, Joyce Arellano, Brendan Snyder.
15 It was basically my district.

16 Q. We may have covered this yesterday, but I can't remember.
17 Did Ms. Levere respond well to that pushback?

18 A. No. That's when she blew up, yelled, ran out of the room,
19 slammed the door, came back about ten minutes later. She had
20 been crying and said that this was the direction that we're
21 going and that's what -- this is our direction.

22 Q. So Ms. Betty, Kim Betty, pushed back in that instance and
23 on the MIRs on the phone call?

24 A. Yes.

25 Q. What happened to Ms. Betty?

1 A. She was no longer at the company. I don't know for sure.

2 Q. Soon thereafter she was no longer employed?

3 A. Yes.

4 Q. Were there other individuals that you just named that soon
5 after this selling dome instance were no longer employed?

6 A. Yeah. I don't know how long it was, but Melissa Wade was
7 gone, Joyce Arellano was gone. There was another gentleman,
8 Preston, in the Arkansas area that was gone. I think it was
9 myself and Brendan were the last two left after that.

10 Q. Was that sort of the culture at Janssen at that time, that
11 you couldn't push back and keep your job?

12 A. It definitely seemed that way.

13 Q. Had you ever worked before or since your time at Janssen
14 at an organization that had that type of culture?

15 A. No.

16 Q. Mr. Grooms, at some point, did you yourself go to human
17 resources, or sometimes what's called HR, to voice your
18 concerns?

19 A. I did.

20 Q. Tell the jury what you did as far as your concerns and who
21 you spoke to?

22 A. I spoke to a woman named Dolores, I don't remember her
23 last name, probably three, four times. With regards of
24 Denise's, my interactions with her were getting more like --
25 were getting more harsh or hostile. And I was not comfortable

1 with the messaging that we were given and being pushed down, so
2 I expressed my concerns to Dolores.

3 Q. The off-label messaging?

4 A. Everything. The off-label messaging, hostile-type work
5 environment. Ms. Levere was, in a field coaching report, she
6 was putting in stuff that was inaccurate so I was pushing back
7 on that. The only response that I got from Dolores was we
8 stand behind our Johnson & Johnson management team, she just
9 kept repeating that.

10 Q. Were these phone calls?

11 A. Yes. I want to say I remember her face and she was
12 wearing white, so one of them was like a Skype or whatever we
13 had back then, it was on a computer.

14 Q. So multiple phone calls and potentially one video
15 conference?

16 A. Yes.

17 Q. With Dolores?

18 A. Yes.

19 Q. You think that was Dolores Smith?

20 A. Sounds right.

21 Q. And in some of those calls you raised concerns about
22 off-label marketing that was being pushed down to you in the
23 messaging that you were being required to give?

24 A. I raised concerns of, yeah, everything, the culture, the
25 marketing, the management style.

1 Q. And she didn't say, oh, my goodness, come to home office,
2 let's get an investigation started and figure out what's going
3 on?

4 A. No.

5 Q. She said what again?

6 A. She said -- she just continually said we stand behind our
7 management team and the direction you're given.

8 Q. Johnson & Johnson stands behind its management team?

9 A. She just kept repeating that.

10 Q. Multiple times?

11 A. Multiple times.

12 Q. Did anything ever get fixed?

13 A. No.

14 Q. Mr. Grooms, I want to talk to you about a couple
15 additional topics. At some point, did you learn that our
16 clients, Ms. Brancaccio and Ms. Penelow, had filed this
17 lawsuit?

18 A. When I was first contacted I think in like 2019 maybe, '18
19 or '19.

20 Q. Somebody contacted you and asked you -- to interview you
21 and figure out about your experience while you were at Janssen?

22 A. Yeah.

23 Q. Did you talk to that person and give an interview?

24 A. I did.

25 Q. Truthful information?

1 A. Yes.

2 Q. Was that truthful information then written up and provided
3 to you to review?

4 A. Yes.

5 Q. Did you review it?

6 A. I did.

7 Q. Did you make sure it was accurate?

8 A. Yes.

9 Q. That's a declaration that you ultimately signed?

10 A. Correct.

11 Q. Did anybody make you sign the declaration?

12 A. No.

13 Q. Do you have any financial interest in this case?

14 A. No.

15 Q. Do you have any stake in any recovery or potential verdict
16 in this case?

17 A. No.

18 Q. The jury's heard a little bit about some friends in this
19 case, and I want to see if you are, in fact, close friends with
20 some individuals that have testified in this case, okay?

21 A. Okay.

22 Q. Are you close friends with Ms. Brancaccio?

23 A. No.

24 Q. Tell the jury, before this trial, this week, when was the
25 last time you saw Ms. Brancaccio?

1 A. 2007 or '08 maybe. Probably a national meeting, the last
2 one I was at.

3 Q. Are you close friends with Ms. Penelow?

4 A. No.

5 Q. Before this trial, and this week, when was the last time
6 you saw Ms. Penelow?

7 A. Would have been the same national meeting, probably 2007
8 or '08.

9 Q. And when you were working at Janssen, you were in Kansas
10 City, Missouri and they were in New York or New Jersey?

11 A. Yeah, up here somewhere.

12 Q. Fair to say you didn't see them very frequently when you
13 worked there?

14 A. No.

15 Q. That is fair to say?

16 A. Yes, that's correct, sorry, fair to say.

17 Q. Bad question, sorry.

18 A. Sorry.

19 Q. You do know a gentleman you used to work with named Mark
20 Wilhelm?

21 A. Yes, he was my manager.

22 Q. You kept in touch with him?

23 A. I did.

24 Q. Tell the jury about your relationship with Mr. Wilhelm?

25 A. Just friends. He lives in Denver. He's a Broncos fan,

1 I'm a Chiefs fan so we banter. My son's a Broncos fan so I
2 have to deal with that.

3 Q. Are you close friends with a woman named Donna Graham?

4 A. No.

5 Q. When was the last time you saw Ms. Graham?

6 A. That would be 2007 or '08 probably.

7 Q. Seventeen years ago?

8 A. Last -- my last time I would have been at a national
9 meeting at Tibotec, yeah.

10 Q. And the last time before this trial that you saw my
11 clients was maybe 17 years ago?

12 A. I didn't even recognize Christine when she walked up. I
13 haven't seen her.

14 Q. What about Joseph Holshoe, close friends with Mr. Holshoe?

15 A. No.

16 Q. Did you work in the same district?

17 A. No.

18 Q. When was the last time before this trial -- you understand
19 he testified yesterday?

20 A. Correct.

21 Q. Did you see him either yesterday or when you arrived here
22 for this trial?

23 A. Yeah, I saw him in the hotel. He didn't recognize me
24 because I haven't seen him since 2008 either, I think, '07 or
25 '08, maybe '09. Whenever the last national meeting was, was

1 the last time I had seen any of them.

2 Q. So the last time you had seen Mr. Holshoe was,
3 conservatively, 15 years ago?

4 A. Correct.

5 Q. Did you talk to any of these individuals that I just
6 mentioned -- oh, forget to ask, are you close friends with Sara
7 Strand?

8 A. No.

9 Q. When was the last time you saw Ms. Strand?

10 A. I actually interviewed with her, she was with Tourig or
11 Turing Pharmaceuticals, but that was probably ten or 12 years
12 ago, so probably ten years ago.

13 Q. About a decade ago?

14 A. Yes.

15 Q. Have you talked to any of those individuals, Ms. Strand,
16 Mr. Wilhelm, Ms. Graham, Ms. Brancaccio, Ms. Penelow,
17 Mr. Holshoe, to coordinate your testimony here in front of this
18 jury?

19 A. No.

20 Q. Mr. Grooms, you agreed to come here to testify?

21 A. Yes, sir.

22 Q. Why?

23 A. I felt like it was the right thing to do after -- I kind
24 of suppressed everything that happened. And then whenever I
25 did the interview in '18 or '19, it brought up a lot of just

1 bad emotions of how things -- and more of a disappointment that
2 I didn't push back at the time -- disappointment in myself that
3 I didn't push back at the time because I knew what we were
4 doing was wrong.

5 Q. Push back more than reporting it to HR multiple times?

6 A. Yeah, but I still could have pushed back to Denise or
7 Doyletta and not went along with it.

8 Q. Understood, sir.

9 MR. RUSS: Thank you for your time. I may have some
10 more questions later this morning.

11 Pass the witness.

12 THE COURT: Thank you, Mr. Russ.

13 Ms. Brown.

14 MS. BROWN: Thank you, Your Honor.

15 May I proceed, Judge?

16 THE COURT: You may.

17 MS. BROWN: Good morning, everyone.

18 CROSS-EXAMINATION

19 BY MS. BROWN:

20 Q. Good morning, Mr. Grooms. How are you, sir?

21 A. Good morning. Thank you, good.

22 Q. So I understood your testimony just now to be that you
23 made a number of reported complaints to Dolores in HR; is that
24 correct, sir?

25 A. Correct.

1 Q. I understood your testimony to give us a list of the items
2 that you recall reporting to HR, correct, sir?

3 A. A specific list?

4 Q. Well, sir, I heard you say you went to HR to report the
5 off-label marketing, correct?

6 A. Correct.

7 Q. I heard you say you went to HR to report concerns you had
8 with Ms. Levere's management style, correct?

9 A. Correct.

10 Q. I heard you say you reported to HR concerns you had with
11 the company's culture and marketing correct, sir?

12 A. Correct.

13 Q. Well, when we asked you in your deposition, sir, what you
14 reported to HR, you said you couldn't recall the conversation
15 at all. Do you know that?

16 A. No, I don't remember that.

17 MS. BROWN: Your Honor, permission to play 301:12 to
18 301:4?

19 MR. RUSS: No objection.

20 THE COURT: All right. You may play it.

21 (Video playing.)

22 BY MS. BROWN:

23 Q. That was your testimony, sir, when we asked you under oath
24 at your deposition, correct, sir?

25 A. Yes.

1 Q. And since that time, you had the opportunity to meet with
2 the lawyers for the Relators to prepare for your testimony,
3 correct, sir?

4 A. Met with them, I think it was Monday night briefly when I
5 got in.

6 Q. Sure.

7 A. Correct.

8 Q. Today, I'm losing track of the days, it's Thursday,
9 correct?

10 A. Yes. Maybe it's Tuesday. I'm sorry, I can't remember
11 with the holiday.

12 Q. Fair, Monday was a holiday?

13 A. Correct.

14 Q. Did you fly into town on Monday, sir?

15 A. No, ma'am, Tuesday, I believe.

16 Q. Tuesday, okay.

17 A. Yes.

18 Q. And did the lawyers pay for your expenses to come out here
19 for the trial?

20 A. Not yet.

21 Q. Do you expect they will, sir?

22 A. I hope so.

23 Q. Your understanding is they'll reimburse you for your
24 travel here, correct?

25 A. Correct.

1 Q. And you're staying at the hotel with them; is that
2 correct?

3 A. I think some are at a different hotel, I'm not sure. Some
4 of them are at that hotel, correct.

5 Q. And you had the opportunity to meet with some of these
6 lawyers to prepare for your testimony, correct, sir?

7 A. Just one really.

8 Q. Mr. Russ?

9 A. Correct.

10 Q. Okay. And one of the things you and Mr. Russ discussed
11 was that he was going to ask you about this conversation with
12 Dolores in HR, correct?

13 A. Multiple things. It could have been, yes. There was
14 multiple things.

15 Q. That was the same question we had asked you at your
16 deposition that we just saw, correct?

17 A. I don't know if it was the exact same question, but, yes.

18 Q. At least at your deposition you couldn't recall what you
19 talked about, correct?

20 A. At that time I did not, no.

21 Q. But after speaking with Mr. Russ today you have a
22 different memory, correct?

23 A. No, not correct.

24 Q. Today you had a memory of that conversation, correct?

25 A. Yeah, I didn't sleep good last night, I had a lot of

1 | anxiety and a lot of things came back in my head and I remember
2 | a lot more stuff.

3 | Q. They came back to you all last night?

4 | A. A lot of it.

5 | Q. Yes, sir.

6 | Let's talk a little bit about your time at Janssen, okay,
7 | Mr. Grooms?

8 | A. Yes.

9 | Q. You were hired in March of 2006, correct, sir?

10 | A. Sounds right, yes.

11 | Q. Okay. And we have already heard in this trial from
12 | Mr. Wilhelm, he was your boss for a period of time, sir, at
13 | Janssen?

14 | A. That's correct, he hired me.

15 | Q. All right. And your duties and responsibilities as a
16 | sales rep at Janssen were to legally and ethically promote
17 | products to physicians through educating them and answering
18 | their questions, correct?

19 | A. Correct.

20 | Q. Okay. And, in fact, you signed with something called a
21 | pledge of ethics when you began your work at Janssen. Do you
22 | recall that, sir?

23 | A. I do not.

24 | Q. Okay.

25 | MS. BROWN: Your Honor, Tab 5, permission to admit

1 D-6063?

2 MR. RUSS: No objection.

3 THE COURT: So admitted.

4 (Exhibit D-6063 admitted into evidence.)

5 BY MS. BROWN:

6 Q. Mr. Grooms, what I'm showing you here, is that your

7 signature down there at the bottom in March of 2006?

8 A. Yes, ma'am.

9 Q. Okay. And do you recognize this at least as a document

10 titled The Professional Sales Representatives Pledge of Ethics?

11 A. I don't recognize it, but it's something we signed

12 obviously, yes.

13 Q. Sure. And we've gone through this with several witnesses

14 before, I don't want to belabor the point, but do you recall

15 agreeing, when you came to Janssen to work for us as a sales

16 rep, that you would follow the company policies?

17 A. I recall agreeing to, yes, with every company I would try

18 to follow the ethical policies.

19 Q. Right. And those policies included promoting our

20 medicines on the FDA label, correct, sir?

21 A. I would assume that's what the policies included, yes.

22 Q. Of course. And I know it was a long time ago, 2006, but

23 you read this pledge before you signed it, right?

24 A. No idea if I read it or not.

25 Q. All right. You think you would have signed a pledge of

1 ethics without reading it?

2 A. It's typical for every single health care company, so
3 yeah, I would have signed it.

4 Q. Yes, sir. But do you think you read it when you signed
5 it?

6 A. I don't know.

7 Q. All right. Did you understand that your job
8 responsibility was to promote the medicines within the
9 appropriate regulations and policies?

10 A. That's, yes, that's what I would have -- yes.

11 Q. Okay. And I understand your testimony here in this
12 lawsuit, sir, is that you did not abide by this pledge of
13 ethics, correct?

14 A. No.

15 Q. Right. But, sir, what you tell the public when you write
16 about your experience at Janssen is that you did promote the
17 product within the FDA indication, correct, sir?

18 A. No.

19 Q. You have a LinkedIn page, right, sir?

20 A. Yes.

21 Q. And your resume is available through that LinkedIn link,
22 right, sir?

23 A. It could be, yes.

24 MS. BROWN: All right. Your Honor, Tab 22, D-9180.

25 MR. RUSS: No objection.

1 THE COURT: All right. So admitted.

2 (Exhibit D-9180 admitted into evidence.)

3 BY MS. BROWN:

4 Q. Sir, I just want to -- your personal address and phone
5 number is on this so I just want to black that out before we
6 put it up.

7 Do you, sir, recognize this as your resume or CV?

8 A. That's an old one. That's probably five years old at
9 least.

10 Q. All right. Could this be the one available on your
11 LinkedIn profile, sir?

12 A. It shouldn't be.

13 Q. All right. You have been gone from Tibotec, though, for
14 more than five years, right, sir?

15 A. Yes, ma'am.

16 Q. All right. And do you know that your resume contains
17 information about the work that you did at the company,
18 correct?

19 A. Correct.

20 Q. And one of the things you put on what was available on
21 your public LinkedIn is that one of your roles and
22 responsibility at Tibotec was: Established credibility with
23 infectious disease and internal medicine physicians by
24 educating them on indication of proper usage.

25 Do you see that, sir?

1 A. I do.

2 Q. Used clinical studies to exhibit product experience.

3 Do you see that, sir?

4 A. Expertise, yes.

5 Q. Expertise, yes.

6 So your resume available on LinkedIn talks about the
7 proper usage and the indication of the medicine, correct, sir?

8 A. Yes.

9 Q. When you got to Janssen, Mr. Grooms, you went through
10 compliance training, correct, sir?

11 A. I don't recall compliance training necessarily. We could
12 have, I just don't remember it.

13 Q. All right. Do you remember we asked you that question in
14 your deposition, sir?

15 A. I don't. I remember sales training. It's probably in
16 there, I just don't recall it specifically.

17 MS. BROWN: All right. Permission to play 154
18 through 9?

19 MR. RUSS: No objection.

20 THE COURT: You may.

21 MS. BROWN: Thank you.

22 (Video playing.)

23 BY MS. BROWN:

24 Q. You recall at the time of your deposition that your
25 training included health care compliance, right, sir?

1 A. Yes.

2 Q. All right. And you were also trained on proper
3 promotional practices, right, sir?

4 A. I believe so, yes.

5 Q. And that training you told us you recall happening at
6 least once a year, correct?

7 A. I think so, yeah. Most companies have it once a year,
8 correct.

9 Q. Okay. And you don't recall ever being instructed or
10 directed by any of the trainers at Janssen to promote
11 off-label, correct?

12 A. Not correct.

13 Q. All right.

14 MS. BROWN: Your Honor, permission to play 47, 12 to
15 23?

16 MR. RUSS: Sorry, Your Honor, just one moment.

17 THE COURT: That's all right.

18 MR. RUSS: No objection.

19 THE COURT: All right. You may publish.

20 MS. BROWN: Thank you.

21 (Video playing.)

22 BY MS. BROWN:

23 Q. At the time of your deposition, sir, you didn't recall
24 that trainers had given you direction to promote off-label; is
25 that correct?

1 A. Yeah, I didn't recall then.

2 Q. Okay. And, in fact, you testified at your deposition and
3 again on direct examination that you were expected to, I think
4 your term was, "show up and throw up," meaning regurgitate the
5 approved messages from the company; is that correct?

6 A. Regurgitate messages from the company, yes.

7 Q. And I want to talk to you about one of those approved
8 messages that you were asked about in your deposition.

9 You, sir, as a sales representative, were provided with
10 company-approved materials to use when you were speaking to
11 physicians, correct, sir?

12 A. Yes.

13 Q. All right. And I want to show you one that you were asked
14 about in your deposition.

15 MS. BROWN: It's Tab 21, D-9179.

16 MR. RUSS: No objection.

17 THE COURT: All right.

18 BY MS. BROWN:

19 Q. I'll try to zoom in on this, I know it's a little small.
20 But you were asked about this Prezista approved promotional
21 piece in your deposition. Do you recall pieces like this that
22 the sales force were provided to use when meeting with doctors?

23 A. I don't recall the specific piece, but I know they gave us
24 stuff to use, correct.

25 Q. Do you recall being shown this and asked about it in your

1 deposition, sir?

2 A. I do not recall.

3 Q. All right. This particular piece states: Low impact on
4 lipids.

5 Do you see that, sir?

6 A. I see that.

7 Q. And I want to show you one of the pages of this piece that
8 you provided some testimony about. This is more details on low
9 impact on lipids. It says: Naïve adult patients in Prezista
10 once daily arm had mean triglyceride levels below the national
11 cholesterol education program, NCEP, cutoff through 48 weeks.

12 Do you see that, sir?

13 A. I do.

14 Q. And you are generally familiar with the NCEP cutoff,
15 correct, sir?

16 A. I am not.

17 Q. Do you recall giving deposition testimony about that
18 cutoff?

19 A. I don't recall.

20 Q. Do you recall, sir, testifying that this graph and this
21 cutoff guideline said to you that Prezista was lipid-neutral or
22 lipid-friendly?

23 A. I don't recall that.

24 MS. BROWN: Your Honor, permission to play 193, 13 to
25 193, 24. Actually to 193, 20?

1 MR. RUSS: No objection.

2 THE COURT: All right. You may play it.

3 MS. BROWN: There's no video. I apologize. Can we
4 show the transcript? Thank you.

5 BY MS. BROWN:

6 Q. You were asked in relation to this promotional piece:

7 Sir, do you see the promotional message on this page that

8 Prezista is lipid-neutral or lipid-friendly?

9 And your answer referring to what we were just looking at
10 is: What I see is it's showing that it's below the NCEP cutoff
11 guidelines, which would mean below 130 or 125, I believe. So
12 that would tell me it's lipid-neutral, lipid-friendly.

13 Do you see that testimony you gave, sir?

14 A. I do.

15 Q. Sir, you testified about using the hub at Janssen to get
16 materials to use with providers.

17 Do you recall that?

18 A. Yes.

19 Q. And is that a central location where you would have had
20 access to approved pieces like the one we just looked at?

21 A. I believe all marketing material studies came from there.

22 Q. And if you were to bring approved promotional pieces to a
23 visit with a provider like the one we just looked at, you could
24 access it from the hub, correct?

25 A. Yes, from the hub, or it would be drop-shipped direct,

1 yes.

2 Q. And you talked a bit about accessing studies from the hub
3 as well, right, sir?

4 A. Correct.

5 Q. And you know that there was a policy and an FDA procedure
6 that allowed sales reps to provide providers with off-label
7 studies in some limited circumstances, correct, sir?

8 A. I don't recall that.

9 Q. Okay. Do you recall being trained during the time period
10 you were at the company on an FDA guidance that allowed sales
11 reps to give out reprints of studies?

12 A. I don't recall. I'm not sure it happened. I don't
13 remember that.

14 Q. All right. Let me see if I can refresh your recollection.

15 MS. BROWN: Your Honor, just for the witness and
16 counsel, permission to display tab 26, 9211.

17 THE COURT: Just for the witness, right?

18 MS. BROWN: Yeah, to see if I can refresh his
19 recollection, Your Honor.

20 THE COURT: Mr. Russ?

21 MR. RUSS: No objection. Maybe potentially an
22 objection to admission.

23 THE COURT: I'm just talking about showing it to the
24 witness.

25 You may.

1 MS. BROWN: Thank you.

2 Just for the witness, Mr. Morales. Thank you.

3 BY MS. BROWN:

4 Q. Sir, do you see the title of this health care compliance
5 training and the date?

6 A. I do.

7 Q. And this was a date that you were still working as a sales
8 rep at Janssen, correct, sir?

9 A. Yes, ma'am.

10 Q. All right. And let me turn to the page that explains what
11 this training is about.

12 Do you see that slide, sir?

13 A. I do.

14 Q. Do you recall being trained on an FDA act that allowed
15 companies like Janssen to provide in certain circumstances
16 peer-reviewed articles about an off-label indication of a
17 product?

18 A. I don't recall being trained. I'm not saying it didn't
19 happen. I just don't remember it.

20 Q. All right. Does looking at this document and the
21 instances in which the reprint could or could not be used
22 refresh your recollection, sir?

23 A. No.

24 Q. All right. Do you recall being trained on the policy that
25 was the subject of that presentation that we just looked at?

1 A. I don't recall that specifically.

2 Q. All right. Do you recall if the studies that you told us
3 you were accessing on the hub were made available pursuant to
4 this FDA regulation we were just looking at?

5 A. I don't know that.

6 Q. All right. Sir, you were trained when you were at Janssen
7 on the various ways that the company had for employees like you
8 to report potential noncompliance; is that right, sir?

9 A. I'm sorry. Repeat that. Trained for what?

10 Q. Sure. You were made available, for example, when you
11 worked at Janssen of the anonymous hotline where employees
12 could report potential issues, correct?

13 A. I don't recall specifically. It's possible. I don't
14 know.

15 Q. Okay. You didn't report any of the concerns that you've
16 raised in this case to health care compliance, correct, sir?

17 A. Not in the beginning, no.

18 Q. Okay. And you said -- I think I heard you testify that
19 one of the reasons that you're testifying here is in
20 retrospect, you wish you would have pushed back more; is that
21 right, sir?

22 A. Yes, that's correct.

23 Q. All right. One of the things you told us in your
24 deposition, sir, is that someone, one of your superiors, Bill
25 Weatherford, do you recall him, sir?

1 A. Yes. He wasn't a superior. He was an equal.

2 Q. He was an equal.

3 He was a KAM or a fellow sales rep?

4 A. I believe he started as a sales rep and then became a KAM,
5 if I recall right. Yes.

6 Q. And one of the things you told us is that he was thrown
7 out of one of your doctor's offices because he was promoting
8 off-label, right, sir?

9 A. That's correct.

10 Q. Okay. And you don't have or know of any documents that
11 would substantiate that that happened, correct, sir?

12 A. I do not have any documents.

13 Q. All right. And you're not aware -- you didn't report that
14 incident, correct?

15 A. I spoke to Denise Levere about it.

16 Q. Dr. Sweet was the doctor that you claimed this happened
17 with, correct?

18 A. No, that's not correct. It was Dr. Ha Ta. It's in
19 Dr. Sweet's office. Dr. H-A-T-A.

20 Q. All right. Sir, there was actually one document --
21 Mr. Weatherford accompanied you on a sales visit one time,
22 correct, sir?

23 A. Correct.

24 Q. And there's actually a coaching document that he filled
25 out that reported the events of that visit, correct, sir?

1 A. Yes. He filled that out.

2 Q. All right. And, actually, on that form, there's a place
3 for you to add your own comments, correct, sir?

4 A. Correct.

5 Q. And none of Mr. Weatherford's comments reflected any
6 doctor throwing him out of the office, correct?

7 A. No.

8 Q. And you in the employee comment section didn't add any
9 comments to suggest that had happened either, correct, sir?

10 A. Absolutely not.

11 Q. You know, Mr. Grooms, that many different factors go into
12 a doctor's decision to prescribe HIV medicine, correct?

13 A. I'm not a doctor. I don't know what they use wholly.
14 It's up to the physicians' discretion.

15 Q. What you've told us before is that even though you're not
16 a doctor, you believe that many different factors go into their
17 decision to prescribe an HIV medicine, correct, sir?

18 A. It should, yes.

19 Q. All right. For instance, doctors consider individual
20 patients they're prescribing to, correct?

21 A. I would hope so, yes.

22 Q. Their experience informs their decision to prescribe,
23 correct?

24 A. I'm not sure on that.

25 MS. BROWN: Permission to play 166:24 to 167:5.

1 MR. RUSS: No objection.

2 THE COURT: You may.

3 (Video playing.)

4 BY MS. BROWN:

5 Q. And, sir, you testified that no doctor ever told you that
6 they switched to Prezista from another product because of the
7 message that you were delivering, correct, sir?

8 A. I don't recall that at all, no.

9 Q. You don't recall that ever happening, correct, sir?

10 A. No. That statement?

11 Q. Yes, sir.

12 A. I don't recall that, no.

13 Q. Okay. Do you have a memory of any doctor telling you that
14 the reason they were switching to Prezista was because of
15 something you said?

16 A. Oh, I'm sorry. I misunderstood. Yes, I do have memories
17 of that.

18 MS. BROWN: Okay. Let's play then 232:10 to 19,
19 please.

20 MR. RUSS: No objection.

21 (Video playing.)

22 BY MS. BROWN:

23 Q. Sir, I want to talk a little bit about the speaker bureau,
24 please, quickly.

25 As a sales representative at the time that you worked at

1 Janssen, you were permitted to make recommendations for the
2 speaker bureau, correct, sir?

3 A. Recommendations for physicians from my territory, is that
4 what you're asking?

5 Q. Yes.

6 A. Yes, ma'am.

7 Q. And in terms of who those recommendations were ultimately
8 evaluated by, you don't know, correct, sir?

9 A. Excuse me. I would refer those to Denise and Doyletta,
10 and then it would go from there.

11 Q. Right. And in terms of the criteria that was used to make
12 the ultimate decision of who got onto the speaker bureau,
13 you're not aware of that, correct, sir?

14 A. No, I was only told what parameters to look for to pick a
15 speaker to move up to them.

16 Q. To recommend, correct, sir?

17 A. Correct.

18 Q. All right. And you don't know the criteria that was used
19 to remove speakers from the speaker bureau, correct?

20 A. Correct.

21 Q. You don't know who made the final decision to remove
22 speakers if they were removed at all, correct?

23 A. Correct.

24 Q. You'd never identified any speakers to be removed from the
25 bureau, correct?

1 A. I did not -- like, identified as far as someone I'd
2 recommend, but it wasn't up to me.

3 Q. And you don't know of any speakers that were removed from
4 the bureau because they didn't write enough prescriptions,
5 correct?

6 A. I wouldn't have that information.

7 Q. You don't know of any doctors that were removed from the
8 speaker bureau because their prescriptions didn't increase
9 after being selected, correct?

10 A. I wouldn't know that.

11 Q. And you don't know of a single doctor who told you that
12 they increased their number of Prezista prescriptions because
13 of lipid messages they heard at a speaker program, correct?

14 A. That's not correct.

15 MS. BROWN: Your Honor, permission to play 244:2 to
16 8.

17 MR. RUSS: No objection.

18 THE COURT: All right. You may play it.

19 (Video playing.)

20 BY MS. BROWN:

21 Q. You don't recall, Mr. Grooms, a single doctor telling you
22 that they increased Intelence prescriptions because of
23 once-daily dosing messages that they heard at an Intelence
24 speaker program, correct?

25 A. No, I don't agree with that.

1 MS. BROWN: Your Honor, permission to play 244:9 to
2 17.

3 MR. RUSS: No objection.

4 THE COURT: All right. You may play it.

5 (Video playing.)

6 BY MS. BROWN:

7 Q. Mr. Grooms, you spoke on direct examination about the
8 ability to dissolve the Intelence pills in water.

9 Do you remember that, sir?

10 A. Yes, ma'am.

11 Q. And as I understood your testimony, you believed that to
12 be an off-label message as well?

13 A. From what I recall at the time.

14 MS. BROWN: Let's take a look at D-1045A. It's
15 tab -- I don't think it's a tab. It's the Intelence label.

16 MR. RUSS: No objection.

17 THE COURT: All right.

18 MS. BROWN: Thank you, Your Honor.

19 BY MS. BROWN:

20 Q. Sir, do you know that actually the ability to dissolve the
21 Intelence pills was in the Intelence label?

22 A. I don't recall, ma'am.

23 Q. Okay. We'll just take a quick look here. This is the
24 Intelence label from 2008.

25 That was during the time period you were working at the

1 company, right, sir?

2 A. Yes, ma'am.

3 Q. All right. And if you turn, in fact, to dosage and
4 administration, do you see some information provided in the
5 label right there, sir?

6 A. I do.

7 Q. All right. And it says here: Patients who are unable to
8 swallow Intelence tablets whole may disperse the tablets in a
9 glass of water.

10 Do you see that?

11 A. I do.

12 Q. And once dispersed, they could stir it up and drink it
13 immediately, correct, sir?

14 A. Correct.

15 Q. And that was actually an on-label way to take Intelence,
16 correct, sir?

17 A. For twice-a-day, it was.

18 Q. Sir, the emails that you wrote at the time you were
19 working at Janssen were focused on making sure you were
20 complying with the company policies, correct, sir?

21 A. The emails? I'm not following you on that. Sorry.

22 MS. BROWN: Okay. Let's take a look at Tab 15,
23 D-9165, please.

24 THE COURT: Ms. Brown, is this admitted, not
25 admitted? Are you looking to show just the witness?

1 MS. BROWN: I'm sorry. Permission to admit, Your
2 Honor, Tab 15, D-9165.

3 MR. RUSS: No objection.

4 THE COURT: Okay. So admitted.

5 (Exhibit D-9165 admitted into evidence.)

6 MS. BROWN: Thank you.

7 BY MS. BROWN:

8 Q. Mr. Grooms, this is an email from you in March of 2009.

9 Do you see that, sir?

10 A. Yes, ma'am.

11 Q. All right. And the title is journal club articles for
12 your review.

13 Do you see that?

14 A. I do.

15 Q. And one of the things that you participated in as a sales
16 representative were journal clubs with your colleagues,
17 correct?

18 A. Correct.

19 Q. And sometimes that was an opportunity for you all to be
20 educated and updated on the developments in the field of HIV
21 and developments with the medicines you were promoting,
22 correct, sir?

23 A. It could have been anything, correct, so I'm not sure --
24 multiple topics, yes.

25 Q. Sure. Because one of the things that happened in your

1 business is HIV -- the science and medicine of HIV was moving
2 pretty quickly at that time, would you agree?

3 A. Yeah. I would say so.

4 Q. All right. And what you say here is that you're attaching
5 these articles, and I think it would also be very helpful if we
6 could devise some compliant, all caps, questions to interact
7 with our physicians during sales calls.

8 Do you see that, sir?

9 A. I do.

10 Q. Your focus in this email was discussing with your
11 colleagues compliant ways to engage with physicians, correct,
12 sir?

13 A. Yes, I would put compliant in for sure.

14 Q. We heard testimony in this trial, Mr. Grooms, from your
15 supervisor for a period of time, Mark Wilhelm.

16 Did you know that, sir?

17 A. I was aware that he came, yes.

18 Q. Okay. And he testified in part that you struggled a bit
19 with your sales performance at Janssen.

20 Would you agree with that?

21 A. No.

22 Q. Okay. Do you recall having discussions with Mr. Wilhelm
23 about your sales performance?

24 A. Yes.

25 Q. All right. Do you recall receiving feedback that your

1 sales performance was not meeting expectations?

2 A. Yes.

3 Q. All right. And as I understood your direct testimony, you
4 disagreed with that feedback, sir?

5 A. Correct.

6 Q. All right. You felt that people like Mr. Wilhelm or
7 others were putting feedback in the coaching reports that in
8 your view was not accurate?

9 A. Mark had told me that he had to put things in the coaching
10 report because it was being looked at from above.

11 Q. Okay. And your view was what he put in those coaching
12 reports wasn't fair, correct?

13 A. Correct.

14 Q. And that's the same with Ms. Levere. You did not feel she
15 was fairly evaluating your performance, correct, sir?

16 A. Not completely correct. Sometimes she was very, very
17 fair.

18 Q. All right. I heard you say on direct that she wrote
19 things in the field coaching report that you took issue with,
20 true?

21 A. Correct.

22 Q. All right. And, in fact, ultimately, at the very end of
23 your time at Janssen, you were put on a performance improvement
24 plan; is that right, sir?

25 A. Correct.

1 Q. And you resigned from Janssen in January of 2010 to pursue
2 a different opportunity, correct?

3 A. I got a severance to resign. I guess it was a mutual
4 agreement.

5 Q. When we asked you why you left Janssen, sir, you indicated
6 it was to get experience in managed care, a different
7 experience.

8 Do you recall that testimony?

9 A. I don't recall.

10 MS. BROWN: Can we play 265:22 to 266:1, please?

11 MR. RUSS: No objection.

12 THE COURT: You may.

13 (Video playing.)

14 BY MS. BROWN:

15 Q. Sir, I understand your testimony that you have not
16 remained in contact with Ms. Penelow and Ms. Brancaccio,
17 correct?

18 A. Correct.

19 Q. But at one point, you did receive outreach from their
20 lawyers, correct?

21 A. Attorneys. I don't know whose they were, but yes.

22 Q. And they asked you to sign a declaration in this case,
23 which you did, correct, sir?

24 A. Correct.

25 Q. And they prepared that declaration for you, correct?

1 A. I did not type it, correct.

2 Q. And they actually -- I think they came out to Kansas City
3 to meet with you; is that right, sir?

4 A. Yes.

5 Q. And I heard you say you weren't really in contact with
6 Ms. Penelow, right, sir?

7 A. Not to my knowledge.

8 Q. But she actually called you to see if you were going to
9 answer questions from her lawyer, correct, sir?

10 A. I don't remember that.

11 Q. Okay. She actually called you after you submitted your
12 declaration, correct?

13 A. I don't recall that either.

14 MS. BROWN: Your Honor, permission to play 125:23 to
15 126:07, please.

16 MR. RUSS: No objection.

17 THE COURT: All right. You may proceed.

18 (Video playing.)

19 BY MS. BROWN:

20 Q. Sir, you mentioned a number of names of individuals that
21 you were on calls with when this off-label direction, you
22 allege, was coming from Ms. Levere.

23 Do you remember that?

24 A. Which specific call or example? I'm sorry.

25 Q. I understand you listed a number of your colleagues that

1 | you worked with in your district who were also participating in
2 | what you claim was the off-label promotion, right, sir?

3 | A. We had weekly calls in our district.

4 | Q. As I understand your testimony, everybody on that call was
5 | aware and participating in the off-label promotion scheme; is
6 | that right?

7 | A. I don't know if it's a scheme. I'm not sure. There's
8 | communication about what direction we have. Yes, that's
9 | correct. Everybody on the call would have been on the call and
10 | listened to it, yes.

11 | Q. And when the lawyers for Ms. Penelow and Ms. Brancaccio
12 | called you to interview you, sir, did they ask you for names,
13 | about other individuals who could corroborate your testimony?

14 | A. I have no idea.

15 | Q. Okay. Do you recall providing them with names of other
16 | individuals like the people you gave us here today?

17 | A. I don't. I may have. I have no idea.

18 | Q. All right. Do you know if other individuals other than
19 | you and the folks that we've heard from in this trial were
20 | contacted to see if their stories support what you're telling
21 | us?

22 | A. I know one person was contacted, but I don't know the
23 | conversation that happened.

24 | Q. Who was that, sir?

25 | A. Russ Moyer.

1 Q. How do you know he was contacted?

2 A. Because I work with him.

3 Q. Where do you guys work together?

4 A. Argenx.

5 Q. That's a pharmaceutical company?

6 A. Correct.

7 Q. What did Mr. Moyer tell you about the outreach?

8 A. He just said he got contacted. That was it.

9 Q. Do you know if Mr. Moyer signed a declaration?

10 A. I have no idea.

11 Q. Do you know if Mr. Moyer is coming into this trial?

12 A. I do not.

13 Q. One of the people you referenced during your testimony was
14 Joyce Arellano?

15 A. Arellano.

16 Q. Okay. And as I understood your testimony, you believe
17 Ms. Arellano was fired from Janssen for pushing back on this?

18 A. I don't recall if she was fired specifically for that. I
19 know she was gone not too much longer after, if I recall right.

20 Q. Do you know if she still works for the company today, sir?

21 A. I have no idea.

22 Q. What made you think she had been fired?

23 A. Because she was gone. She was no longer there. Out of
24 the district.

25 Q. Do you know she moved to a different department at Johnson

1 & Johnson?

2 A. No clue. Nothing was ever told to us of that.

3 MS. BROWN: Your Honor, may I have one moment,
4 please?

5 THE COURT: You may.

6 (Sotto voce discussion.)

7 MS. BROWN: Mr. Grooms, I have no further questions.
8 Thanks very much for your time, sir.

9 THE WITNESS: Thank you.

10 THE COURT: All right. Thank you, Ms. Brown.

11 Mr. Russ.

12 MR. RUSS: Thank you, Your Honor. May I proceed?

13 THE COURT: You may.

14 REDIRECT EXAMINATION

15 BY MR. RUSS:

16 Q. Mr. Grooms, let's start with your resume.

17 Why didn't you put all the fraud that you saw in your
18 resume?

19 A. That would definitely be a career-limiting move to put
20 anything like that in writing on my resume.

21 Q. How long would that resume be?

22 A. Multiple pages, but more than likely I would never be
23 hired again.

24 Q. Is that the type of thing that in your experience people
25 normally put on their resume?

1 A. No.

2 Q. Because you didn't list out all the illegal conduct that
3 you witnessed at Janssen on your resume, does that mean it
4 didn't happen?

5 A. No.

6 Q. I want to talk to you about some of the deposition clips.
7 And by the way, Mr. Grooms, your deposition was fairly
8 lengthy, wasn't it?

9 A. Yes.

10 Q. I want to take a look at this sales aid discussion that
11 you had with Ms. Brown.

12 MR. RUSS: If I could have the ELMO, please.

13 BY MR. RUSS:

14 Q. Mr. Grooms, do you remember Ms. Brown going over this
15 sales aid with you for Prezista just now?

16 A. Yes. That's the one she put up, I believe.

17 Q. Do you recall in your testimony in your deposition that
18 you were actually testifying that you believed that that
19 information in there was showing an off-label lipid-friendly
20 message, and you were asked where is it? Do you remember that?

21 A. Yes. Yes, sir.

22 Q. When Ms. Brown put your testimony in front of you, she
23 asked you do you agree that this actually proves it's
24 lipid-friendly.

25 A. Correct.

1 Q. You were saying in your deposition -- we can take a look
2 at it -- that you believed it reflected a lipid-friendly
3 message that was not approved by the FDA?

4 A. Correct.

5 Q. So you weren't agreeing that Prezista was lipid-friendly
6 at all, were you?

7 A. No.

8 Q. In fact, let's just take a look at it.

9 Do you see your deposition at the top, Matthew Grooms?

10 A. Yes, sir.

11 Q. You were being asked by counsel for Janssen about this
12 sales aid and why you thought it was actually an inappropriate
13 lipid-friendly message for Prezista.

14 Do you recall that?

15 A. Yes, sir.

16 Q. You were asked: This document, the sales aid, have any
17 promotional messages in it that Prezista is lipid-neutral,
18 right?

19 A. Correct.

20 Q. Then you had trouble reading the page. We can see maybe
21 why.

22 A. It was tiny, yes.

23 Q. Right?

24 A. Correct.

25 Q. And you said: I'm not trying to be difficult. I'm having

1 trouble seeing it.

2 You were asked again: Is there anywhere else in the sales
3 aid that you see a message that Prezista is lipid-neutral or
4 lipid-friendly?

5 Do you see that?

6 A. Yes, sir.

7 Q. You said yes at page 14?

8 A. Correct.

9 Q. What Ms. Brown showed you was just this portion of your
10 testimony: Do you see the promotional message on this page
11 that Prezista is lipid-neutral or lipid-friendly?

12 So you were being asked by Janssen's counsel, show us
13 where that unapproved message is on this document, and you said
14 --

15 MS. BROWN: I'm sorry, Counsel. Can you just tell me
16 what page you're on?

17 MR. RUSS: 193.

18 BY MR. RUSS:

19 Q. And you said: What I see is it's showing that it's below
20 the NCEP cutoff guidelines.

21 By the way, the guidelines aren't on the package insert,
22 right?

23 A. No, they're just guidelines.

24 Q. Which would mean below 130 or 125, I believe. So that
25 would tell me that it's lipid-neutral, lipid-friendly.

1 What you meant by that, Mr. Grooms, was that sales aid was
2 inappropriate?

3 A. Correct.

4 Q. You weren't saying Prezista is lipid-neutral or
5 lipid-friendly?

6 A. No.

7 Q. Ms. Brown didn't show you the rest of that, did she?

8 A. No, sir.

9 Q. I want to also turn to page 170 of your deposition.

10 You were asked: What's false and misleading about the
11 statement that Prezista's lipid-neutral?

12 And you asked: What's false and misleading now or then?

13 Then, when you were using the message.

14 I don't believe it was in -- I don't believe it was in our
15 label to use as lipid-neutral or lipid-friendly.

16 Is that still your testimony today?

17 A. Yes, sir.

18 Q. You said, when we launched the drug, I don't believe it
19 was in the label to be able to say you're lipid-neutral or
20 lipid-friendly, correct?

21 A. Correct.

22 Q. Still the same today?

23 A. Yes, sir.

24 Q. So it's not a fair and balanced message, which is what
25 we're supposed to stick to in my recollection.

1 Do you see that?

2 A. Yes, sir.

3 Q. Again, what's false and misleading about the statement
4 that Prezista is lipid-friendly?

5 And you said: Lipid-friendly to me would mean the same.
6 It's not going to -- it's lipid-friendly, lipid-neutral. It's
7 somewhere to me the same. In my opinion, it means that you're
8 safe to use this, and it's not going to increase lipids or
9 cause any more issues. It's not going to cause any lipid
10 issues to your patient.

11 Correct?

12 A. Correct.

13 Q. So when Ms. Brown showed you that one little clip, you
14 weren't saying Prezista is lipid-friendly?

15 A. No.

16 Q. In fact, in your deposition, you were saying that sales
17 aid was inappropriate?

18 A. Yes, sir.

19 Q. While we're at it, let's talk about the deposition
20 testimony from -- about your HR meetings.

21 Ms. Brown showed you one question, again, from your
22 deposition.

23 You told our jury that you had multiple conversations with
24 Dolores in HR?

25 A. Yes, sir.

1 Q. Okay. Let's see what you said in your deposition back in
2 2019.

3 A. Yes, sir.

4 MR. RUSS: This is on page 176.

5 BY MR. RUSS:

6 Q. Did you ever report your concerns to anyone else in the
7 company?

8 Do you see that, sir?

9 A. Yes, sir.

10 Q. Could you please read your answer from your deposition
11 five years ago that Ms. Brown did not show you?

12 A. I reported a lot to Dolores in human resources about
13 Denise Levere and how she was portraying and asking me to do
14 illegal stuff, illegal information, yes.

15 Q. And you said she was the head of HR over at the Tibotec
16 division, correct?

17 A. That's what I remember, yes.

18 Q. You said you did it multiple times approximately a year
19 before you left?

20 A. Yes, sir.

21 Q. You specifically told Janssen's counsel you reported the
22 illegal information?

23 A. Yes.

24 Q. To Dolores?

25 A. Yes, sir.

1 Q. Ms. Brown didn't show you that portion of your testimony,
2 did she?

3 A. No, sir.

4 Q. Did you report to Dolores all the unlawful stuff they were
5 having you do?

6 A. Yes. On multiple occasions, I had discussions with
7 Dolores.

8 Q. And her response was?

9 A. We stand behind Janssen's management. Or Johnson &
10 Johnson's, excuse me.

11 Q. Let's be accurate. Let's be detailed.

12 A. We stand behind Johnson & Johnson's management.

13 Q. We stand behind Johnson & Johnson's management?

14 A. Yes, sir.

15 Q. You were also showed some deposition testimony about
16 whether or not a doctor told you that they increased their
17 prescriptions after speaker programs.

18 Remember that?

19 A. Yes, sir.

20 Q. I believe you said you disagreed?

21 A. Correct.

22 Q. Why did you disagree?

23 A. Because I remember specifically Dr. Verstraete, Dr. Dietz
24 talking to me after programs about increasing their
25 prescriptions. Actually, the first time Dr. Dietz had written

1 was, hey, I finally wrote one after our program. So I remember
2 that.

3 Q. Now, even in your deposition transcript that was shown
4 before this jury, you were saying that's pretty specific. You
5 were talking about the question that was asked.

6 Did they tell you in these words?

7 A. Correct. I believe so, yes.

8 Q. But you did see an increase in prescriptions from speaker
9 programs because you were watching the prescription volume?

10 A. Correct. I was watching the TAR reports.

11 Q. I also want to show you some deposition testimony on
12 page 51, Mr. Grooms, about the company's lipid-neutral
13 messaging increasing Prezista.

14 Do you remember some conversation with Ms. Brown about
15 that issue?

16 A. Yes, sir.

17 Q. And you said back in 2019 -- and, again, I don't remember
18 Ms. Brown showing you this. Correct me if I'm wrong.

19 Did you see your doctors' prescriptions increase after
20 delivering the lipid-neutral messages or that Prezista is
21 comparable to Reyataz?

22 And you say what?

23 A. Yeah, for sure. It had some key physician market shares
24 had changed.

25 Q. And would you happen to remember the names of those key

1 physicians?

2 A. Yeah. Dr. Craig Dietz. Dr. Ha Ta. Middle name is T.

3 Q. So the same doctors you told this jury yesterday and this
4 morning that their prescriptions were increasing after you
5 delivered an off-label lipid-friendly message to them, correct?

6 A. Correct.

7 Q. You were also asked -- and I believe some deposition
8 testimony was played about this -- about remembering if your
9 physicians that you called on increased their Intelence
10 prescriptions for once-a-day dosing.

11 Do you remember that?

12 A. Yes, sir.

13 Q. This is on page 67 of your deposition. Correct me if I'm
14 wrong.

15 I don't think this clip was played either, Mr. Grooms, was
16 it?

17 A. I don't believe so.

18 Q. Mr. Grooms, you were asked five years ago: To the extent
19 you can remember, do you remember any of your physicians that
20 you called on increasing their Intelence prescriptions after
21 hearing your once-a-day message?

22 And what did you say?

23 A. Yeah. Dr. Dietz and Dr. Ta, both.

24 Q. You were asked some questions about dissolving Intelence
25 into a slurry and then drinking, and then you were showed the

1 Intelence label.

2 Do you remember that?

3 A. Yes, sir.

4 Q. When you were asked that's on label, you said for
5 twice-a-day?

6 A. Correct.

7 Q. What did you mean by that?

8 A. We promoted it for QD, for dosing symmetry once a day.

9 Q. And tell the jury how you would promote swirling and
10 dissolving the drug and taking it once a day.

11 A. So, for example, Intelence would be twice a day. The
12 regimen you put with it would be once a day, so it would be
13 confusing for a patient. So I would say you can drop the
14 Intelence in the water, swirl it, drink your one pill with
15 Intelence, and now you only have a one-pill regimen
16 essentially. So it would be QD.

17 Q. Mr. Grooms, you were also shown an email that you wrote
18 back in 2009 about journal club.

19 Do you remember this?

20 A. Yes, sir.

21 Q. I think you testified yesterday that journal club was
22 one -- maybe this morning, journal club was one of the ways
23 that salespeople would talk about off-label marketing and
24 off-label studies; is that right?

25 A. Yes, sir.

1 Q. And I circled there in all caps the word "compliant."

2 A. Yes, sir.

3 Q. And you were asked -- well, you wrote compliant, so you
4 must have been compliant, right?

5 A. Correct.

6 Q. Why did you write that and why did you put it in all caps?

7 A. Because I'm not going to put anything in writing that is
8 not compliant. I'm not going to allude to using and talking
9 about our off-label messaging.

10 Q. Is that similar to the way you wouldn't put all the fraud
11 you saw at Janssen on your resume?

12 A. Exactly.

13 Q. Is that similar to the way that Ms. Levere taught you to
14 be careful about what you put in writing?

15 A. Exactly.

16 Q. At some point in your career at Janssen, you were actually
17 fairly highly ranked on your sales?

18 A. Yes, sir.

19 Q. You started reporting to HR some of the allegations that
20 you saw, including what we just saw. All the illegal stuff, I
21 believe, is what you said in your deposition.

22 A. Correct.

23 Q. You weren't fired, were you?

24 A. It was not fired. It was a mutual, like, a parting, I
25 guess you would say.

1 Q. But it wasn't well received, was it?

2 A. No.

3 Q. In fact, they didn't say your performance is so bad,
4 you're out of here. They gave you a severance, didn't they?

5 A. Yes. From what I remember, three months.

6 MR. RUSS: May I have one moment, Your Honor?

7 THE COURT: You may.

8 (Sotto voce discussion.)

9 BY MR. RUSS:

10 Q. One more topic, Mr. Grooms.

11 A. Yes, sir.

12 Q. Do you know whether the FDA itself ever took a position
13 about Janssen's use of the phrase "low impact on cholesterol or
14 lipids" as we sit here today in this courtroom?

15 A. I do not know.

16 MR. RUSS: No further questions, Your Honor.

17 THE COURT: All right. Thank you, Mr. Russ.

18 Mr. Grooms, you're excused from trial.

19 THE WITNESS: Thank you, sir.

20 (Witness excused.)

21 THE COURT: Folks, it's that time. Let's take a
22 break before the next witness to make sure who you're calling
23 next, folks, is lined up. We'll take ten minutes, and then
24 we'll proceed.

25 THE DEPUTY CLERK: All rise.

1 (The jury exits the courtroom at 10:51 a.m.)

2 THE COURT: All right. Folks, remain seated. We're
3 on recess for ten minutes.

4 (Recess taken from 10:51 a.m. to 11:01 a.m.)

5 THE DEPUTY CLERK: Please remain seated.

6 THE COURT: By the way, who is the next witness?

7 MR. MARKETOS: Your Honor, it's Mr. Amit Patel.

8 THE COURT: Right, okay. And then we're going to do
9 the doc.

10 Are you guys ready? Should I get the jurors?

11 MR. KLEIN: Your Honor, we had just one issue to
12 raise.

13 THE COURT: Yeah.

14 MR. KLEIN: Something that may come up with
15 Dr. Patel. We anticipate that Relators' counsel may want to
16 show him documents relating to direct-to-consumer marketing and
17 correspondence with the FDA on those issues. We would object
18 to that. They're not relevant. There are no
19 direct-to-consumer claims in this action, and totally different
20 standards apply to direct-to-consumer --

21 THE COURT: When you say "may" -- who is handling
22 this witness? Is that an issue, Mr. Marketos?

23 MR. MARKETOS: Oh, yes, Your Honor. This is the
24 witness on the DDMAC letter, and they've made a relevance
25 objection to it. And as I told Your Honor, it's an artificial

1 distinction, and this is the witness that we're calling. They
2 filed no motion in limine on this issue. They just made a
3 relevance objection at trial.

4 And in my opinion, Your Honor, that was so that we
5 could siphon this testimony to this witness instead of asking
6 Mr. Mattes about it, asking other witnesses about it. But this
7 is the witness.

8 THE COURT: Mr. Klein, you're handling this witness?

9 MS. BROWN: I am, Your Honor.

10 THE COURT: Ms. Brown, you're handling this witness?

11 MS. BROWN: Yes, Your Honor.

12 THE COURT: Let me get this straight. Mr. Patel is
13 from compliance?

14 MS. BROWN: Your Honor, regulatory and compliance,
15 correct.

16 THE COURT: All right. So he knows the difference
17 between marketing to consumer and marketing to physicians?

18 MS. BROWN: Yes, Your Honor.

19 THE COURT: So if you want to establish the limited
20 probative value of this, can't you establish that in your
21 examination of the witness? Because relevance -- my point is
22 simply that this is a relevance objection, right?

23 MS. BROWN: I think it's also prejudicial, Your
24 Honor, and I think the problem is the fear that it becomes
25 confusing for the jury to distinguish and there is prejudice

1 that they conflate the two when we know there are two very,
2 very separate regimes for what is appropriate in a
3 direct-to-consumer marketing versus what is appropriate in a
4 direct-to-health care marketing regime.

5 And we've argued this at sidebar a couple of times
6 throughout the trial, which is why we wanted to raise it in
7 advance. But they know that that's true because they asked
8 Dr. Patel about this at his deposition, and he explained the
9 different regimes and the fact that different reviewers at
10 DDMAC consider the pieces under different guidelines.

11 THE COURT: All right. So let me ask Mr. Marketos.
12 Again, I'm not understanding. Where are you going with this?
13 I don't have the documents in front of me, and I don't want to
14 spend a lot of time on this, because I want the witness in the
15 witness stand.

16 MR. MARKETOS: Your Honor, that's not true. What
17 they just said is not true. There's no distinction between the
18 two. They're governed by the same laws, and you're going to
19 see exactly why it's relevant and what they did with it as it
20 relates to their health care provider sales and marketing.

21 This goes to the heart of the case, and that's why
22 they didn't file a brief on it, they didn't file a motion in
23 limine on it. It's just evidence they don't want to come in.

24 THE COURT: All right. Well, here's what I'm going
25 to do. I'm going to wait to hear what the question is and what

1 the anticipated response is. If there's an objection, I'll
2 have to deal with it in real time.

3 By the way, why wasn't this briefed? With all the
4 amount of paperwork you've all filed with me prior to trial and
5 during the trial, how is this being brought up, you know, the
6 morning of when the witness is going to testify?

7 MS. BROWN: It's come up a couple of times, Your
8 Honor. I thought it was resolved at sidebar actually. The
9 Court had agreed that direct-to-consumer marketing is not
10 relevant and the two times they tried to use the piece
11 sustained the objection.

12 So our view is that it's a different scheme. It's
13 not appropriate here for at least two reasons. And we thought
14 this was resolved at sidebar twice.

15 MR. MARKETOS: I'm sorry, Your Honor. I disagree. I
16 specifically, when they raised this when I was trying to get
17 into it with Mr. Mattes, pointed out the fact that this is a
18 false distinction, it was going to fall flat, but we would then
19 address it with this witness.

20 THE COURT: I recall some of that response from
21 Mr. Marketos. So I don't think he withdrew any objection or
22 revisiting this issue at a later date. I don't have the
23 transcript of that sidebar in front of me, but I do recall that
24 Mr. Marketos walked back a bit, but that it was going to come
25 up again. So here it is.

1 So, look. Like I said, I'm going to get the witness
2 in the witness stand. We're going to hear the examination. If
3 there's an issue, I'll see what the witness says, and we'll
4 deal with an objection in real time.

5 What else?

6 MR. MARKETOS: That's all, Your Honor.

7 THE COURT: Okay. Kim, do you want to get the
8 jurors?

9 THE DEPUTY CLERK: Sure.

10 THE COURT: Did we call him yet?

11 MR. MARKETOS: No, Your Honor.

12 THE COURT: Sorry, Mr. Patel. You got to go back,
13 only because they're going to be, like, who are you, why are
14 you sitting in the witness box. Once you're in, you're in, but
15 until then...

16 THE DEPUTY CLERK: All rise.

17 (The jury enters the courtroom at 11:07 a.m.)

18 THE COURT: All right. Folks, everyone be seated.

19 Mr. Marketos, do you have the next witness?

20 MR. MARKETOS: I do, Your Honor. The Relators call
21 Mr. Amit Patel.

22 THE COURT: Mr. Patel, I'm just going to have you
23 sworn in when you come in, and then you can proceed.

24 THE DEPUTY CLERK: Please raise your right hand.

25 (Witness sworn.)

1 THE DEPUTY CLERK: Please state your name and the
2 spelling of your last name.

3 THE WITNESS: Amit Patel, P-A-T-E-L.

4 THE COURT: You may be seated.

5 Mr. Marketos, whenever you're ready to proceed, you
6 may.

7 MR. MARKETOS: Thank you, Your Honor.

8 DIRECT EXAMINATION

9 BY MR. MARKETOS:

10 Q. Mr. Patel. Good morning, sir.

11 A. Good morning.

12 Q. My name is Pete Marketos. I represent the Relators in the
13 lawsuit that's been filed in a whistleblower action against
14 Janssen.

15 Are you aware of that, sir?

16 A. Yes.

17 Q. You and I have not had an opportunity to speak before
18 today, true?

19 A. True.

20 Q. You, sir, are represented today by counsel for Janssen,
21 correct?

22 A. Yes.

23 Q. Now, you have lawyers who have represented Janssen, and
24 they're also representing you, correct?

25 A. Correct.

1 Q. And you have also given a deposition in this case, sworn
2 testimony under oath, right, sir?

3 A. Yes.

4 Q. That was actually very recently.

5 That was this year, correct?

6 A. Yes.

7 Q. And you used to work at Janssen, right, sir?

8 A. Yes.

9 Q. For a number of years within the Johnson & Johnson family
10 of companies, correct?

11 A. I worked primarily in the pharmaceutical business of
12 Johnson & Johnson.

13 Q. Yes, sir. You worked for Johnson & Johnson
14 pharmaceuticals, including involvement with the Janssen
15 subsidiaries, correct?

16 A. Yes.

17 Q. And as I understand it, sir, before you gave your
18 deposition testimony in this case this year, you had prepared
19 for that testimony for approximately 30 hours, correct?

20 A. Correct.

21 Q. And since that time, since you gave that testimony, you've
22 had further opportunities to prepare for your testimony today
23 with the lawyers who are representing Janssen in this case,
24 correct?

25 A. Yes.

1 Q. And when did you arrive in this state, Mr. Patel, in order
2 to prepare for your testimony?

3 A. I arrived on Tuesday night, and Wednesday I met with my
4 lawyers to prepare for the testimony.

5 Q. Thank you, sir.

6 So -- and prior to arriving in town physically on Tuesday,
7 you had a number of preparatory sessions after your deposition
8 for your testimony today, correct?

9 A. No, I didn't have any conversation after testimony.

10 Q. Okay. So as I understand it, you provided your deposition
11 testimony in this case and had prepared approximately 30 hours
12 for that deposition testimony, correct?

13 A. Approximately, yeah.

14 Q. And since that testimony -- that was in or about March of
15 this year, correct?

16 A. I think so.

17 Q. All right. And then since then, you came into town on
18 Tuesday, and then you met with lawyers for Janssen who are
19 representing Janssen in this trial, correct?

20 A. They're representing Janssen and me also.

21 Q. You met with them for a number of hours, correct?

22 A. Yes, yesterday.

23 Q. All right. Approximately how many hours did you meet with
24 them yesterday?

25 A. Five hours.

1 Q. About five hours?

2 A. Yeah.

3 Q. Okay. So it's fair to say that you have, for the purposes
4 of the testimony that you've offered in this lawsuit brought by
5 the Relators, Ms. Brancaccio and Ms. Penelow, you've put in
6 about 35 hours of your own time; is that right?

7 A. Correct.

8 Q. How about -- now, specifically, that's with respect to
9 meeting with lawyers and preparing.

10 How about on your own time, sir? Have you been reviewing
11 deposition testimony on your own time?

12 A. No. I was asked to confirm my deposition written
13 testimony was accurate, so that -- you can add a few hours to
14 that to make sure the written testimony -- written document
15 reflected my deposition testimony. So I reviewed that. So you
16 can add two more hours to that.

17 Q. Okay, sir. And how about with respect to the time in
18 between? Were you able to review documents provided to you by
19 Janssen in order to prepare for your deposition without
20 lawyers?

21 A. No.

22 Q. All right. Sir, you have a degree in biochemistry and a
23 degree in pharmacology; is that right?

24 A. I have a degree in biochemistry, and I'm a Doctor of
25 Pharmacy. Pharmacy degree, not pharmacology.

1 Q. So you have a bachelor's degree in pharmacy, right?

2 A. I have a Doctorate degree in pharmacy.

3 Q. I'm going to get to that. Sorry.

4 A. Sorry.

5 Q. You do have a bachelor's degree in pharmacy; is that
6 right?

7 A. Right.

8 Q. And you have a doctorate in pharmacy?

9 A. Correct.

10 Q. So two bachelor's degrees and a doctorate; is that right?

11 A. Correct.

12 Q. As I understand it, you received that Doctorate in
13 pharmacy in 2003, right?

14 A. Yes.

15 Q. And then you began a fellowship where you worked for nine
16 months at the Food & Drug Administration, correct?

17 A. As part of my fellowship, yeah, training.

18 Q. As part of your fellowship training, you worked at the
19 Food & Drug Administration itself, right, sir?

20 A. Yes.

21 Q. Specifically, you spent time with the Division of Drug
22 Marketing, Advertising, and Communications, what's also known
23 as DDMAC, correct?

24 A. Correct.

25 Q. And that is the division of the food and drug agency that

1 actually looks at marketing and promotional materials that
2 pharmaceutical companies share with patients, with consumers,
3 and with health care providers, correct?

4 A. Correct.

5 Q. And then you spent nine months, as I understand it, during
6 that fellowship at Johnson & Johnson?

7 A. Correct.

8 Q. In 2005, sir, you became a manager of regulatory
9 advertising and promotion at Johnson & Johnson, correct?

10 A. Correct.

11 Q. And your main responsibility was reviewing Janssen's
12 marketing materials and helping them comply with the FDA's
13 regulation on marketing in this country, right, sir?

14 A. Correct.

15 Q. And your job was, as you've explained it to us, was to
16 interpret FDA regulations pertaining to prescription drug
17 promotion, right?

18 A. Correct.

19 Q. And then you would guide Janssen and help it with its
20 marketing messages to ensure Janssen complied with the FDA's
21 laws, right?

22 A. Correct.

23 Q. And in 2006, you were promoted to the director of
24 regulatory advertising and promotion, correct?

25 A. No.

1 Q. Okay. I understood that in 2006 you were promoted to a
2 director. Are you saying that's not true?

3 A. It would be associate director.

4 Q. I'm sorry?

5 A. Associate director.

6 Q. Associate director. Okay. And that was in 2006 as well?

7 A. I believe that sounds right.

8 Q. All right, sir. And you had the similar job
9 responsibilities as we've just described, fair?

10 A. Fair.

11 Q. And then except that you worked closer with senior
12 executives on matters relating to regulatory and transactional
13 promotion, right?

14 A. Yes.

15 Q. Now, in both of those jobs that you held with Johnson &
16 Johnson, you yourself, Mr. Patel, communicated with the FDA,
17 specifically with DDMAC, correct?

18 A. I was a liaison between the company and the FDA and
19 communicated, yes.

20 Q. Okay. So when I say you communicated with DDMAC, you
21 communicated with DDMAC, fair?

22 A. Yes.

23 Q. All right. And again, just as a reminder, that's the
24 specific subdivision within the FDA that looks at marketing
25 messages that pharmaceutical companies are spreading throughout

1 the United States, correct?

2 A. Correct.

3 Q. Now, in 2010, as I understand it, you made a lateral
4 transfer to become the head compliance officer of Janssen; is
5 that right?

6 A. That's not correct.

7 Q. Okay. Did you become a compliance officer for
8 Janssen/Tibotec in 2010?

9 A. No.

10 Q. No. Were you ever a compliance officer for Janssen?

11 A. Yes. I was a compliance officer for Janssen CNS and as
12 part of my responsibility also I had Tibotec Therapeutics, but
13 I had somebody reporting to me who was the primary responsible
14 for day-to-day function of compliance.

15 Q. Sorry, sir, you said Janssen CNS, that's a different
16 Janssen company?

17 A. It's within Janssen, Janssen CNS focused on psychiatry
18 products.

19 Q. One more time, I just need to make sure I get this right.

20 THE COURT: Mr. Patel, can you put the microphone a
21 little bit closer to you so it's a little louder? Thanks.

22 BY MR. MARKETOS:

23 Q. Have you ever served as a compliance officer? To be
24 sure --

25 A. Yes.

1 Q. To be clear, sir, let me make a distinction here. We
2 talked about your original job with Johnson & Johnson as a
3 manager of regulatory advertising and promotion and associate
4 director of regulatory advertising and promotion, right, sir?

5 A. Uh-huh.

6 Q. Is that correct?

7 A. Yes.

8 Q. I'm sorry. The court reporter --

9 A. Yes, that's correct.

10 Q. Sorry, Mr. Patel, I apologize. The court reporter's
11 taking down my questions and your answers, so we'll try not to
12 speak over one another.

13 A. Okay.

14 Q. And if you would, sir, we can't really say uh-huh, because
15 that doesn't translate to a transcript, okay, sir?

16 All right. So as I understand it, sir, you did become a
17 compliance officer for the Janssen entity that we're talking
18 about in this trial; is that true?

19 A. Yes.

20 Q. Was that in 2010?

21 A. Yes.

22 Q. And you were in that position until 2015 when you
23 resigned, right?

24 A. Correct.

25 Q. And that was due to personal reasons?

1 A. Yes.

2 Q. So from 2006 through the first half of 2010, you were not
3 performing a compliance officer role for Janssen/Tibotec?

4 A. Correct.

5 Q. At that time, 2006 through 2010, your role at Janssen was
6 in the product and advertising department, correct?

7 A. Regulatory advertising and promotion department.

8 Q. And then you became a compliance officer in 2010, which is
9 a different role, correct?

10 A. Correct.

11 Q. Before 2010, you did not give compliance advice at Janssen
12 because that was the job of the compliance officers, not you,
13 right?

14 A. On -- that's correct, and I can further explain.

15 Q. Before 2010, your role relating to compliance was only
16 about giving advice relating to advertisement, not speaker
17 programs, correct?

18 A. Can you repeat the question, sir? I didn't understand
19 your question.

20 Q. Before 2010, your role relating to compliance, if at all,
21 was about advice relating to advertising, not speaker programs?

22 A. That's incorrect.

23 Q. Okay. Before 2010, you had no role in compliance with
24 respect to hiring speakers for the Prezista/Intelence speaker
25 programs, correct?

1 A. That's incorrect.

2 Q. Okay.

3 If we could, sir, I'm going to play a deposition
4 transcript.

5 MR. MARKETOS: I'm going to play lines 23 and 13.

6 This is page 65, 23 through 66, 13.

7 THE COURT: Ms. Brown, any issue?

8 MS. BROWN: No, Your Honor.

9 THE COURT: All right. You may play it.

10 (Audio playing.)

11 BY MR. MARKETOS:

12 Q. Before 2010, Mr. Patel, you had no role in compliance with
13 respect to hiring speakers for the Prezista/Intelence speaker
14 program, true?

15 A. That's not true.

16 Q. Okay. Is there a different answer than you gave during
17 your deposition? That's all I want to know for now.

18 A. No. I was involved as part of a SAFE committee to review
19 speaker program, so I did have involvement. Your question is
20 was I involved or not, so that's why I'd have to say no.

21 Q. Okay. Sir, you were part of the SAFE committee?

22 A. Yes.

23 Q. Okay. We'll come back to that.

24 A. Okay.

25 Q. Before 2010, you had no personal knowledge whether Janssen

1 tracked speaker prescriptions. Do you recall that?

2 A. I don't remember.

3 Q. You have no personal knowledge as we sit here today as to
4 whether Janssen was tracking prescriptions of the speakers that
5 it was paying to speak on the speaker bureau, true?

6 A. Correct.

7 Q. And before 2010, you don't recall attending any speaker
8 programs for Prezista and Intelence, correct?

9 A. I don't recall. I have to look at the -- if I did, it
10 would be documented.

11 Q. You don't remember attending any speaker programs for
12 Prezista or Intelence, the promotional speaker bureau, before
13 2010, correct?

14 A. I don't remember.

15 Q. You also don't remember attending speaker programs for
16 Prezista or Intelence after 2010, correct?

17 A. No, that's not correct.

18 Q. You do recall attending, is that what you're saying?

19 A. Yes, yes.

20 Q. Okay. So let's just take it from there. From 2006 to
21 2010, you don't recall attending any speaker programs for
22 Intelence or Prezista; is that right?

23 A. Correct.

24 Q. Sir, you understand what the allegations that the Relators
25 have brought forward in this lawsuit, correct?

1 A. Yes.

2 Q. You understand that the Relators have alleged that Janssen
3 was engaged in the off-label marketing of Prezista and
4 Intelence from the time period of 2006 through 2014, right?

5 A. Yes.

6 Q. And that Janssen was using speaker programs, promotional
7 speaker bureaus, as a vehicle to pay kickbacks to doctors so
8 they would increase their prescriptions of those two drugs.
9 You understand those are the allegations, right, sir?

10 A. I understand those are the allegations, yes.

11 Q. One of those allegations involves messaging that Janssen
12 was delivering to health care providers relating to its lipid
13 profile. You understand that?

14 A. Yes.

15 Q. And you understand it's one of the allegations in this
16 case that Janssen was giving messages for its sales force to
17 deliver nationwide with respect to Prezista's lipid profile,
18 right, sir?

19 A. Yes.

20 Q. And it's the Relators' allegations in this case that those
21 messages were false and misleading. Do you understand that?

22 A. Yes, I understand those are the allegations.

23 Q. Specifically as it relates to the lipid profile, that
24 those messages were intended to minimize the side effects
25 associated with Prezista, right, sir? Those are the

1 allegations?

2 A. Yes, those are allegations.

3 Q. You also understand the allegations brought by the
4 Relators includes that Prezista was marketed to naïve patients
5 through health care providers before it had a label for naïve
6 patients. Do you understand that's another allegation?

7 A. Yes.

8 Q. And also, that Intelence was marketed to doctors as
9 suitable for once a day QD dosing, right, sir? That's an
10 allegation in this case?

11 A. Yes.

12 Q. And, finally, sir, that the drug Intelence was marketed to
13 doctors for their patients who were naïve when Intelence was
14 only labeled on label for treatment-experienced patients, do
15 you understand that that's another allegation that's been made
16 in this case?

17 A. Yes.

18 Q. Now, I'd like to turn your attention to the promotional
19 materials that Janssen provided to its sales force and that
20 they would share with health care providers, okay, sir?

21 A. Sure.

22 Q. And your involvement in those marketing materials was to
23 review materials that were provided to you from the marketing
24 department within Janssen, correct?

25 A. I was part of a multidisciplinary team to review those

1 materials, yes.

2 Q. But I'm just asking about your role, sir, not the
3 multidisciplinary team. I'm asking about your role, okay?

4 A. Okay.

5 Q. Your role, how you were involved from 2006 to 2010, was
6 reviewing promotional materials that were going to be used by
7 the sales force to help sell the drug to doctors, right, sir?

8 A. Yes, I was involved, yes.

9 Q. And the way that you were involved, sir, was you would
10 review the materials and you would determine or help Janssen
11 determine whether they were compliant with FDA laws and
12 regulations, correct?

13 A. Correct.

14 Q. And then you would serve as the liaison between Janssen
15 and the Food & Drug Administration, the FDA, correct?

16 A. Yes.

17 Q. One of the ways you would do that, sir, was you would take
18 a promotional material from Janssen and you would submit it to
19 the DDMAC with what's called a Form 2253, right, sir?

20 A. There is a step before that, but what you mentioned is
21 accurate for final materials that are submitted on 2253.

22 Q. Yes, sir, I thought I went through the process, but let me
23 make sure I got it right, okay?

24 First, you would review the material itself internal to
25 Janssen, right, sir?

1 A. Correct.

2 Q. All right. When you believed that that material was in
3 final form ready to send to the Food & Drug Administration, you
4 would send it with a form, right, sir?

5 A. So Prezista and Intelence, both products, were put under
6 subpart H. And per regulation, you had to submit all your
7 draft materials. So based on draft label, you submit to FDA
8 prior to approval or during the approval for advisory feedback.
9 Once you receive the feedback, you incorporate all the feedback
10 into the final material. And that's the material you submit on
11 Form 2253. So the step was there was advisory requirement by
12 regulations.

13 Q. Thank you, Mr. Patel.

14 Prezista was actually approved by the Food & Drug
15 Administration and it received a specific label, right, sir?

16 A. That is correct.

17 Q. And then when marketing takes place in the United States
18 by a pharmaceutical company, it is required to market only on
19 label; that is, on the label that the Food & Drug
20 Administration had approved, correct?

21 A. Correct.

22 Q. And after a label is approved, now you're out of subpart
23 H, you can submit promotional materials to DDMAC going forward,
24 correct?

25 A. Can you rephrase the question?

1 Q. Sure. Let me just turn your attention to the
2 November 2008 time frame. November 2008 time frame was
3 approximately two and a half years after Prezista had received
4 its FDA label, correct?

5 A. 2006, yeah, that's right.

6 Q. If we go with June 2006?

7 A. Yeah.

8 Q. And November 2008, that's approximately two and a half
9 years, right, sir?

10 A. Sure.

11 Q. All right. So during that time period, if you're
12 submitting something to DDMAC, you're submitting it with a Form
13 2253, correct?

14 A. I think you're not correctly describing the process.

15 MR. MARKETOS: All right. Let's take a look for the
16 witness, please, at DX-2088. For the witness and counsel only,
17 please, Ms. Johnson.

18 BY MR. MARKETOS:

19 Q. Sir, I'm showing you Defendants' Exhibit 2088, do you
20 recognize that as a Form 2253 document?

21 A. Yes.

22 Q. And so that we're clear, this is essentially a cover sheet
23 where information is provided about what type of promotional
24 materials are attached and being sent to the government,
25 correct?

1 A. Correct.

2 MR. MARKETOS: Your Honor, we'd offer Defendants'
3 Exhibit 2088.

4 MS. BROWN: No objection, Your Honor.

5 THE COURT: So admitted.

6 (Exhibit D-2088 admitted into evidence.)

7 MR. MARKETOS: Now, let's turn to Defendants' Exhibit
8 2089, please. This has been previously admitted.

9 BY MR. MARKETOS:

10 Q. What you can see here, sir, and we can publish it, this
11 has been admitted, do you see in front of you, sir, materials
12 that were sent with the Form 2253 that we just looked at?

13 A. Yes.

14 MR. MARKETOS: And if you turn to the second page.

15 BY MR. MARKETOS:

16 Q. Do you see there's a reference here to the promotional
17 material for Prezista, low impact on lipids?

18 A. Yes.

19 Q. Again, this is information that Janssen is providing
20 because it wants to use these marketing materials out in the
21 field to market to doctors, correct?

22 A. Yes.

23 MR. MARKETOS: If we look at Exhibit 2100, DX-2100.

24 BY MR. MARKETOS:

25 Q. This is a February 25, 2009, Form 2253. Do you see that,

1 sir?

2 A. Yes.

3 Q. And you actually signed it yourself, that's your signature
4 on it, correct?

5 A. A representative of Janssen signed on behalf of me.

6 Q. Somebody signed your name?

7 A. Yes.

8 Q. Okay. You recognize this document?

9 A. Yes.

10 MR. MARKETOS: We'd offer Defendants' Exhibit 2100,
11 Your Honor.

12 MS. BROWN: No objection, Your Honor.

13 THE COURT: So admitted.

14 (Exhibit D-2100 admitted into evidence.)

15 BY MR. MARKETOS:

16 Q. And what was attached to this form has previously been
17 admitted as Defendants' Exhibit 2101. Can you see, sir, this
18 is Prezista once daily promotional materials that Janssen was
19 sending to the Food & Drug Administration?

20 A. Yes.

21 MR. MARKETOS: If we take a look at page 15 of this
22 document.

23 BY MR. MARKETOS:

24 Q. Do you see the reference there, sir, to low impact on
25 lipids?

1 MR. MARKETOS: Turn to the next page. Sorry, the
2 prior page, ma'am, I'm sorry.

3 Thank you, Ms. Johnson. Would you go to page 15? I
4 apologize.

5 BY MR. MARKETOS:

6 Q. All right. Sir, do you see there's a reference here to
7 the mean low-density lipoprotein LDL and total cholesterol
8 values?

9 A. Yes.

10 Q. And in this marketing material Janssen was also promoting
11 Prezista as having low impact on lipids, correct?

12 A. Correct. Based on the document, yes.

13 Q. Now, sir, given your experience with working for DDMAC,
14 given your role in regulatory compliance with Janssen, you knew
15 that any marketing materials for pharmaceutical drugs must
16 contain true statements, correct?

17 A. Correct.

18 Q. And the Food & Drug Administration, you know, requires
19 that in order for a statement to be true, it cannot minimize
20 side effects, right, sir?

21 A. I don't understand your question, sir.

22 Q. Yes. Not minimizing side effects is one of the
23 regulations?

24 A. Correct.

25 Q. Thank you. Let's make sure that we're clear here. You

1 understand that minimizing side effects is against FDA
2 regulations, right, sir?

3 A. Correct.

4 Q. And that's part of what would make a statement not true,
5 if you were to minimize side effects, that would make a
6 statement that is promotional about a drug not true, correct?

7 A. I disagree.

8 Q. I'm sorry, let me make sure I do this in order. You
9 understand that it is a requirement of the Food & Drug
10 Administration that you cannot minimize the side effects of a
11 drug, correct?

12 A. Correct.

13 Q. And if a promotional material does, in fact, minimize the
14 side effect of the drug, that would make it not true, correct?

15 A. That would make it false and misleading.

16 Q. Okay. So that's what I meant by not true. So let me just
17 go ahead and define not true. If it's not true, it's false,
18 right, sir?

19 A. Correct.

20 Q. Okay. So if a pharmaceutical manufacturer is marketing a
21 drug and it's minimizing the side effects, that would make that
22 promotional material false and misleading, correct?

23 A. It may be false and misleading.

24 Q. Well, if you are minimizing the side effects, that is
25 false and misleading under FDA regulations, correct?

1 A. It's if. If you minimize, then it is false and
2 misleading.

3 Q. Yes, sir. I'm sorry. I thought that was my question. If
4 a pharmaceutical company minimizes the side effects of its
5 drugs in its promotional materials, that is false and
6 misleading, correct?

7 A. That is correct.

8 Q. And that is not permitted in this country, correct?

9 A. That is against FDA regulations.

10 Q. I'm sorry?

11 A. That is against FDA regulations.

12 Q. Yes, sir, the Food & Drug Administration, which is in this
13 country, right?

14 A. Yeah.

15 Q. Okay.

16 What you also know that you can't do if you're a
17 pharmaceutical manufacturer, you can't omit material facts
18 about a drug in your promotional materials, correct?

19 A. That is a requirement of the regulation, correct.

20 Q. It is a requirement of the regulations that pharmaceutical
21 companies not omit material facts about their drugs in their
22 promotional materials, correct?

23 A. Correct.

24 MR. MARKETOS: Let's turn to Defendants' Exhibit
25 4263.

1 BY MR. MARKETOS:

2 Q. Defendants' Exhibit 4263 is compliance guidelines for
3 promotional speakers. Do you see that, sir?

4 A. Yes.

5 Q. And you wrote this document?

6 A. Yes.

7 MR. MARKETOS: We'd offer Defendants' Exhibit 4263,
8 Your Honor.

9 MS. BROWN: No objection.

10 THE COURT: So admitted.

11 (Exhibit D-4263 admitted into evidence.)

12 MR. MARKETOS: If we could publish that? Thank you,
13 Ms. Johnson.

14 BY MR. MARKETOS:

15 Q. Now, Mr. Patel, this is October 2010 compliance guidelines
16 for promotional speakers. And this is a document that we can
17 see on the cover page that you authored, correct?

18 A. Yes.

19 Q. And this is after you've become a compliance officer
20 within Janssen, correct?

21 A. Correct.

22 Q. And if we turn to page 9 of this document, you were
23 providing guidelines within the organization as to what makes
24 something on label and what would make it false or misleading.
25 Do you see that?

1 A. Correct.

2 Q. And with respect to false or misleading, product claims
3 not consistent with the FDA-approved package insert, PI is the
4 label, right, sir?

5 A. Yeah.

6 Q. Product claims not consistent with the FDA-approved label,
7 or not supported by substantial evidence or substantial
8 clinical experience, that would make a promotional material
9 false and misleading, correct?

10 A. That's, yes, accurate.

11 Q. Sir, just so we're clear, that would include minimizing
12 side effects, correct?

13 A. Minimizing side effects is one example of false and
14 misleading.

15 Q. Yes, that's what I meant by including, Mr. Patel.

16 A. Yeah.

17 Q. Minimizing side effects is an example of something that is
18 false or misleading, right, sir?

19 A. Yes.

20 Q. And that would be considered off-label promotion, correct?

21 A. That is incorrect.

22 Q. Okay, sir. I understand you're not aware of this, sir,
23 you're saying something can be false and misleading in terms of
24 minimizing a side effect that is on a drug's label and that
25 would not be considered off-label promotional; is that your

1 testimony?

2 A. That is, right, correct.

3 MR. MARKETOS: If we turn to page 10.

4 BY MR. MARKETOS:

5 Q. These are examples that you were giving to other employees
6 at Janssen, right, sir?

7 A. These are based on regulations, yes.

8 Q. All right. But that wasn't my question.

9 These were examples that you were providing to other
10 employees at Janssen, correct?

11 A. Based on the document, this sounds like a speaker
12 training, so I was explaining to the speakers what is the FDA
13 regulations.

14 Q. Okay. And you provide examples of what's false and
15 misleading, and that includes the number of bullet-pointed
16 items that you, I guess, provided to doctors; is that right?

17 A. Correct.

18 Q. Now you're telling doctors what's false or misleading; is
19 that fair?

20 A. That's part of the speaker training, yes.

21 Q. And that includes broadening of the product indication,
22 right? Making the labeled drug broader than what was actually
23 approved by the FDA, correct?

24 A. Yes.

25 Q. Data taken out of context, that's false and misleading,

1 right?

2 A. Yes.

3 Q. Minimization of safety issues, that's false and
4 misleading, right, sir?

5 A. Yes, sir.

6 Q. Omitting material information, that would be false and
7 misleading, correct?

8 A. Yes.

9 Q. Or comparing the efficacy or safety claims without
10 substantial evidence, like two well-controlled head-to-head
11 trials. That's what you were telling the doctors --

12 A. Correct.

13 Q. -- right?

14 Are you saying that this -- as I understand it, sir, are
15 you saying that this actual program was not also delivered to
16 the employees of Janssen itself?

17 A. Can you rephrase the question?

18 Q. Yes, sir. You said earlier that this was a training, you
19 believe, of doctors for the speaker program.

20 This was also used to train those who were implementing
21 the program at Janssen, correct?

22 A. They were always part of the process, so people
23 responsible for speaker program were participating in training
24 also. So they will get the same training. And this is part of
25 our compliance program about what speakers should and should

1 not do.

2 Q. Thank you, sir.

3 So the people who implemented the speaker bureau programs
4 at Janssen, that was the sales force, right, sir?

5 A. It was a marketing responsibility.

6 Q. Marketing owned the program, and the sales force
7 implemented it.

8 You know that, right?

9 A. Execution, yes, correct.

10 Q. Execution, that's what I meant by implemented. I
11 apologize.

12 A. Okay.

13 Q. The sales force executed on, they implemented the program,
14 right, sir?

15 A. Sure.

16 Q. So this training was provided not just to the speakers but
17 also, as I understand it, to the marketing and sales force who
18 were implementing the program, correct?

19 A. What I can testify is this particular document is focused
20 on speaker program training. There are other trainings that
21 cover similar principles, but the reps go through different
22 training on company policies on speaker program related.

23 Q. These policies were delivered to the sales force as well,
24 correct?

25 A. Yes.

1 Q. And to the marketing department as well since it owned the
2 promotional speaker bureau program, correct?

3 A. Yes.

4 Q. Another thing you're not permitted to do because it would
5 make your promotional materials false or misleading is
6 overstating the safety, efficacy or safety, right, sir?

7 A. Yes.

8 Q. Superior to, more effective, better than, safer than, more
9 tolerable. You can't do that. You can't compare two drugs to
10 one another in terms of safety and efficacy that have not been
11 compared in a clinical trial that was approved by the FDA,
12 correct?

13 A. Correct.

14 MR. MARKETOS: If we take a look at page 11.

15 BY MR. MARKETOS:

16 Q. Another example of something that would be false and
17 misleading, sir, you were teaching doctors and the sales force
18 and marketing, was that efficacy or safety claims based on
19 healthy volunteers in vitro or other nonclinical information
20 with unknown clinical relevance, that would be false and
21 misleading, correct?

22 A. Correct.

23 MR. MARKETOS: Let's take a look quickly at Relators'
24 Exhibit 74.

25 BY MR. MARKETOS:

1 Q. Relators' Exhibit 74 is already in evidence, sir. This is
2 a document that we looked at earlier in the trial. This is an
3 email from Mr. Tim McSherry that was circulated within the
4 Janssen sales force.

5 Have you ever seen this email, Mr. Patel?

6 A. Can you give me a minute to look through it?

7 Q. Sure. Absolutely.

8 A. I was not copied on the email, so I have no knowledge of
9 this email.

10 Q. Okay. Sir, I've just got some questions for you about it.

11 What is attached to this document, this email that's
12 already in evidence, that Mr. McSherry was referring to was
13 called a DART study, D-A-R-T.

14 Do you see that attachment referring to Lipid Prezista vs.
15 Reyataz.doc at the top?

16 A. Yes. From this document, yes, I do see it.

17 Q. You know Tim McSherry, right, sir?

18 A. I don't recall.

19 Q. You don't remember him; is that right?

20 A. No.

21 Q. Do you remember that he was part of the sales force?

22 A. I don't recall.

23 Q. You can see at the top there he's actually copying one of
24 the Relators, Ms. Christine Brancaccio.

25 Do you see that?

1 A. Okay.

2 Q. Okay. And he's attaching what is an off-label study known
3 as the DART study.

4 Have you seen the DART study before, Mr. Patel?

5 A. Not to my knowledge.

6 Q. Okay. Well, if we take a look at the attachment, this is
7 a study that looked at TMC114. That was Prezista, right, sir?

8 MR. MARKETOS: You can blow up the top half for now,
9 please, Ms. Johnson.

10 BY MR. MARKETOS:

11 Q. A study of the metabolic changes in healthy volunteers
12 compared to Reyataz.

13 Do you see that?

14 A. Yes, I do.

15 Q. TMC114, just for the benefit of the members of the jury,
16 that was Prezista, right, sir?

17 A. Yes.

18 Q. And this study was looking at healthy volunteers and in
19 comparison to Reyataz, correct?

20 A. Correct.

21 Q. If we go down to the actual description, you can see the
22 methods -- Ms. Johnson, thank you.

23 This was a study that was performed in 49 HIV-negative
24 healthy male volunteers, right, sir?

25 A. Sure.

1 Q. And it was screening for lipids, and it looks like they
2 were on a drug for about seven days and then they were tested
3 for 21 more days, right, sir?

4 A. According to the document, yes.

5 Q. Okay. And as I understand it, you've not reviewed the
6 DART study before today?

7 A. No.

8 Q. All right, sir. So just to summarize, 49 patients,
9 they're healthy, they're taking a drug for 28 days, right, sir?

10 A. This is a clinical study, so according to the protocol,
11 that's what it sounds like.

12 MR. MARKETOS: Okay. So if we go back to exhibit --
13 well, let's take a look at the email if you would, please.

14 BY MR. MARKETOS:

15 Q. This is what Mr. McSherry is sharing with other members of
16 the sales force.

17 Do you see that?

18 A. Yes.

19 Q. He even says to himself, one side note, the study design
20 had patients on ritonavir alone for seven days before going on
21 boosted Prezista or boosted Reyataz for 21 additional days. I
22 don't understand my -- I think he meant why -- why the
23 investigators did this besides just trying to improve the
24 results.

25 Do you see that?

1 A. I do see it.

2 MR. MARKETOS: All right. Let's go back to 4263,
3 please, Ms. Johnson, and we'll turn to page 11.

4 BY MR. MARKETOS:

5 Q. Based on what your role was, Mr. Patel, and the guidance
6 that you were providing to employees of Janssen and to doctors,
7 it would be false and misleading for any member of the sales
8 force to use a DART study like the one we just looked at to
9 promote Prezista to doctors, agreed?

10 A. Agree. It was never approved.

11 Q. And if, in fact, a study like the DART study, which was
12 off label in healthy patients comparing to Reyataz and was not
13 FDA approved, if a study like that were being used to promote
14 the drug to doctors, that would be false and misleading.

15 You would agree?

16 A. According to FDA regulation, yes.

17 MR. MARKETOS: We'll take a look at page 12.

18 BY MR. MARKETOS:

19 Q. You gave further examples of what is considered off-label
20 information in your own slide, right, sir?

21 A. Yes.

22 Q. Any information about a drug's use or safety not found
23 within the label is considered to be off label, right, sir?

24 A. That is not a correct definition according to what current
25 standards are by FDA. So this is probably, I don't know, in

1 2010.

2 Q. Yes, sir. It's the relevant time period for this lawsuit,
3 and it's a document that you wrote in 2010.

4 A. Yes. What I wrote is what you see here, yeah.

5 Q. Of course we're talking about a time frame in this lawsuit
6 from 2006 to 2014, correct?

7 A. Okay.

8 Q. And I assume that what you wrote at the time was true,
9 correct?

10 A. That's my understanding of the regulation, yes.

11 Q. That's your understanding about the regulation.

12 That was your job, right, Mr. Patel?

13 A. Yes.

14 Q. Any information about a drug's use, administration, or
15 safety not found within the label is considered to be off
16 label.

17 That's what you wrote, fair?

18 A. Fair.

19 Q. And then you gave examples of what that might include.
20 Examples of off-label information include a different use or
21 indication for the drug, correct?

22 A. Yes.

23 Q. Different patient population or age group, right?

24 A. Yes.

25 Q. For instance, if something is on label for

1 treatment-experienced patients but it's marketed to
2 treatment-naïve patients, that would be a different patient
3 population?

4 A. Correct.

5 Q. A different dosing schedule was considered off label,
6 correct?

7 A. Yes.

8 Q. For instance, if something is on label for twice-a-day
9 dosing, BID, and it's marketed or promoted as once-a-day
10 dosing, QD, that would be considered off-label marketing,
11 correct?

12 A. Correct.

13 Q. A different stage of the disease is also off label. For
14 instance, if an on-label requires two mutations or more,
15 resistance to two types of drugs or more, and it's marketed to
16 patients with less than two mutations, that would be considered
17 off label, correct?

18 A. I have to look at the label, the indication, to answer
19 that question.

20 Q. If, for example, Mr. Patel, a drug were approved for use
21 in two or more, right, treatment-experienced patients with two
22 or more resistance to protease inhibitors, and it were marketed
23 to other patients who did not have two or more resistance to
24 protease inhibitors, that would be a different stage of the
25 disease, correct?

1 A. I'm having a hard time to answer that question. To my
2 knowledge, different stage of disease is if you're second line
3 therapy and you're marketing a product as a first-line therapy,
4 in oncology, that would be a different stage of disease.

5 Q. Okay, sir. A different route of administration and a
6 discussion of drugs in development, those are what you were
7 telling people at Janssen was considered off label, correct?

8 A. To our speakers, yes.

9 Q. And you also told the sales and marketing department as
10 well who were implementing that program, correct?

11 A. Yes.

12 MR. MARKETOS: And if we look at slide 26, please.

13 BY MR. MARKETOS:

14 Q. You made one point that you wanted to emphasize here, sir,
15 in the summary of this slide.

16 Never minimize any potential safety information, right?

17 A. Correct.

18 Q. Since 1985, Mr. Patel, the FDA has regulated prescription
19 drug advertising to health care providers and to consumers
20 under the same laws, correct?

21 A. Yes.

22 Q. And a prescription drug advertisement or promotion must
23 contain true statements regardless of its intended audience,
24 correct?

25 A. Correct.

1 Q. With respect to approval by the Food & Drug
2 Administration, ads that are directed at health care
3 professionals must be fairly balanced and include not just
4 major indications but also major adverse effects, correct?

5 A. Correct.

6 Q. And those are the same rules that apply to
7 direct-to-consumer and to health care professionals, correct?

8 A. Correct. Correct.

9 Q. When it comes to the FDA's approval of promotional
10 materials for a pharmaceutical manufacturer, notification of
11 the FDA's approval must be in writing whether or not those
12 materials are considered to be in violation or not in
13 violation, correct?

14 A. Can you repeat the question?

15 Q. It was not a good one. I'll try another one.

16 A. Okay.

17 Q. With respect to the FDA's approval process, for the FDA to
18 formally approve any marketing materials that a pharmaceutical
19 company wants to use to market to consumers or to health care
20 providers, that notification to the advertiser must be in
21 writing, true?

22 A. That is not correct.

23 Q. Notification to the advertiser that a proposed
24 advertisement is or is not considered to be in violation shall
25 be in written form.

1 That is a regulation of the Food & Drug Administration,
2 correct?

3 A. That's the violation. You used the term "approval." So
4 there's two distinction. If the advertisement is false and
5 misleading, FDA will issue enforcement in writing. So that is
6 the regulation, and that is correct.

7 Q. The only official communications from DDMAC are those in
8 writing?

9 A. Correct.

10 Q. The FDA may provide comments on a pharmaceutical company's
11 marketing and promotional materials, but only those in writing
12 are considered official, correct?

13 A. Correct.

14 Q. Sir, there came a time in January of 2009 that you, on
15 behalf of Janssen, provided materials to the FDA relating to
16 Prezista having a low impact on cholesterol.

17 Do you recall that?

18 MS. BROWN: Objection, Your Honor. May we approach?

19 THE COURT: You may.

20 (Sidebar discussion as follows:)

21 MS. BROWN: Your Honor, this piece that was provided,
22 low impact on cholesterol, was never provided for a -- was only
23 provided direct-to-consumer, not for the health care provider.

24 THE COURT: So what? Your witness just testified
25 that there's no difference between the two, exactly the

1 opposite of what Janssen's been representing to me throughout
2 this trial.

3 How do you feel about that testimony that we just
4 heard?

5 MS. BROWN: Your Honor, I don't believe that's what
6 --

7 THE COURT: That's exactly what he said. I've been
8 reading the transcript, literally staring at it.

9 MR. KLEIN: I think, Your Honor, he'll explain
10 certainly throughout the course of the day that the standards
11 that are applied for the two -- there's a stricter standard for
12 direct-to-consumer because the ads are --

13 THE COURT: He didn't say that now. Are you watching
14 what I'm watching? So you want me to presume he's going to
15 testify differently than what he just said? If he wants to say
16 something different later, so be it. But what he's testified
17 to right now is absolutely consistent with what Mr. Marketos
18 represented to me today and not consistent with what you all
19 have been representing.

20 MS. BROWN: Your Honor, we can all look at the
21 deposition transcript. And I have spoken with him and read his
22 deposition testimony and he --

23 THE COURT: I'm not talking about his deposition
24 transcript. I'm talking about his testimony over the last 20
25 minutes.

1 MS. BROWN: I understand, Your Honor. I don't
2 believe he's been able to contextualize it. We know what the
3 testimony is. We also know what the regulations are. They are
4 different. There is different requirements because when you
5 detail --

6 THE COURT: You have to establish that on cross.

7 MS. BROWN: I understand, Your Honor, but I think
8 there is prejudice to allowing something that comes in with a
9 different standard on a consumer piece because -- and I just
10 want to say why, Your Honor, it's not guidance is that when you
11 detail a health care professional, the standards assume two
12 things. One, there is more information, more detailed
13 information being given to a doctor, and two, you're also given
14 the label. As a result, the critique of this particular
15 statement that Mr. Marketos is about to go in was that it
16 didn't have any of the backup information with it because it
17 was one line in a consumer piece.

18 THE COURT: And you've spoken with Dr. Patel, so he
19 knows this issue was coming, right?

20 MS. BROWN: Well, I mean, he knows what the law is,
21 so it's his experience. He spoke about it in the deposition.

22 THE COURT: So far he spoke about the law. He said
23 there's no difference.

24 MS. BROWN: Well, Your Honor, I did not see that
25 question.

1 THE COURT: I'm confident that's his testimony so
2 far.

3 MS. BROWN: I understand. I think he wasn't able to
4 contextualize it.

5 THE COURT: That may be true.

6 MS. BROWN: I think there's prejudice allowing the
7 consumer piece to come in.

8 THE COURT: Then you'll have to correct it on
9 cross-examination.

10 MS. BROWN: I understand.

11 THE COURT: But the Janssen witness who is in
12 compliance at least for now hasn't contextualized anything.

13 MS. BROWN: I understand.

14 THE COURT: And what's even, I think, more relevant
15 to this discussion is this isn't blind to him. He knows this
16 issue was coming.

17 MS. BROWN: Well, he's been deposed on it. We are
18 telling you truthfully what his deposition testimony was, Your
19 Honor, so --

20 THE COURT: Well, then why isn't he testifying to
21 that now?

22 MS. BROWN: I think he's trying to answer yes or no
23 and he's not contextualizing the question, Your honor.

24 THE COURT: Dr. Patel has not been answering yes or
25 no. I mean, this is taking much longer than it should be

1 because there were certain questions that we had to continue to
2 feed him the same question multiple times.

3 MS. BROWN: Trying to be very precise, Your Honor. I
4 mean, the question -- I understand, Your Honor.

5 THE COURT: If you're telling me that if he were to
6 contextualize it, there's going to be some established
7 difference, then you can do that when you have the witness.

8 MS. BROWN: I understand.

9 THE COURT: But based on his testimony, which I've
10 been -- I'll be candid. I've been carefully reviewing his
11 testimony because I knew this issue was coming up because I
12 appreciate counsel putting this before me earlier this morning.

13 Based on his testimony, it has come out the rules are
14 pretty much the same.

15 Now, if you're going to clean that up in your
16 examination, then you can clean up before the jury. And don't
17 get me wrong. Any piece of evidence that is admitted in a
18 trial is prejudiced against one party or the other. So that's
19 not my analysis. I mean, I absolutely think right now it
20 sounds prejudicial. If you all clean it up, maybe it will be a
21 wash. I don't know the answer to it.

22 But I'm going to proceed with this line of
23 questioning and this document based on the testimony that
24 Mr. Marketos has elicited. That's the best I can do because
25 that's the testimony that's before me.

1 MS. BROWN: I understand.

2 THE COURT: Thanks.

3 (End of sidebar discussion.)

4 THE COURT: You may proceed, Mr. Marketos.

5 MR. MARKETOS: Thank you, Your Honor.

6 BY MR. MARKETOS:

7 Q. Mr. Patel, there was a time in January of 2009 that you,
8 on behalf of Janssen, submitted certain promotional materials
9 to the FDA relating to Prezista having a low impact on
10 cholesterol, true?

11 A. I need to understand the context of what types of material
12 you're referring to to answer the question.

13 MR. MARKETOS: Why don't we take a look at RX-1720.
14 You can just show that for the witness.

15 BY MR. MARKETOS:

16 Q. Sir, you can see that Relators' 1720 is an FDA consumer
17 package, and, if you flip through, there you can actually see
18 where you sent the UPS label.

19 A. Okay.

20 Q. See the label, UPS, to Aline Moukhtara, and it was a
21 consumer package sent by Ms. Sylvia Lee.

22 Do you see that?

23 A. Yes, I see.

24 Q. She worked for you, right?

25 A. She didn't report to me.

1 Q. She worked with you at Janssen?

2 A. Yes.

3 Q. All right. And if we take a look, you can flip through
4 the documents, and you can see what's attached thereto.
5 There's a fax cover sheet that comes back --

6 MR. MARKETOS: Turn to the next page, please. Keep
7 going, ma'am. Thank you, Ms. Johnson.

8 BY MR. MARKETOS:

9 Q. You can see that there's a package at 1720 of
10 communications between Janssen and the Food & Drug
11 Administration, right, sir?

12 MR. MARKETOS: Go back one page, please.

13 THE WITNESS: Yes, sir. You scrolled through too
14 fast, so can you -- can I look through the package quickly, if
15 you don't mind, to refresh my memory?

16 BY MR. MARKETOS:

17 Q. Yeah, sure. I'll refresh your memory right now, sir.

18 If you take a look at the screen in front of you, there's
19 a letter from you to --

20 THE COURT: Mr. Marketos, have him review it. It's
21 not admitted yet.

22 MR. MARKETOS: Okay, Your Honor. Sure.

23 MS. BROWN: Can I provide him with my hard copy, Your
24 Honor -- it's many pages -- so he can review?

25 THE COURT: Dr. Patel, would that be easier -- is it

1 Dr. Patel?

2 THE WITNESS: That would be great.

3 THE COURT: Is it easier if you see a hard copy?

4 THE WITNESS: Yes, that would be great.

5 THE COURT: Why don't you approach Mr. Marketos, and
6 he can hand it to the witness.

7 MR. MARKETOS: May I approach, Your Honor.

8 THE COURT: You may.

9 BY MR. MARKETOS:

10 Q. Here you go, sir.

11 A. Thank you.

12 Q. Sure.

13 THE COURT: Hold on. Is it marked up?

14 MS. BROWN: I had started to --

15 THE COURT: Mr. Marketos, grab it. If he's going to
16 review a document, it's got to be clean.

17 BY MR. MARKETOS:

18 Q. I believe we asked you if you prefer doctor or mister
19 during your deposition, and you said either.

20 A. Either is fine.

21 Q. You're a Ph.D. You're not a medical doctor?

22 A. I'm not a medical doctor, correct. Just a doctor of
23 pharmacy.

24 Q. Okay. sir.

25 A. Okay. I reviewed it, yes. I remember this package.

1 Q. Thank you, sir. This was actually discussed with you at
2 your deposition.

3 Do you recall?

4 A. Correct.

5 MR. MARKETOS: All right. We'd offer RX-1720, Your
6 Honor.

7 MS. BROWN: Subject to the same objection, Your
8 Honor.

9 THE COURT: So the objection is overruled; but it's
10 preserved, and I'll allow it in.

11 MR. MARKETOS: Thank you.

12 BY MR. MARKETOS:

13 Q. Take a look, sir, at page 1. This is a consumer package.

14 And then if we take a look at page 2, you see the UPS
15 label with certain materials being sent to DDMAC at the Food &
16 Drug Administration.

17 And then we can turn to page 11, and there is a submission
18 letter from you, right, sir?

19 A. Yes.

20 Q. All right. That's -- just so that we all have our
21 bearings here, what we're looking at is a letter that you,
22 Mr. Patel, put in writing and sent to DDMAC with a consumer
23 package that contains three proposed ads for Prezista.

24 Do you recall that?

25 A. Yes.

1 Q. And if we take a look at, you know, one of those ads,
2 page 13, one of those promotional materials referred to, it was
3 called Belief. This was a Belief campaign.

4 Do you recall this?

5 A. Yes.

6 Q. And it referred to having a low impact on cholesterol,
7 right, sir?

8 A. Correct.

9 Q. Now, we'll get a cleaner copy. There is a response that
10 came to Janssen in April of 2009 pertaining to this material,
11 correct?

12 A. We receive advisory feedback on draft materials, correct.

13 Q. I'm sorry. There was a response from DDMAC, the federal
14 agency responsible for reviewing promotional ad materials for
15 pharmaceutical manufacturers, right, sir?

16 A. Correct.

17 Q. And they responded to this material, including to this
18 specific claim, right, sir?

19 A. Correct. They respond to draft materials, yes.

20 Q. Yes.

21 MR. MARKETOS: We'll take a look at RX-190 just for
22 the witness. Thank you.

23 BY MR. MARKETOS:

24 Q. Can you see that that's a clean copy, sir, of the response
25 that came to you, specifically to you, from the Department of

1 Health and Human Services at the Food & Drug Administration?

2 Do you see that?

3 A. Yes, uh-huh.

4 MR. MARKETOS: All right. We'd offer RX-190, Your
5 Honor.

6 MS. BROWN: Same objection, Your Honor.

7 THE COURT: All right. So admitted.

8 (Exhibit R-190 admitted into evidence.)

9 BY MR. MARKETOS:

10 Q. All right. Let's turn, if we could, sir, just to the
11 front page, and I'd like to display this to the jury if we
12 could.

13 Do you see that this is a letter that came to you, sir, on
14 April -- actually -- thank you. Let's go to page 5.

15 You can see there's a date at the bottom from Aline
16 Moukhtara.

17 Do you see that, sir?

18 A. Yes.

19 Q. That's dated 4/29/2009, right, sir?

20 A. Correct.

21 Q. And that individual was a member of the government,
22 specifically DDMAC, at the Food & Drug Administration, correct?

23 A. Correct.

24 Q. All right. And if we take a look at the first page of the
25 letter, this is a letter: Dear Dr. Patel, This letter advises

1 Johnson & Johnson Pharmaceutical Services, LLC, of comments for
2 proposed promotional material submitted on January 27, 2009, to
3 DDMAC, right? The Division of Drug Marketing, Advertising, and
4 Communications, right, sir?

5 A. Yes.

6 Q. If we turn to page 3, now, this is an official
7 communication from the Food & Drug Administration, right, sir?

8 A. Correct.

9 Q. It's in writing, right, sir?

10 A. It is in writing, yes.

11 Q. What was told to you while you were with Janssen was that
12 there were items of concern to the Food & Drug Administration
13 relating to the minimization of risk in those promotional
14 materials, right, sir?

15 A. Yes.

16 Q. Specifically, the claim that Prezista had low impact on
17 cholesterol is misleading because it minimizes the risks
18 associated with the use of Prezista.

19 Do you see that?

20 A. Yes.

21 Q. Specifically, it suggests that patients will not
22 experience an increase in cholesterol, low-density
23 lipoproteins, and/or triglycerides, when this is not the case,
24 right, sir?

25 A. Yes.

1 Q. In fact, the Food & Drug Administration goes on to state,
2 according to the serious adverse drug reactions, the adverse
3 drug reactions section of the package insert -- that's the
4 label, right, sir?

5 A. Yes.

6 Q. The following serious adverse drug reactions of at least
7 moderate intensity occurred in the Phase 2b studies.

8 Do you see that?

9 A. Yes, I do see.

10 Q. And DDMAC specifically pointed out hypercholesterolemia,
11 low-density lipoprotein increases, and hypertriglyceridemia as
12 side effects of Prezista, correct?

13 A. Correct.

14 Q. So what the Food & Drug Administration communicated to you
15 at Janssen was that low impact on cholesterol is misleading,
16 right, sir?

17 A. Based on this letter, they communicated if you don't
18 present other contextual information about the adverse events
19 that were reported in clinical trial, this claim is misleading.

20 Q. Let's unpackage that a little bit.

21 What they said was the claim that Prezista had low impact
22 on cholesterol is misleading because it minimizes the risks
23 associated with the use of Prezista.

24 That's what the words say, right, Mr. Patel?

25 A. Those words are in conjunction with the draft ad, so you

1 have to look at the draft ad, how it was submitted and how the
2 comments relate to it. So you have to look at both together.

3 Q. The claim that Prezista, quote, had low impact on
4 cholesterol is misleading because it minimizes the risks
5 associated with the use of Prezista.

6 That's what the government told you, true?

7 A. Your summarization of the FDA letter is incorrect. I
8 think what FDA pointed out is the claim that was submitted did
9 include to inform consumer that there are adverse reactions
10 serious that have been reported in clinical trial.

11 In absence of that data, the claim that was proposed is
12 misleading. It could minimize the risk. The consumer may read
13 it and believe that there are no side effects associated with
14 the cholesterol, which, in fact, it was in the package insert,
15 as they pointed out here. So the presentation was not
16 complete.

17 Q. Sorry. Mr. Patel, do you remember what my question was?

18 A. Can you repeat again, please? Sorry.

19 Q. Mr. Patel, you just gave us a lengthy explanation, but
20 those words that you just provided are not, in fairness, in the
21 Food & Drug Administration's letter that we're all looking at,
22 fair?

23 A. I think the way I read it, that's how I interpret it based
24 on my experience working at FDA, working with the reviewer,
25 ongoing conversation, is how they write it. This is how you

1 interpret.

2 Q. Okay. Let me see if we can interpret the second sentence.

3 Specifically, low impact on cholesterol suggests that
4 patients will not experience an increase in cholesterol,
5 low-density lipoprotein, and/or triglycerides, when this is not
6 the case.

7 That's what the FDA was saying, fair?

8 A. That's their statement, yes.

9 Q. What the FDA also said, sir, was that this ruling, that
10 this information, this authorized letter, this guidance applied
11 to the advertising in question and to all future promotional
12 materials containing the same or similar claims or
13 presentations, true?

14 A. True.

15 Q. Let's go ahead and take a look at that for the members of
16 the jury.

17 MR. MARKETOS: That's on page 1, Ms. Johnson. Second
18 paragraph. There you go.

19 BY MR. MARKETOS:

20 Q. DDMAC has reviewed the proposed launch direct-to-consumer
21 journal advertisements and offers the following comments, which
22 apply to this as well as future promotional materials
23 containing the same or similar claims or presentations, right,
24 sir?

25 A. Correct.

1 Q. That means until and unless there is a letter from the
2 Food & Drug Administration that says this message, low impact
3 on cholesterol, is okay, this guidance is that claim would be
4 misleading, right, sir?

5 A. Can you rephrase the question? Hard to understand your
6 question.

7 Q. Any future claims relating to low impact on cholesterol
8 would also fall under this guidance from the FDA.

9 That's what they're telling you in that sentence we're
10 looking at, right?

11 A. This applies means if you make the same claim as in a
12 draft ad, which, you look at it, it didn't have all the
13 contextual information. If you present same claim as proposed,
14 it would be misleading. So exact same wording, exact same
15 presentation, it would be misleading.

16 Q. Exact same wording.

17 Exact same, is that what you said?

18 A. Exact same wording, exact same presentation that we had
19 proposed that FDA took issue.

20 Q. What they actually said, sir, was any future promotional
21 materials that contain the same or similar claims or
22 presentations. That's what they were referring to, right?
23 Same or similar, right, Mr. Patel?

24 A. I think you have to look at the -- what you mean by
25 similar, like so we have to look at the context of the claim

1 and to say does the guidance apply. So that's the review. We
2 have to review that claims.

3 Q. Yes, sir. Low impact on cholesterol is the same or
4 similar as low impact on lipids, isn't it?

5 A. With proper context, it could be explained.

6 Q. It's your testimony to the members of this jury that low
7 impact on cholesterol and low impact on lipids are not the same
8 or similar claims?

9 A. I think my testimony is you have to look at the -- how the
10 claims and additional context is presented to see if the FDA
11 comments on consumer materials applied to other materials if
12 they have the same claim or same presentation.

13 Q. But my question was different, Mr. Patel.

14 Is it your testimony to the members of the jury that low
15 impact on cholesterol and low impact on lipids are not the same
16 or similar?

17 A. I think I would use word "similar" because cholesterol is
18 a very specific number, and lipid could include triglycerides,
19 cholesterol, LDL, HDL. There's more information on that. So
20 it depends on how you describe in the promotional material.

21 Q. Is low impact on lipids similar to low impact on
22 cholesterol, Mr. Patel?

23 A. As face value, yes, it's similar.

24 Q. Sir, with respect to Prezista's promotional marketing
25 materials, this letter from the FDA in April of 2009 was the

1 only written communication that Janssen ever received with
2 respect to low impact on cholesterol, correct?

3 A. This is the only advisory feedback we received, yes.

4 Q. This letter that the members of the jury can see right
5 here, Relators' Exhibit 190, is the only written guidance,
6 advisory opinion, or otherwise, that Janssen ever received
7 about Prezista and lipids, correct?

8 A. Written, yes.

9 Q. As we sit here today, Mr. Patel, you can tell us, sir,
10 Janssen never received written approval from the FDA about any
11 message pertaining to low impact on lipids, correct?

12 A. Sorry. Can you restate the question?

13 Q. Yes, sir. The FDA never provided written approval to
14 Janssen with respect to the marketing message low impact on
15 lipids, true?

16 A. That is not true.

17 Q. I'm sorry, sir. A moment ago I asked you whether or not
18 this letter was the only written authorization that Janssen
19 ever received with respect to same or similar claims to low
20 impact on cholesterol. Perhaps I misunderstood you, so let me
21 ask my question again.

22 A. Sure.

23 Q. This letter that we're looking at dated April of 2009,
24 Relators' Exhibit 190, this is the only written communication,
25 the only authorized written communication from the FDA to

1 Janssen pertaining to cholesterol, lipids, and Prezista, true?

2 A. My testimony is this is advisory feedback. That's a
3 written advisory feedback we received. Your question is
4 approval. That's two different things.

5 Q. Okay. Let me phrase it differently.

6 A. Thank you.

7 Q. Whether it was approval, advisory, or otherwise, Janssen
8 never received anything in writing pertaining to Prezista,
9 cholesterol, lipids, or otherwise other than this letter that
10 we're looking at, true?

11 A. Correct.

12 Q. Janssen never received FDA's written approval with respect
13 to any message that Prezista had a low impact on lipids, true?

14 A. I cannot answer that question because it's not consistent
15 with FDA process of providing approval letters.

16 Q. Janssen never received any advisory information approving
17 of the message low impact on lipids, correct?

18 A. This is the only advisory feedback we received.

19 Q. One more time, Mr. Patel.

20 Janssen never received any advisory opinion from the Food
21 & Drug Administration in writing approving of the use of the
22 message low impact on lipids for Prezista, true?

23 A. We never submitted to FDA that --

24 THE COURT: Dr. Patel, listen to the question and
25 answer the question that is posed to you, not some other

1 question that's not being asked. I'm directing you to do that.

2 Understood?

3 BY MR. MARKETOS:

4 Q. Janssen never received written advisory opinion from the
5 Food & Drug Administration approving of the use of the message
6 low impact on lipids for Prezista, true?

7 A. Correct.

8 Q. Janssen never received written advisory opinion or written
9 approval of the promotional message minimal impact on lipids
10 for Prezista, true?

11 A. True.

12 Q. Janssen never received written advisory opinion approving
13 of the message proven lipid profile for Prezista, true?

14 A. True.

15 Q. Janssen never received written approval or an advisory
16 opinion from the Food & Drug Administration with respect to the
17 message lipid-friendly for Prezista, true?

18 A. True.

19 MR. MARKETOS: Can we switch to the ELMO, please,
20 Ms. Johnson?

21 BY MR. MARKETOS:

22 Q. So that we can help the members of the jury understand
23 your testimony, Mr. Patel, is it accurate to say that the FDA
24 never approved in writing of the promotional message low impact
25 on lipids for Prezista?

1 A. Can you rephrase the question?

2 Q. Yes, sir. The FDA never provided written approval of the
3 message low impact on lipids for Prezista, correct?

4 A. I can only answer never received advisory feedback. I
5 think you're switching the question.

6 Q. Well, let's do both. You certainly never received any
7 written approval from the FDA with respect to low impact on
8 lipids message, right, sir?

9 A. Sure.

10 Q. And you never received any advisory opinion in writing
11 stating it was okay either, right, sir?

12 A. Correct.

13 Q. You never received -- Janssen never received any written
14 advisory opinion from the FDA pertaining to minimal impact on
15 lipids, right, sir?

16 A. We never received advisory feedback on that claim.

17 Q. Well, if you never sought it, you never got it; is that
18 fair?

19 A. That's fair.

20 Q. So you can tell the members of the jury that Janssen never
21 received written advisory opinion or written approval for the
22 promotional message minimal impact on lipids, true?

23 A. True.

24 Q. You can also tell the members of the jury, sir, that
25 Janssen never received an FDA written advisory opinion or

1 approval for the promotional message proven lipid profile,
2 true?

3 A. True.

4 Q. And you can also tell the members of the jury that Janssen
5 never received written FDA approval or an advisory opinion
6 pertaining to the promotional message lipid-friendly, true?

7 A. True.

8 Q. And, sir, that also pertains to a message like similar to
9 Reyataz.

10 Janssen never received a written advisory opinion or
11 written approval from the FDA to market its drug Prezista as
12 similar to Reyataz, true?

13 A. True.

14 Q. Any suggestion at any time that Janssen had received FDA
15 approval for these messages that we're looking at here, sir,
16 any suggestion, during the course of this trial, that Janssen
17 had received FDA approval for these messages, that would be a
18 false statement.

19 Do you agree?

20 A. Can you repeat the question?

21 Q. Yes, sir. You can tell us that any suggestion from
22 anybody, during the course of this trial, that Janssen actually
23 obtained approval for low impact on lipids, minimal impact on
24 lipids, proven lipid profile, or lipid-friendly, that's not
25 true, is it?

1 A. I have to look at the -- how they are summarizing to
2 provide the answer.

3 Q. You need more context?

4 A. Context, yes.

5 Q. Okay. Here's more context, sir. Let me see if I can
6 provide it.

7 MR. MARKETOS: I might need the help from my resident
8 genius to bring this into focus. Resident genius?

9 THE COURT: Ms. Wendel. Yeah, we all know who the
10 resident genius is over there.

11 Mr. Marketos, let me just ask you this. Is this
12 particular topic, are we going to go past in just a few
13 minutes?

14 MR. MARKETOS: I think I can do this part.

15 THE COURT: You want to do this part, then we can
16 close for lunch recess?

17 MR. MARKETOS: Yes.

18 THE COURT: Okay.

19 MR. MARKETOS: All right. Maybe not. Maybe now is a
20 good time so I can get it focused.

21 THE COURT: Why don't we do that. You can work that
22 out over the lunch break.

23 Folks, we're going to break for lunch. 1:00 p.m.
24 Let's get the jurors out of here.

25 All right. Folks, I'll see you guys in about 35

1 minutes.

2 (The jury exits the courtroom at 12:27 p.m.)

3 THE COURT: Folks, be seated.

4 Dr. Patel, you can step outside and take your break
5 as well.

6 THE WITNESS: What should I do with the document?

7 THE COURT: You can leave that there for now, but
8 you're on break. We're off the record.

9 (Discussion held off the record.)

10 (Recess taken from 12:28 p.m. to 1:06 p.m.)

11 THE DEPUTY CLERK: Please remain seated.

12 THE COURT: Are we ready, Mr. Marketos?

13 MR. MARKETOS: Yes, Your Honor, thank you.

14 THE COURT: Should we get Dr. Patel back in the
15 witness box? Come on up, Doc.

16 Kim, you'll see if these guys are done eating over
17 there?

18 THE DEPUTY CLERK: Yeah.

19 (The jury enters the courtroom at 1:07 p.m.)

20 THE COURT: Have a seat, folks. Welcome back from
21 lunch.

22 Mr. Marketos, you can continue when you're ready.

23 And, Dr. Patel, just to remind you, you're still
24 under oath from earlier, prior to lunch, okay?

25 THE WITNESS: Yes.

1 MR. MARKETOS: Thank you, Your Honor.

2 BY MR. MARKETOS:

3 Q. Good afternoon, Dr. Patel.

4 A. Good afternoon.

5 Q. Sir, I may have solved my technological difficulties.

6 We'll see if that actually happens.

7 MR. MARKETOS: Ms. Johnson, can we switch to over on
8 the ELMO? There we go. Look at that.

9 BY MR. MARKETOS:

10 Q. Sir, I just want to ask you, it would assist the jury in
11 understanding your testimony to review the discussions we had
12 about these messages.

13 Do you agree?

14 A. Yes.

15 MR. MARKETOS: Your Honor, I'm going to mark this as
16 a demonstrative, Plaintiffs' Exhibit 1733 for demonstrative
17 purposes only.

18 THE COURT: Okay.

19 (Exhibit R-1733 marked for identification.)

20 MR. MARKETOS: Thank you.

21 We can switch back, Ms. Johnson.

22 BY MR. MARKETOS:

23 Q. Sir, I wanted to turn briefly back to the letter from
24 DDMAC that we were just discussing before we took the break.

25 MR. MARKETOS: And go back to RX-190, please,

1 Ms. Johnson. And we'll take a look at the first page.

2 BY MR. MARKETOS:

3 Q. A couple of things, Dr. Patel, before I move on from this
4 letter. Let's take a look at that second paragraph again,
5 please. What DDMAC, with the federal government, said in this
6 letter is that the advisory opinion it was rendering about the
7 claim low impact on cholesterol, that opinion from the federal
8 Food & Drug Administration would apply to this as well as
9 future promotional materials containing the same or similar
10 claims or presentations.

11 Do you see that, sir?

12 A. Yes.

13 Q. All right. And let's just explain what that means. That
14 means that the claim that they were focusing on was low impact
15 on cholesterol, right, sir?

16 A. Yes.

17 Q. And a presentation, that's something different. That's
18 how information is actually displayed. For instance, it might
19 be some type of scientific information that is presented as
20 part of the promotional materials, right?

21 A. Presentation could include layouts, format. So it's many
22 things in the regulation.

23 Q. Okay. Sir, so what the -- just so that we're clear, what
24 the Food & Drug Administration was saying is that its advisory
25 opinion that low impact on cholesterol was misleading would

1 apply to the same or similar claims or presentations, right?

2 A. As written, yes.

3 Q. And that would be for all future promotional materials as
4 well, correct?

5 A. Correct. And we clarified with the FDA.

6 Q. That would apply to all future promotional materials also,
7 correct?

8 A. As written, yes.

9 Q. As written. As written in the written letter from the
10 FDA?

11 A. Correct.

12 Q. And if we take a look at the bottom, the last paragraph,
13 of course what matters is what's in writing, right, Mr. Patel?
14 They actually remind you of that in the last part of the
15 letter, of page 4.

16 MR. MARKETOS: Right above the signature block if you
17 would, please. There we go.

18 BY MR. MARKETOS:

19 Q. DDMAC reminds you that only written communications are
20 considered official, right, sir?

21 A. Correct.

22 Q. And, of course, you know that that's part of the
23 regulations, right?

24 A. Correct.

25 Q. Now, after this letter was received, Janssen continued to

1 put promotional materials into the field containing the
2 promotional message low impact on lipids, true?

3 A. Incorrect.

4 Q. One more time, sir. Let me make sure I've accurately
5 framed my question, okay?

6 After this letter, after the date of this letter, after
7 April of 2009, Janssen continued to have the promotional
8 message low impact on lipids provided to its sales force; is
9 that true?

10 A. We didn't pursue or we did not promote this claim in any
11 direct-to-consumer materials. That's -- the feedback was on
12 direct-to-consumer material.

13 Q. My question was maybe a little inarticulate, Dr. Patel.

14 All I'm asking about right now is the promotional
15 materials that went to health care providers after this letter
16 was received, okay? Do you understand what I'm asking about?

17 A. Thanks for clarification. Okay.

18 Q. After this letter was received by Janssen, Janssen
19 continued to put the message low impact on lipids on its
20 promotional materials that the sales force used across the
21 country with doctors?

22 A. Yes, that's correct.

23 MR. MARKETOS: If we take a look at Relators'
24 Exhibit 1724. You can show that just for the witness, please,
25 Ms. Johnson, and counsel.

1 BY MR. MARKETOS:

2 Q. As part of being in regulatory, sir, were you also
3 responsible for reviewing business plans or communications to
4 ensure that they didn't contain false statements in them?

5 A. Business plans are not promotional, so compliance will
6 review, and if they have any question, they will refer to me if
7 there is any conversation about promotional tactics.

8 Q. Understood, sir.

9 In 2009, you can tell the members of the jury that Janssen
10 continued to promote Prezista as having a low impact on lipids
11 to doctors, correct?

12 A. Correct.

13 Q. If we look at -- and the same with 2010, correct?

14 A. Correct.

15 Q. And the same with 2011, '12, '13, and '14?

16 A. Correct.

17 Q. But in 2010, something else happened, Dr. Patel, that I'd
18 like to ask you about.

19 A. Okay.

20 MR. MARKETOS: Let's take a look at Relators'
21 Exhibit 1727.

22 BY MR. MARKETOS:

23 Q. While we're bringing that up, sir, Janssen also continued,
24 after having received that DDMAC letter in April 2009, it also
25 put the message out, "proven lipid profile" for Prezista, to

1 doctors, right, sir?

2 A. Sorry, I was reading the letter. Can you repeat the
3 question? Sorry.

4 Q. Yes, sure. I'm going to get to what's in front of you in
5 just a second.

6 After that letter April 2009 from the federal government,
7 Janssen continued to put the message out, "proven lipid
8 profile," to doctors, correct?

9 A. I remember reviewing low impact on lipids. If the claims
10 had changed later, I don't recall that. But, yes, we did
11 continue.

12 Q. You don't recall whether or not Janssen was also promoting
13 Prezista as having a proven lipid profile?

14 A. While I was in regulatory I remember low impact on lipid.

15 Q. That's a different question. I'm sorry. I'm just asking
16 whether you remember proven lipid profile as a message pushed
17 to the sales force to sell to doctors the drug Prezista?

18 A. I don't recall.

19 Q. How about "minimal impact on lipids," do you recall that
20 message being promoted by Janssen sales force to doctors?

21 A. No.

22 Q. You don't recall that at all?

23 A. No, I don't -- I don't remember approving that claim, so I
24 have no -- that claim was never approved by me.

25 Q. All right. If that happened, that was before your time in

1 2010; is that right?

2 A. I was there from '06 to '10, so never remember approving
3 that claim.

4 Q. I'm sorry. Thank you, sir.

5 You were overseeing regulatory promotional advertising
6 from 2006 to 2010. You don't recall approving the message,
7 "minimal impact on lipids" for Prezista; is that right?

8 A. Correct.

9 Q. If that message was being used out in the field by the
10 sales force and there were promotional materials shown to
11 doctors with the message "minimal impact on lipids," you're
12 here to tell the jury you did not approve of that message?

13 A. I didn't approve that specific claim. I have to look at
14 the context of what they were presenting.

15 Q. I'm not asking about context, sir, I'm asking about words,
16 "minimal impact on lipids," four words.

17 A. No, I did not approve it.

18 Q. I'm sorry, I stepped on you.

19 You did not approve of any claim "minimal impact on
20 lipids" at any time that you were at Janssen?

21 A. Correct.

22 Q. Now, after the letter --

23 MR. MARKETOS: Let's go back just briefly to
24 Exhibit 190, please, Ms. Johnson. RX-190, and we'll turn to
25 page 3.

1 BY MR. MARKETOS:

2 Q. Page 3 of RX-190 --

3 MR. MARKETOS: You can show it, this is in evidence.

4 Thank you.

5 BY MR. MARKETOS:

6 Q. Page 3 is the page of the letter that came from the
7 government that referred to minimization of risk with respect
8 to the lipids and Prezista. Do you recall that? We discussed
9 this for a little bit.

10 A. Yes.

11 Q. And to be clear, they're talking about a claim, not a
12 presentation. It says: The claim that Prezista had -- and
13 it's in quotation marks -- had low impact on cholesterol is
14 misleading, right, sir?

15 A. Yes.

16 Q. And they gave the reason because it minimizes the risks
17 associated with the use of Prezista, correct?

18 A. Correct.

19 Q. Okay. And in 2010, sir, you were concerned about an
20 enforcement action that occurred against another manufacturer
21 because you were concerned that the same outcome might happen
22 to Janssen with its promotional messages, true?

23 A. I have to look at the context of the letter to answer your
24 question.

25 MR. MARKETOS: All right. Let's take a look at

1 RX-1727. Just for the witness, please, Ms. Johnson, 1727.

2 Thank you. There we go.

3 BY MR. MARKETOS: --

4 Q. Dr. Patel, there's an email from you to Jason Kenig, Guy
5 De La Rosa, and Bryan Baugh, those are all Janssen/Tibotec
6 employees. And it's dated May 10, 2010. Do you see that?

7 A. Yes.

8 MR. MARKETOS: We'd offer RX-1727.

9 MS. BROWN: No objection.

10 THE COURT: So admitted.

11 (Exhibit R-1727 admitted into evidence.)

12 MR. MARKETOS: Thank you. We can publish that.

13 BY MR. MARKETOS:

14 Q. Dr. Patel, the subject here was Prezista lipid data and
15 patient case studies, do you see that?

16 A. Yes.

17 Q. You attached materials related to Invirase, do you see
18 that?

19 A. Yes.

20 Q. That was actually a competitor's drug, a drug that was
21 promoted by Roche, right, sir?

22 A. I don't recall, but...

23 Q. Okay. You say here: Jason, Guy, and Bryan, tomorrow we
24 should plan to review the recent DDMAC letter to Roche. See
25 attached. And our current promotional materials.

1 Right, sir?

2 A. Yes.

3 Q. So we'll look at the letter that's attached. But what you
4 wanted to do with the other members of Janssen, Mr. Kenig,
5 Mr. De La Rosa and Mr. Baugh, was you wanted to review a letter
6 that had gone from the government to a competitor about its
7 drug, and Janssen's current promotional materials, right?

8 A. To review it, yes.

9 Q. Yes, to review it.

10 All right. Sir. And if we see what's attached, what was
11 attached was a letter from the FDA from DDMAC to Roche stating
12 specifically concerns that it had with the presentation of the
13 lipid profile for Invirase. Do you recall that?

14 A. I don't recall the substance of the letter.

15 MR. MARKETOS: All right. Let's turn to the second
16 paragraph. There's a background section. And we can keep
17 going, Ms. Johnson, you'll see minimization of risks. Page 2
18 of the letter. Thank you. There we go.

19 BY MR. MARKETOS:

20 Q. You can take a look at that, sir, and you can see --

21 MR. MARKETOS: And if you want to blow up just the
22 top half of it, Ms. Johnson, for the witness so we can see what
23 the letter is about. Thank you.

24 BY MR. MARKETOS:

25 Q. Take a moment to review it, sir, see if this comes back to

1 memory. I'll represent to you that the discussion with the FDA
2 was its concerns with that drug and how it was being promoted
3 with respect to lipids.

4 Would it help if we turned to the next page, Dr. Patel?

5 A. Sorry, I'm a little slow, but let me finish reading.

6 Sorry.

7 MS. BROWN: Your Honor, could I request, if the
8 witness wants it, can he have a copy, since it's multipages?

9 THE COURT: How many pages is it?

10 MR. MARKETOS: I'm just going to the next page, Your
11 Honor.

12 THE COURT: It's fine. He can just see it off the
13 screen.

14 Dr. Patel, can you read off of that screen?

15 THE WITNESS: I can, I just need time.

16 BY MR. MARKETOS:

17 Q. All right, sir. Can you see that the discussion from
18 DDMAC with respect to this competitor's drug refers to
19 precautions relating to hyperlipidemia and elevated
20 cholesterol?

21 A. Yeah, I do see that.

22 Q. All right. And if you turn to page 7, the fourth
23 paragraph refers to minimization of risk, right, sir?

24 A. Yes.

25 Q. And that competitor's drug was making the claim minimal

1 impact. You can see that in the bottom right, right, sir?

2 A. Yes. Can I -- do you mind if I read the entire two
3 paragraphs to get a context?

4 Q. Sure.

5 A. (Reading.)

6 Okay.

7 Q. Dr. Patel, the Food & Drug Administration and DDMAC, that
8 agency was concerned with representations by pharmaceutical
9 manufacturers about side effects relating to lipid profiles
10 after a patient would take a drug.

11 Do you agree?

12 A. Yes.

13 Q. And the reason that the Food & Drug Administration and
14 DDMAC is concerned about messages from drug manufacturers like
15 Janssen or Roche in this case is because if you minimize the
16 impact, if you minimize the risk associated with lipids and
17 cholesterol and triglycerides, patients might not know that
18 that could lead to congestive heart failure, right, sir?

19 A. Can you rephrase your question?

20 Q. Sure. What we're talking about here is a side effect that
21 can lead to bad things happening to somebody's heart, you
22 understand that, right?

23 A. That's really a medical question. I would defer to
24 medical to answer that.

25 Q. Okay. You do understand at least that this subject,

1 lipids, cholesterol, triglycerides, that's something that you
2 are aware DDMAC was concerned with as it relates to
3 representations from drug companies, right?

4 A. The letter you shared with me, the drug has specific
5 warnings or precautions in their label, and how they present it
6 in light of efficacy claim, FDA found that overall presentation
7 of risk was minimizing.

8 Q. Yes, sir.

9 A. So this drug had warning and precautions related to
10 hyperlipidemia.

11 Q. Yes, sir. And of course, as we all know, Prezista itself
12 had adverse effects and serious ADRs associated with
13 hyperlipidemia and hypercholesterolemia and triglycerides,
14 right, sir?

15 A. Correct.

16 Q. That was on Prezista's label, right, sir?

17 A. Yes.

18 Q. And you know that that subject matter, lipids, is of
19 concern to the Food & Drug Administration, correct?

20 A. I can't answer that question.

21 Q. Okay. Minimizing risks you do know is a subject matter
22 that the FDA is very serious about?

23 A. Correct.

24 MR. MARKETOS: We turn to RX-1728 and this is just
25 for the witness, please, Ms. Johnson.

1 BY MR. MARKETOS:

2 Q. This is, sir, a meeting that was actually scheduled so
3 that you and your colleagues at Janssen could talk about the
4 letter that had come from DDMAC to a competitor about its
5 cholesterol information in Janssen's promotional materials,
6 right?

7 A. I'm looking at the subject. Yes.

8 Q. And you can see it's dated May 11, 2010?

9 A. Yes.

10 Q. It was the next day.

11 MR. MARKETOS: All right. We'll offer Relators'
12 1728, Your Honor.

13 MS. BROWN: No objection.

14 THE COURT: So admitted.

15 (Exhibit R-1728 admitted into evidence.)

16 BY MR. MARKETOS:

17 Q. And the subject is: Discuss Invirase FDA feedback letter
18 and Prezista material review, right, sir?

19 A. Yes.

20 Q. So you're going to discuss with your colleagues -- let me
21 back up for a second. Mr. Jason Kenig, he was the product
22 manager at Janssen for Prezista, correct?

23 A. Correct.

24 Q. Mr. Guy De La Rosa, Mr. Bryan Baugh, they were also
25 involved with the promotion of Prezista to physicians, correct?

1 A. No. They were medical affairs colleagues.

2 Q. I see. But their input is what was being asked for with
3 respect to the promotional materials for Prezista, right, sir?

4 A. Correct. As I said, it was part of multidisciplinary
5 review. Medical is part of the reviews, so that was -- their
6 role is to provide medical feedback.

7 Q. Yes, for Prezista material review, that's promotional
8 material?

9 A. Correct.

10 Q. So you had that meeting, you attended that meeting, and
11 you had that discussion, right, sir?

12 A. Based on this email, it looks like I had a meeting, yes.

13 Q. You were a required attendee at that meeting, right?

14 A. Yes, yes.

15 MR. MARKETOS: All right. And if we take a look at
16 Relators' Exhibit 1729 just for the witness, please,
17 Ms. Johnson.

18 BY MR. MARKETOS:

19 Q. Dr. Patel, Relators' Exhibit 1729, this is an email from
20 you to Jason Kenig, the product manager for Prezista, and for
21 Benjamin Kozub, he was the head of the marketing department
22 overseeing Prezista's marketing, right, sir?

23 A. Yes.

24 Q. This was two days after the meeting we just saw, right?

25 A. It sounds right.

1 Q. May 14?

2 A. Yeah. Sorry, I'm not keeping track of all the dates.

3 Q. No problem.

4 MR. MARKETOS: We'll offer Relators' 1729.

5 MS. BROWN: No objection.

6 THE COURT: All right. So admitted.

7 (Exhibit R-1729 admitted into evidence.)

8 MR. MARKETOS: Let's publish that to the jury.

9 BY MR. MARKETOS:

10 Q. What you sent to Mr. Kozub and Mr. Kenig, sir -- and you
11 can actually show the entire email if you would, please,
12 Ms. Johnson.

13 The entire email is just one line from you, right, sir?

14 A. Yes.

15 Q. And you attach -- in May of 2010, you attach that DDMAC
16 letter from April 2009 where DDMAC had given you advice that
17 low impact on cholesterol was misleading, correct?

18 A. Correct.

19 Q. And what you said in one line was "See page 3 of the
20 letter," right?

21 A. That's what I see on the email, yes.

22 Q. Yes, sir. You received information about a competitor
23 drug and an enforcement action relating to its representations
24 about lipids and cholesterol, Invirase, correct?

25 A. Yes.

1 Q. You set up a meeting with your colleagues to discuss that
2 enforcement action against a competitor and Janssen's own
3 promotional materials, right?

4 A. Correct.

5 Q. And then two days later, you sent a letter from April of
6 2009 where DDMAC had given you the guidance that that claim,
7 low impact on cholesterol, was false and misleading, correct?

8 A. Correct. I share what we received on direct-to-consumer
9 material.

10 Q. Yes, you shared what you received on direct-to-consumer
11 material, and to be clear, as you have testified, messages that
12 go to consumers and messages that go to physicians are governed
13 by the same regulations by the FDA, correct?

14 A. They are governed by the same regulation, correct.

15 Q. They all have to be true and they can't be misleading,
16 right, sir?

17 A. Correct.

18 Q. Same standards apply to doctors; same standards apply to
19 consumers, right, sir?

20 A. I can't answer the question. It's a very complex process
21 to understand. Consumer audience is different than health
22 group professionals, so expectations from FDA are different for
23 each audience. I can explain more, but I can't simply answer
24 yes or no.

25 Q. Well, we'll see if you can answer yes or no to this

1 question.

2 The same rules and regulations, as you've already told us,
3 the same rules and regulations from the FDA govern
4 communications and marketing messages to patients, consumers,
5 and to doctors. That's 21CFR -- 24CFR201, right, sir?

6 A. 21CFR202.1, same regulation.

7 Q. You got it. 21CFR202.1, right?

8 A. That's the regulation that governs the prescription drug
9 advertising and promotion.

10 Q. And it governs it with respect to consumers and to
11 doctors?

12 A. Correct.

13 Q. Any audience, right, sir?

14 A. Correct.

15 Q. And so you sent this letter to Mr. Kozub and Mr. Kenig,
16 and you said "see page 3" and that's all you said, right, sir?

17 A. That's all I said, yes.

18 Q. If you go to page 3 of the letter, of course, if we go
19 back to page 3 of the letter, which is attached to your email,
20 that's, of course, the part of the letter that was talking
21 about minimization of risk, the claim that Prezista had low
22 impact on cholesterol is misleading, because it minimizes the
23 risks associated with the use of Prezista, right, sir?

24 A. Yes, I see it on the screen. Yep.

25 Q. And that's what you were bringing to the attention of the

1 head of the marketing department and the product manager for
2 Prezista, right, sir?

3 A. I was informing them what we had received so we can have a
4 discussion with the team.

5 Q. Over a year after you received the letter, right?

6 A. I'm sorry. I missed the time. This was in 2009.

7 Q. Yeah.

8 MR. MARKETOS: Let's go ahead and take a look at the
9 email cover if we could, please, Ms. Johnson.

10 BY MR. MARKETOS:

11 Q. This is now May of 2010, Dr. Patel.

12 A. I see. Yeah.

13 Q. Just to be clear, it's more than a year after this letter
14 has been sent to you and Janssen by the Food & Drug
15 Administration?

16 A. Correct.

17 Q. And you're now sharing it with the head of -- the product
18 manager for Prezista and the head of marketing for Prezista,
19 correct? Mr. Kenig and Mr. Kozub, you're sharing it with them,
20 right?

21 A. Correct, to prepare for the conversation you showed me,
22 the Invirase letter the FDA had issued. So all these topics
23 align.

24 Q. Thank you. That's so you could discuss with the people
25 that needed to know the fact that this message might become a

1 problem, right?

2 A. That's speculating. I simply shared we should look at the
3 comments and discuss as a team.

4 Q. What you said was "see page 3 of the letter," right, sir?

5 A. Yes.

6 Q. It was a careful communication, would you agree?

7 A. I think the people knew, when I set up the meeting to
8 discuss FDA enforcement, so the topic was already that we're
9 going to discuss the lipid message. So this is in context of
10 that.

11 Q. All right. So what we know then is that you had those
12 discussions with the other members of your team after having
13 received an enforcement action against a competitor, right?

14 A. Yes.

15 Q. And you discussed specifically the letter you got from
16 DDMAC about low impact on cholesterol being misleading,
17 correct?

18 A. Correct, for the direct-to-consumer materials, yes.

19 Q. Direct-to-consumer materials, sure.

20 Are you telling the members of the jury, sir, that you
21 weren't concerned that messages being relayed to doctors about
22 low impact on cholesterol was misleading?

23 A. That is correct.

24 Q. Okay. Sir, if we take a look at what happened after this
25 meeting, safe to say Janssen did not make any changes to its

1 marketing materials after you had this meeting, correct?

2 A. If that was a team decision, yes.

3 Q. That wasn't part of my question, Dr. Patel. My question
4 was only about whether Janssen made any changes to its messages
5 that it delivered to doctors about the lipid profile of
6 Prezista after the meeting that we just saw.

7 A. I have to look at the material that you are referring to
8 to answer your question. If we made any changes or not, I have
9 to look at the final material.

10 Q. Proven lipid profile, low impact on lipids continued to be
11 the marketing message to doctors throughout your tenure at
12 Janssen, true?

13 A. Correct. That is correct.

14 MR. MARKETOS: May I have the ELMO, please,
15 Ms. Johnson?

16 BY MR. MARKETOS:

17 Q. We've seen a slide that's been featured during this trial,
18 sir -- I know you've not been here -- with some sales
19 representatives and prescribers and a pharmacy, a Part D
20 sponsor, and I'll see if I can zoom out a little bit. There we
21 go.

22 Do you see this slide, sir?

23 A. Yes.

24 Q. Okay. Sir, I'm going to put Janssen right up top here.
25 So the way it worked in real life is that Janssen was

1 delivering messages to prescribers through its sales force,
2 right?

3 A. From the schematic, yes.

4 Q. The prescribers would write prescriptions that were filled
5 at pharmacies, right, sir?

6 A. Correct, according to the schematic.

7 Q. The pharmacies would submit their prescriptions to the
8 Part D sponsors for Medicare and Medicaid, correct?

9 A. I'm not a reimbursement specialist, so I cannot answer
10 questions on that.

11 Q. You're aware of the fact that these drugs were reimbursed
12 by the federal government?

13 A. Yes.

14 Q. Medicare and Medicaid, right, sir?

15 A. Yes.

16 Q. And so that money would then go back to Janssen, right,
17 sir?

18 A. Again, I'm not a specialist on reimbursement to say it's
19 money or it's a cost of a drug. I don't know what's being sent
20 to Janssen, so I can't answer that question.

21 Q. Cash money went from the federal government to taxpayers
22 to Janssen.

23 You're aware of that fact, are you not?

24 A. Janssen was reimbursed for the drug.

25 Q. Yes. In money, in US dollars?

1 A. I assume so.

2 Q. All right, sir. Are you aware of any time, Dr. Patel,
3 that Janssen ever retracted any message that its sales force
4 had been delivering to doctors low impact on lipids, minimal
5 impact on lipids, lipid-friendly, proven lipid profile, similar
6 to Reyataz? Are you aware of any time that Janssen ever
7 retracted that message out in the field that was going to
8 doctors?

9 A. To answer your question, only two claims that were
10 approved was low impact on lipid, and I understand proven lipid
11 profile may have been approved. Other claims were not
12 approved. So there is no -- to my knowledge, I don't know if
13 other claims were retracted, but low impact on lipid and proven
14 lipid profile we continued to include in the promotional
15 materials.

16 Q. Are you aware of any message that was delivered to doctors
17 in the United States by Janssen's national sales force that was
18 ever retracted by Janssen with respect to lipids?

19 A. I don't recall.

20 Q. You don't recall that happening, or you know it did not?

21 A. I don't recall if -- because your question is pretty
22 broad.

23 Q. It is broad, sir, yes.

24 A. So I can't answer the question without knowing all the
25 context, like did we have a label change or did we have

1 enforcement by FDA that we had to retract. But to my
2 knowledge, we continued to present two claims that we included
3 in the promotional materials for health care professional.

4 Q. I just want to tighten this up so we can move on, sir.

5 As we sit here today, are you, Dr. Patel, aware of any
6 time that Janssen retracted a message about Prezista's lipid
7 profile in any form or fashion that had been delivered to
8 doctors?

9 A. Not to my knowledge.

10 Q. Are you aware, Dr. Patel, as we sit here today of any time
11 Janssen reimbursed the federal government for monies it had
12 received from Prezista prescriptions as a result of a false or
13 misleading message?

14 A. I'm not expert to answer that question.

15 Q. You can tell me if you're aware of it or not, sir. That
16 was my question.

17 A. No, I'm not aware of.

18 Q. Sorry. Let me reframe it, okay?

19 A. Sure.

20 Q. From the whole time that you were at Janssen, from 2006 to
21 2014 until you left in 2015 -- from that time period, that's
22 what I'm asking about, okay?

23 A. Okay.

24 Q. Are you aware of any time that Janssen reimbursed the
25 federal government for any monies it had received for Prezista

1 prescriptions that were based upon a false or misleading
2 message about its lipid profile?

3 A. I'm not aware of that.

4 Q. As I understood your testimony, sir, you said there were
5 only two approved messages, as I understood, relating to
6 Prezista's lipid profile -- relating to Prezista's lipid
7 profile.

8 Did I understand you correctly?

9 A. Yes. The documents you shared definitely showed that low
10 impact on lipid with all the data underneath was approved for
11 health care professional materials, and you referenced that
12 proven lipid profile was approved in 2010. So those are only
13 two that I remember reviewing and approving, but I don't
14 remember other claims that you referenced that were ever
15 approved by company.

16 Q. Thank you, sir, but let's make sure that we're clear with
17 our language here.

18 You're talking about two messages, low impact on lipids
19 and proven lipid profile, that were approved by you, right?

20 A. Approved by me, yes.

21 Q. Not approved by the Food & Drug Administration, right?

22 A. I disagree with that. It's a complex answer. It takes --
23 it requires some explanation to answer your question.

24 Q. One more time, sir. Let me just make sure I get it.

25 When you were telling the members of the jury that there

1 were only two approved messages, you were talking about only
2 two approved messages that you had approved by use of the sales
3 force, correct?

4 A. We approved those messages we shared with FDA. We never
5 received enforcement.

6 Q. I think it was a yes-or-no question.

7 Should I ask it again, Dr. Patel?

8 A. Yes, I approved those claims.

9 Q. One more time, sir. There are two approved messages,
10 proven lipid profile and low impact on lipids, and you approved
11 them, right, sir?

12 A. Yes.

13 MR. MARKETOS: Can we switch to the ELMO, please?

14 Thank you.

15 BY MR. MARKETOS:

16 Q. All right. I'm going to do my best with this, sir.

17 Is it true that proven lipid profile, lipid-friendly, low
18 impact on lipids was approved by the FDA?

19 A. As I say, it's a complex answer. I cannot simply answer
20 yes or no.

21 Q. Is it your testimony, sir, that the term "proven lipid
22 profile" was actually approved by the FDA?

23 A. Yes. Consistent with the current process, that's my
24 understanding.

25 Q. I'm sorry?

1 A. Based on current FDA process, those claims are deemed as
2 approved for sales force to promote.

3 Q. I'm sorry. What do you mean by current FDA process?

4 A. The way the review process works, company approves those
5 materials. We submit to FDA on Form 2253. Once you submit to
6 FDA, if they have any objection, they will inform you in a
7 writing enforcement that those claims are misleading. We never
8 received any feedback from FDA once we submitted those
9 materials with those claims. So we continued to promote those
10 because we believe that the claim had adequate information to
11 support the claim.

12 Q. I'm sorry, sir. You said "current FDA process."

13 Those were the words you used, right?

14 A. Correct.

15 Q. Are you talking about current 2024 FDA process?

16 A. The process at that time too. For any traditional --

17 Q. Mr. Patel, I'm just asking what you meant by the term
18 "current," sir, and then you're going to get an opportunity to
19 give us all the context when Janssen's lawyers start asking you
20 questions, okay?

21 A. I misspoke the word "current." What the process existed
22 at that time, based on the understanding of the process, we
23 believe those are approved claims that reps should be able to
24 disseminate to health care professional.

25 Q. All right. Sir, let me see if I can unpack that.

1 A. Okay.

2 Q. You have testified to the members of the jury that the
3 only form of approval that the FDA can provide is in writing,
4 true?

5 A. That's not true.

6 Q. The only authorized communications that come from DDMAC or
7 the FDA must be in writing per the regulations, true?

8 A. Per regulation, FDA provides advisory feedback and
9 enforcement. You're referring to approval. That does not
10 exist.

11 Q. Dr. Patel, you've never received anything in writing with
12 respect to any lipid profile message from the FDA, advisory or
13 otherwise, that approves of any lipid profile message for
14 Prezista; isn't that true, sir?

15 A. My testimony --

16 Q. No, sir. I'm sorry. Not your testimony. I asked you a
17 yes-or-no question.

18 Shall I reframe it?

19 A. Yes.

20 Q. Never did Janssen receive in writing from the FDA, whether
21 it was advisory or approval or otherwise, anything that
22 approved of the message relating to Prezista's lipid profile,
23 true?

24 A. It's false because we did receive for direct-to-consumer
25 materials. So, again, this is -- your question is misleading.

1 I'm not understanding what materials you're referring to.

2 Q. I'm sorry. Are you saying that there was something
3 approving direct-to-consumers that came from the FDA? Are you
4 saying, Dr. Patel, that there was something that came from the
5 FDA that approved -- I don't care what form it took. I don't
6 care if it came by carrier pigeon. I don't care if it came by
7 letter, FedEx, fax, or otherwise.

8 Are you saying -- are you telling the members of the jury
9 that something came in writing from the FDA approving of any
10 lipid profile message for Prezista?

11 A. I think my --

12 THE COURT: Dr. Patel, he's not asking you to
13 characterize your testimony. He's asking you to answer the
14 question he's posing to you right in this moment. Listen to
15 the question. Answer it.

16 THE WITNESS: Okay. Sorry. Repeat again.

17 BY MR. MARKETOS:

18 Q. The FDA never put anything in writing to you or to Janssen
19 approving or giving advice in approval of a lipid profile
20 message for Prezista, true?

21 A. It's false.

22 Q. It's false?

23 A. Because we just reviewed direct-to-consumer material that
24 was advisory feedback we got on low impact on cholesterol. So
25 I think your question is we never received anything. That's

1 not true. We did receive on consumer materials the feedback on
2 the claim that was presented.

3 MR. MARKETOS: Your Honor, may I ask for my question
4 to be read back?

5 MS. BROWN: Your Honor, may we approach on this?

6 THE COURT: No, I'm just going to ask the question
7 again.

8 Dr. Patel, listen to me. Maybe it's my voice. He's
9 not asking whether you got anything in writing, so this is the
10 question.

11 The FDA never put anything in writing to you or to
12 Janssen approving or giving advice in approval of a lipid
13 profile message for Prezista, true?

14 THE WITNESS: The first part is true, Judge. The
15 second part, they did advise us.

16 THE COURT: Not approving the lipid profile, right?

17 THE WITNESS: They did approve -- there is no
18 approval document, yes.

19 THE COURT: So that was the question.

20 THE WITNESS: Sorry. I misunderstood, because first
21 question was yes, second question is no. Second part of the
22 question -- because we did have advisory.

23 THE COURT: But the advisory piece you received
24 before didn't approve of the message. Didn't it actually say
25 they had concerns about the message?

1 THE WITNESS: They had concerns, correct.

2 THE COURT: So then the answer would have been -- I
3 got to be honest, Dr. Patel. I want you to listen to the
4 question that's being asked, because I just asked the same
5 question that Mr. Marketos did, and your response came fairly
6 clear to me.

7 Now you want a sidebar? We can sidebar. Let me see
8 counsel.

9 (Sidebar discussion as follows:)

10 THE COURT: He answered my question fine, and I read
11 it verbatim.

12 MS. BROWN: I just wanted to say to the Court I think
13 he is truly trying to answer that he believes that consumer
14 piece was providing advice. And the question had two pieces to
15 it --

16 THE COURT: Right. And --

17 MS. BROWN: -- approval and advice.

18 THE COURT: -- the advice piece was about approving
19 the message. It wasn't just advice. So you have to listen to
20 the question. It said you never received anything in writing
21 from the FDA approving of this message or advice approving of
22 the message. And he says, oh, well we got advice before. We
23 just went through that document for 35 minutes where they
24 weren't approving of anything. That document says they had
25 concerns about the lipid message and said that it minimized the

1 impact that's on the PI. So it's not a difficult question.
2 He's highly educated, and he answered my question fairly
3 quickly.

4 MS. BROWN: I think it's a little more nuanced, Your
5 Honor, and I'll have him explain when I question him. I think
6 he was truly trying to answer the advice piece, and I think he
7 believes that DTC feedback gave advice of how they should
8 interpret the --

9 THE COURT: It did give advice, but I think it's
10 clear to everyone, including the jury, that was not advice
11 saying we approve of your message.

12 MS. BROWN: I understand, Your Honor.

13 THE COURT: It was advice that was criticizing the
14 message.

15 MS. BROWN: I just think there was a disconnect, but
16 I understand.

17 THE COURT: He needs to focus on the questions.

18 MS. BROWN: I understand.

19 THE COURT: I understand your position but -- I get
20 it.

21 MS. BROWN: I just think we're losing a little in
22 translation. I really do think he's trying to answer.

23 THE COURT: Well, I read it verbatim.

24 MS. BROWN: I understand.

25 (End of sidebar discussion.)

1 BY MR. MARKETOS:

2 Q. Dr. Patel, I'm going to give you one last opportunity to
3 answer this question for the members of the jury, okay, sir?

4 A. Okay. Sorry about that.

5 Q. That's all right, sir. I'm going to try to frame it
6 fairly so that you can give an honest answer, okay?

7 A. Yes.

8 Q. At no time are you aware of the Food & Drug Administration
9 putting in writing any approval of a lipid profile message for
10 Prezista, true?

11 A. Correct, true.

12 Q. At no time are you aware of the FDA putting in writing any
13 advisory opinion wherein it approved of a lipid profile message
14 for Prezista, correct?

15 A. Again, this answer, advisory feedback does not give
16 approval. They provide feedback on draft claims that were
17 submitted. So they never approved those claims because they're
18 a draft.

19 Q. At no time did you ever receive an advisory opinion from
20 the FDA about Prezista's lipid profile that contained any
21 advice other than low impact on cholesterol is misleading?

22 A. Correct. That's a correct statement.

23 Q. Very quickly, sir, as I understand it, you were in
24 compliance also a portion of your time at Janssen over the
25 promotional speaker bureau for Prezista and Intelence, correct?

1 A. Sure.

2 Q. And during that time, sir, that you were at Janssen
3 providing compliance oversight to that program, are you aware
4 of the fact that Janssen was tracking speaker prescriptions for
5 the speakers who were paid to speak on that bureau?

6 A. To my knowledge, when I was a compliance officer, that was
7 against policy.

8 Q. That wasn't my question to you, sir.

9 A. No.

10 Q. Let me make clear. Need to be clear. You just said
11 something was against policy.

12 It's your testimony that tracking the prescriptions of
13 speakers on a promotional speaker bureau is against or was
14 against Janssen's policy while you were there?

15 A. Yes.

16 Q. I'm asking a different question. I'm not asking about
17 what's written on a piece of paper as a policy. I'm asking
18 about what was actually happening in real life, okay? Do you
19 understand the distinction?

20 A. Okay.

21 Q. Are you aware of the fact that in real life, Janssen was
22 tracking the prescriptions that the speakers who were being
23 paid to speak on that bureau were writing for Prezista?

24 A. No.

25 Q. Are you aware of the fact that Janssen was tracking the

1 prescriptions of Intelence for the speakers on the Intelence
2 promotional speaker bureau?

3 A. No.

4 Q. Are you aware of the fact that doctors were removed from
5 the speaker bureau for Prezista for not writing enough Prezista
6 prescriptions?

7 A. No.

8 Q. Are you aware of the fact that doctors were removed from
9 the Intelence promotional speaker bureau for not writing enough
10 Intelence prescriptions?

11 A. No.

12 Q. If those facts had been made known to you, sir, you would
13 have said that's against company policy?

14 A. Correct.

15 Q. And that's because, sir, that makes the program look like
16 it's providing kickbacks to doctors?

17 A. I had to consult with the --

18 (Technical interruption.)

19 THE COURT: I don't think that was for you, Doc. I
20 don't know what's going on there.

21 THE WITNESS: So I would have to consult with my
22 legal counsel to understand if that activity occurred would be
23 a violation of the law.

24 (Technical interruption.)

25 THE COURT: I feel like my courtroom just got hacked.

1 I honestly don't know what that was.

2 MR. MARKETOS: Just turn off all the TVs, Judge.

3 THE COURT: Is this for the next witness potentially?

4 MR. MARKETOS: Not ours.

5 THE COURT: Let's get back on track. I don't know
6 what that was, but we'll continue.

7 MR. MARKETOS: Thank you.

8 BY MR. MARKETOS:

9 Q. Pardon the interruption, Dr. Patel.

10 The reason that there's a policy in place at companies
11 like Janssen and other pharmaceutical companies that you can't
12 track speaker prescriptions for the drugs that you're selling
13 is because you're paying those speakers to speak to an
14 audience, right, sir?

15 A. That was a company policy, correct.

16 Q. That was the company policy. I heard that.

17 The reason those policies exist is because you don't want
18 to run afoul of the Anti-Kickback Statute, right?

19 A. Again, I would have to consult with my legal counsel to
20 see if that's the right interpretation of the statute.

21 Q. You were the head of compliance for the company.

22 Are you telling us you don't know why that policy was in
23 place?

24 A. I was not a head of compliance. I was a compliance
25 officer for CNS franchise.

1 Q. From 2010 until 2015 when you left, you were in compliance
2 overseeing this unit of Janssen, correct?

3 A. I had management responsibility for Tibotec Therapeutics
4 and CNS, yes.

5 Q. So that's a yes, right?

6 A. Yes.

7 Q. Thank you. And during that time period, are you telling
8 us that you don't know why that policy existed?

9 A. I understand why the policy existed.

10 Q. The policy exists so that Janssen doesn't track the
11 speakers that it's paying cash money to to speak on a speaker
12 bureau, right, sir? That's why the policy exists.

13 A. I don't understand your question. Sorry.

14 Q. The reason why you don't want to remove speakers who are
15 being paid cash money to speak on a speaker bureau if they're
16 not writing enough prescriptions is because then it seems like
17 the program is a vehicle to funnel cash to doctors for
18 prescriptions; isn't that true?

19 A. No, I disagree with your assessment.

20 Q. I see. Okay. You think those policies existed at Janssen
21 for some reason other than the Anti-Kickback Statute; is that
22 right?

23 A. Those policies are based on laws and regulations, so I
24 have to look at which one we are referring to. So I think
25 anti-kickback is one of them.

1 Q. Okay, sir. Anti-Kickback Statute is one of the reasons
2 those policies exist; is that right?

3 A. Correct.

4 Q. And you can tell the members of the jury that the
5 Anti-Kickback Statute relates to the payment to induce a doctor
6 for prescriptions that turn into money that come back to
7 Janssen, right, sir?

8 A. Correct.

9 Q. And the law is in place -- and you know this given your
10 training -- the law is in place to prevent pharmaceutical
11 companies from corrupting doctors' medical judgment, right,
12 sir?

13 A. Correct.

14 Q. And you don't want to use a vehicle, a cash vehicle, to
15 pay doctors who will then prescribe your drugs. You don't want
16 that to be an inducement to those doctors, right, sir?

17 A. Providing inducement to prescribe was against company
18 policy, correct.

19 Q. Okay, sir. And if, in fact, the president of the company
20 that goes by the name of Glenn Mattes has testified that, in
21 fact, speaker prescriptions were being tracked by Janssen, you
22 would have told him that's a violation of company policy?

23 A. Yes.

24 Q. If, in fact, speakers were being removed from the Prezista
25 and Intelence speaker bureau because the doctors weren't

1 writing enough prescriptions of those drugs, you would tell
2 Mr. Mattes that was against company policy, right?

3 A. Yes.

4 MR. MARKETOS: No further questions. Thank you, Your
5 Honor.

6 THE COURT: All right. Thank you, Mr. Marketos.

7 Ms. Brown.

8 MS. BROWN: May I proceed, Your Honor?

9 THE COURT: You may.

10 MS. BROWN: Thank you.

11 CROSS-EXAMINATION

12 BY MS. BROWN:

13 Q. Good afternoon, everyone. Good afternoon, Dr. Patel.
14 How are you?

15 A. Good afternoon.

16 Q. Good. Let's just pick up where we left off quickly on the
17 speaker bureau program.

18 A. Sure.

19 Q. Do you understand that Janssen has a policy that governs
20 the selection of speakers for its speaker bureau?

21 A. Yes.

22 Q. And do you understand that that policy includes objective
23 criteria by which speakers are selected for service on the
24 bureau?

25 A. Correct.

1 Q. Do you understand that that policy includes compensation
2 at fair market value for the services speakers provide?

3 A. Yes.

4 Q. Do you understand that one of the criteria that is used to
5 select speakers is, in fact, their experience with our
6 products?

7 MR. MARKETOS: Objection, Your Honor, leading the
8 witness.

9 THE COURT: I'd ask you to rephrase it. I'll sustain
10 it.

11 BY MS. BROWN:

12 Q. To your knowledge, Dr. Patel, is experience with our
13 products one of the criteria that is used to objectively
14 evaluate speakers?

15 A. Yes.

16 Q. Does that make sense to you from a compliance standpoint?

17 A. Yes.

18 Q. And why is that, sir?

19 A. Because we want them to share their experience with the
20 product, so appropriate patients can get our product that are
21 consistent with their indication. So we would want them to
22 share their experience as part of speaker program.

23 Q. Would you have a concern, Dr. Patel, from a compliance
24 standpoint if Janssen was engaging doctors to speak on the
25 bureau who had very little or no experience prescribing our

1 medicines?

2 A. Yes.

3 Q. Why is that?

4 A. If somebody didn't have any experience or knowledge of our
5 medicine, that would not meet the criteria. How would they
6 communicate about the product information. So I think having
7 experience is not the only requirement. It's one of the
8 requirement.

9 Q. Was it the case, Dr. Patel, during the time period you
10 were at Janssen, that you never saw a return on investment done
11 on whether, once we compensated a speaker for a speaking
12 engagement, they increased their prescriptions?

13 A. Correct, that was against our policy too.

14 Q. Okay. Do you understand, however, Dr. Patel, did you
15 learn at your time at Janssen that the sales force has data of
16 prescribing of all doctors they're visiting?

17 A. Correct.

18 Q. And from a compliance standpoint, analyzing that data can
19 be appropriate?

20 A. Yes.

21 Q. All right. Let's talk, Dr. Patel, a little bit about some
22 of the questions you were asked today.

23 First of all, would you tell us just generally, when it
24 comes -- we've heard a lot in this trial about approved
25 messages that were given to sales reps to share with doctors.

1 Are you familiar with those?

2 A. Yes.

3 Q. Can you tell us -- I want to walk through the steps of how
4 something gets approved to be given to the sales force.

5 Can you tell us first what the internal process is?

6 A. Sure. Marketing team will create materials, will submit
7 to a committee called promotional review committee that is made
8 up of medical experts. We have a medical doctor on our
9 committee, legal, regulatory, and compliance, depending on the
10 topic.

11 We cross-functionally review the material, the data, to
12 make sure the data supports the claim that we want to make. We
13 interpret the FDA regulation and try to comply with the FDA
14 regulation to our best knowledge. And those materials are then
15 submitted to FDA on Form 2253 before the reps are allowed to
16 use.

17 Q. Okay. There was a lot of discussion today about advisory
18 opinions or another type of process.

19 Are there generally two types of processes that you used
20 to give information to the FDA about potential promotional
21 materials?

22 A. Yes.

23 Q. And is one of those processes something called a Subpart H
24 process?

25 A. Subpart H is a regulation, so if your product delivers an

1 unmet medical need with limited data, FDA will allow the drug
2 to come on the market earlier before completing large clinical
3 trials.

4 Q. Let me stop you right there, Dr. Patel. The drugs we're
5 here speaking about are Prezista and Intelence.

6 Did FDA give Subpart H early approval to both of those
7 medicines?

8 A. Yes.

9 Q. And how does that impact the review process of promotional
10 materials?

11 A. So under Subpart H regulation, it's FDA mandate that any
12 communication we want to do with health care professional or
13 consumer has to be submitted to FDA. They will look at our
14 proposed claims, the supporting documents, and they provide
15 feedback.

16 And once they provide feedback, company incorporates
17 feedback. Or sometimes we disagree with them, and we will go
18 back to FDA and say we have different interpretation of the
19 statement or your feedback.

20 But if we implement FDA feedback, then we submit final
21 material addressing all the comments from FDA -- again, to FDA
22 on a Form 2253, which is a final submission, say this is the
23 final material we're using. And then FDA have opportunity at
24 that point to issue an enforcement.

25 An enforcement is the second process. Advisory opinion

1 and enforcement. So those are only two processes. FDA never
2 writes a letter to say we approve your claim. They give you
3 advice, and if they have issue with the promotional material
4 they've been submitted, they will issue enforcement. We looked
5 at today that some company had received if they didn't like the
6 presentation that's in the final piece.

7 Q. Let me see if I can break that down a little bit to help
8 me understand.

9 So you were asked a lot of questions about nothing in
10 writing, nothing in writing.

11 Do you recall those questions, sir?

12 A. Yes.

13 Q. Okay. I want to show you this -- something I just wrote
14 up. So let's just start with some questions I have about this
15 "nothing in writing" as it relates to Subpart H.

16 So Subpart H is before the medicine gets the formal
17 approval; is that right?

18 A. Correct.

19 Q. Okay. Did you say, Dr. Patel, that under that time
20 period, Janssen was submitting draft promotional pieces?

21 A. Correct.

22 Q. Did Janssen, when we were under the Subpart H time period,
23 ever use a promotional piece that did not first go to the FDA?

24 A. No.

25 Q. Did we ever use a promotional piece that we did not hear

1 back from the FDA on?

2 A. We did.

3 Q. Okay. So tell us how that would work?

4 If you're under Subpart H and you get nothing in writing,
5 do you use the piece, do you not use the piece?

6 A. So Subpart H regulation requires FDA 30 days to review and
7 provide feedback. So once you submit the material for its
8 approval, they have 30 days to review. After 30 days, it's up
9 to sponsor to wait for the comments, or if we have already
10 received the comments on the same -- similar claim, similar
11 presentation, we incorporate those comments and we inform FDA
12 that we're not waiting for your feedback on these materials.
13 And we move forward and we submit on 2253.

14 Q. Under Subpart H, you get nothing in writing, you wait 30
15 days. Would you, Dr. Patel, use the piece or not use the
16 piece?

17 A. We will submit the piece on Form 2253 before we use it.

18 Q. So really here the answer is send final piece to FDA?

19 A. Correct.

20 Q. Okay. Then tell us about the 2253 process.

21 A. Sure. That's the requirement for all company -- all
22 products that are approved by FDA, that sponsor must submit --
23 our company must submit the final material that they intend to
24 use, either health care professional or consumer, and we have
25 to submit before the day of first use.

1 And once you submit that material, FDA reviewers -- and my
2 experience at DDMAC, when I did fellowship, we review all those
3 materials, and if there are claims that are problematic, if
4 they believe the claims are off label or false and misleading,
5 at that point, FDA will issue an enforcement. Because the
6 piece is already out, so that's the enforcement. They will
7 issue enforcement to let the manufacturer know the claims are
8 false and misleading, and you should remove it from the
9 promotional materials.

10 Q. So under the 2253 process, if you get nothing in writing
11 back from the FDA saying there's a problem with what you sent,
12 do you use the piece, or do you not use the piece?

13 A. We continue to use the piece because we believe that we
14 have done our best as a company to meet the regulation, meet
15 the requirement, and FDA has an opportunity to let us know if
16 they have issues with our materials.

17 Q. Is there such a thing under this 2253 process that you're
18 describing to us of the FDA sending a letter saying we approve
19 what you sent us?

20 A. No. FDA never -- sorry.

21 Q. Go ahead.

22 A. FDA never sends approval letter saying your promotional
23 material is approved. That's not their process.

24 Q. Okay. And so you were asked a number of questions about
25 whether we received approval letters from the FDA in writing.

1 Do you remember those, sir?

2 A. Correct.

3 Q. Does the FDA regulation 2253 that governs this review,
4 does it provide for an approval letter process?

5 A. No.

6 Q. Does it instead provide for an enforcement process?

7 A. That is correct.

8 Q. And tell us about what that looks like.

9 A. So once the piece is out in the public domain, it's been
10 used by -- with the physicians or consumers, at that point, FDA
11 will make a determination if the claims are misleading, creates
12 public health risk, if companies promoting off label. They
13 will issue two types of enforcement, warning letter or a notice
14 of violation. And that's the only regulatory mechanism they
15 can communicate with the industry because the piece are already
16 submitted on 2253.

17 Q. Okay. So if we just try to understand what our options
18 are, Dr. Patel, under 2253, it sounds like approval letter is
19 not an option, correct?

20 A. Correct.

21 Q. Okay. So that's no.

22 But an enforcement letter is an option, right?

23 A. Yes.

24 Q. And it's also an option that you get nothing back in
25 writing, right?

1 A. Correct.

2 Q. And if you get nothing back in writing, you told us you
3 can use the piece, correct?

4 A. Yes.

5 Q. And if you get an enforcement letter, what do you have to
6 do?

7 A. So typically enforcement is FDA made a determination that
8 what you presented is minimization of risk, false and
9 misleading, off label. Whatever the regulation you violated,
10 they'll ask to remove those claims from that material or any
11 future materials.

12 And if it's a warning letter, then we have to do a
13 corrective campaign, go back to health care professional and
14 let them know that what we shared was misleading and here is
15 the correct information.

16 Q. You were shown a letter that was sent to a competitor at
17 Hoffmann-La Roche.

18 Do you recall that document?

19 A. Yes.

20 Q. Okay. And I want to ask you, is this -- let's take a look
21 at that document. It was Plaintiffs' 1727.

22 This is a letter that got sent to another company, not us,
23 right?

24 A. Yes.

25 Q. Okay. This is sent to a different pharmaceutical company

1 in Nutley, New Jersey, right?

2 A. Yes.

3 Q. And what I can see here, it says -- it's referring to
4 professional sales aids that were sent under cover Form 2253.

5 Do you see that?

6 A. Correct.

7 Q. Is that the same 2253 we were just talking about where we
8 essentially have two options that the FDA can take?

9 A. Yes.

10 Q. All right. They either do nothing and you use the piece,
11 right?

12 A. Yes.

13 Q. Or they send an enforcement letter like the one a
14 competitor got, right?

15 A. Correct.

16 Q. All right. So what do you understand was happening in the
17 feedback that was coming from the FDA to another company about
18 the materials they sent under 2253?

19 A. As a regulatory professional, it's always our -- we look
20 at enforcements from FDA to learn from it to see if our
21 presentations are similar, do we have same issue. So we
22 discuss as a core team with legal, medical, because sometimes
23 there are apples-to-orange comparison. But we really learn
24 from those letters to see what the topics that FDA is concerned
25 about and are we making the similar presentation or not, and we

1 make then a final determination, should we update the materials
2 or not update the materials.

3 Q. Do I understand you to say, Dr. Patel, that even when
4 Janssen doesn't get an enforcement letter, we're considering
5 letters that are being sent to other companies in case they
6 might inform us?

7 A. Yes.

8 Q. Okay. And this letter that got sent to another company
9 under 2253, it had to do in part with that company's lipid
10 messaging, correct, sir?

11 A. Correct.

12 Q. And one of the things the FDA points out on page 2 is that
13 for this company's medicine, hyperlipidemia was listed in the
14 precaution section of the label.

15 Do you see that?

16 A. Yes.

17 Q. What's the significance of that to you as you interpreted
18 this letter?

19 A. So from a regulatory regulation and my experience working
20 in FDA, typically the risk category, our box warning is the
21 highest risk. Second is your warning and precautions, and then
22 you talk about the adverse drug reaction.

23 So when somebody has a warning and precaution or
24 precaution about a particular topic, if you present something
25 that minimizes the precaution, then FDA will definitely have

1 objection to that.

2 Q. When you reviewed this letter that went to a different
3 company, did you consider the fact that we did not have
4 hyperlipidemia in the precaution section of Prezista or
5 Intelence?

6 A. Correct.

7 Q. Okay. And would you have considered -- this was the
8 paragraph that had to do with the particular message this
9 company was distributing.

10 Do you see that?

11 A. Yes.

12 Q. Would you have considered the context of the promotional
13 message the other company was distributing?

14 A. That is a very important part of regulatory analysis is
15 not only we look at the letter, but we look at what they were
16 promoting. So what was not shared is what is their material,
17 what claim, and how they were presenting, what information they
18 were omitting that was in the label.

19 So all those analysis goes into make a determination is
20 what is really why FDA took enforcement. So the context and
21 totality of the presentation is very important.

22 Q. Okay. This letter was sent to this other company in April
23 of 2010.

24 Do you see that, Dr. Patel?

25 A. Yes.

1 Q. And during that period of time, were we sending
2 promotional pieces about Prezista and Intelence to the FDA
3 under 2253?

4 A. Correct.

5 Q. What does this letter tell you about whether or not the
6 FDA, when it gets a submission under 2253, whether it actually
7 looks at it and considers whether it's appropriate?

8 A. Sorry. Can you repeat that question?

9 Q. Sure. When you evaluate this letter, the enforcement
10 letter that goes out from the FDA to another company, what does
11 that tell you about whether the FDA is actually looking at the
12 2253 submissions and sending out letters, if needed?

13 A. Based on my training at FDA, reviewers do review all 2253.
14 They're responsible for reviewing, and if they have concerns
15 like they have concerns here, then they'll take the next step
16 to issue enforcement.

17 So the materials that we were submitting prior to 2010
18 that included the lipid message, they were definitely
19 reviewing, and there was a long history with FDA on Prezista.
20 Same reviewer that issued enforcement was the same reviewer
21 that reviewed all of Prezista materials too.

22 Q. What's the significance of that, Dr. Patel?

23 A. If she had concern with our promotion of lipid messages,
24 we would have received a similar enforcement too.

25 Q. Did we ever get an enforcement letter like the one that

1 went to Hoffmann-La Roche following up on our FDA 2253
2 submissions about the lipid messages?

3 A. Never.

4 Q. How do you interpret that as the regulatory specialist at
5 Janssen?

6 A. When you look at this letter and look at our presentation
7 and not getting any FDA communication that what you are
8 promoting is false and misleading, from a regulatory
9 perspective, that means that we have done our best to present
10 all the facts that supports the claim and our studies were
11 supporting the claim, so we continued to use those claim. We
12 believe that those claims are proven indirectly by FDA.

13 Q. And I want to show you some of those submissions and talk
14 about what went to the FDA on those pieces.

15 You were shown -- and I believe it's now already in
16 evidence -- D-2088, and this is -- is this the cover letter of
17 a 2253 submission, sir?

18 A. Yes.

19 Q. Okay. And if we look down here at the bottom, we see that
20 you are the responsible agent, Amit Patel, correct?

21 A. Yes.

22 Q. Okay. And just tell us briefly, what is everything listed
23 here on the cover sheet going to the FDA?

24 A. So as I explained, these are all the final materials that
25 we submitted to FDA supporting the launch of naïve indication

1 that included data that was approved by FDA in the label. So
2 this is a final submission of all the materials for Prezista.

3 Q. It says up here Form 2253 is required by law.

4 A. Yes.

5 Q. Do you see that?

6 A. Uh-huh.

7 Q. Did Janssen ever provide to its sales representatives any
8 approved promotional pieces to use with doctors that it did not
9 submit to FDA under 2253?

10 A. No.

11 Q. Okay. Did Janssen ever receive an enforcement letter from
12 FDA about the 2253 materials it sent on Prezista and Intelence
13 for use with doctors?

14 A. No, not with the use with doctors.

15 Q. Okay. I want to talk to you about that consumer piece,
16 but this case is about messages that went to doctors.

17 A. Okay.

18 Q. So let me show you what went in this submission here.

19 If we go to page 46, do you see this claim, low impact on
20 lipids?

21 A. Yes.

22 Q. Okay. Low impact on lipids was a promotional claim
23 submitted to the FDA pursuant to 2253, correct, sir?

24 A. Correct.

25 Q. Janssen did not receive any enforcement letter or

1 follow-up from the FDA providing comments on the low impact on
2 lipids claim we submitted for use with doctors, correct?

3 A. Correct.

4 Q. Okay. You testified, sir, that you were -- all right.
5 Let's come back to that.

6 In addition, sir, we also submitted to FDA promotional
7 speaker materials; is that right?

8 A. Correct.

9 MS. BROWN: Your Honor, permission to admit D-2084?

10 I don't think it's tabbed.

11 MR. MARKETOS: No objection, Your Honor.

12 THE COURT: So admitted.

13 (Exhibit D-2084 admitted into evidence.)

14 BY MS. BROWN:

15 Q. In addition, sir, to the low impact on lipids being
16 submitted in connection with promotional pieces, are you aware
17 of lipid language being submitted to the FDA via speaker decks
18 that were being approved by the company at the time?

19 A. Yes.

20 Q. All right. And this is another Form 2253 as required by
21 the law, correct, sir?

22 A. Yes.

23 Q. And once again, is that your name that appears down here?

24 A. Yes.

25 Q. All right. And if we -- it looks like we sort of get a

1 list.

2 Does this work like you can package up a bunch of
3 different promotional materials and send them all at once,
4 Doctor?

5 A. Yeah. On a Form 2253, you have to designate are you
6 submitting these materials -- and you can see under eight,
7 please check one, it says professional or consumer. So all
8 professional materials goes together in one form. And if you
9 are submitting consumer materials, you have to do a separate
10 form.

11 Q. Why does the FDA make a distinction between the submission
12 of professional materials and consumer materials based on your
13 experience?

14 A. While I was at FDA, there is two different groups.
15 Professional reviewers and consumer reviewers are two separate
16 reviewers. They look at the intended audience. Consumer
17 level, consumer audience, they expect company to include
18 information that is at the fifth or sixth grade level versus
19 health care professional materials they expect company to
20 include a lot of contextual information or scientific data that
21 consumers may not understand. So that's more appropriate for a
22 company to disseminate that.

23 It's same as if you look at prescribing information.
24 First part of prescribing information is very technical
25 jargons. That is for health care professional. They're

1 trained to understand. And then the last page of a prescribing
2 information is medication guide or called patient labeling.
3 It's very simple, consumer-friendly.

4 So that's the distinction, is the content is different in
5 professional materials versus the consumer material.

6 Q. And, Doctor, did you just say that there are two different
7 sets of reviewers at the FDA for consumer pieces versus
8 professional pieces?

9 A. Yes.

10 Q. Okay. But I thought I heard you testify on direct that
11 the same regulation applies to both, that they have to be fair
12 and balanced; is that true?

13 A. That's a very general regulation requirement. Promotion
14 should be on label, should include risk information. Fair
15 balanced means is if you're talking about efficacy, you should
16 talk about safety.

17 But what was not discussed is what does the context
18 require for professional versus consumer, and you can look
19 through all the Subpart H FDA comments that we received.
20 Professional materials, they ask for a lot of context. Without
21 the context, the claim can be misleading.

22 For consumer it has to be more face valid, because
23 consumers cannot understand technical jargons. So their
24 concerns are company including claims that requires a lot of
25 context, if it's not included, it's not appropriate for

1 consumer audience.

2 Q. Based on your experience both at the FDA, the DDMAC agency
3 that evaluates Form 2253 requests, and your experience at
4 Janssen, is there a difference between the way the FDA
5 implements these regulations as it relates to consumer pieces
6 versus professional pieces?

7 A. I think FDA does look at the audience in mind when they
8 are reviewing the content and providing the feedback. And they
9 do look at the regulation requirement because there are
10 regulation in the 21 CFR 202.1. There are different ways that
11 things can be false and misleading.

12 So they look at that more from a consumer audience, what
13 you present, is information enough for consumer to adequately
14 understand the risk of the product. And if it's not included,
15 they would object to that.

16 Q. Do you -- as part of your job when you were reviewing
17 these pieces internally and liaising with the FDA, do you ever
18 have conversations with the FDA about these pieces?

19 A. Yes.

20 Q. Did you do that as it related to any Prezista or Intelence
21 pieces?

22 A. Yes.

23 Q. Counsel showed you some regulations, though, that say --
24 or letters that say only written guidance from the FDA is
25 official.

1 Did you see that?

2 A. Yes.

3 Q. So how do the conversations with the FDA inform the job
4 that you do evaluating and approving these pieces?

5 A. As part of the Subpart H, FDA is pretty open to
6 communicate. If we get a advisory feedback on a draft claim,
7 we can talk to a reviewer to understand better what is FDA
8 concern, what would be -- what could company do to address the
9 concern. And they will share their concern and feedback, but
10 it does not change their opinion. It's written, and we have to
11 interpret the guidance we get, but I think it provides more
12 color, just a better understanding to -- so I can work with the
13 organization to -- how to revise the material to incorporate
14 FDA feedback. So it's more of a clarification, and that is
15 important because sometimes you read the letter and it's not
16 clearly understood what is meant by when they write multiple
17 languages -- multiple sentence to describe their concern.

18 Q. Do you recall any of your discussions with the FDA
19 regarding any Prezista pieces?

20 A. Yes.

21 Q. Did you have a conversation with the FDA about the
22 consumer letter we looked at this morning?

23 A. Yes.

24 Q. Tell us about that.

25 A. So --

1 MR. MARKETOS: Your Honor, I'm going to object to
2 hearsay. She's asking about a telephone conversation.

3 THE COURT: Let me see you folks at sidebar.

4 (Sidebar discussion as follows:)

5 MR. MARKETOS: She's trying to elicit a telephone
6 conversation with Mr. Patel and a third party unidentified over
7 the phone who is now going to try to explain this.

8 THE COURT: What's the difference between the letter
9 you put in?

10 MR. MARKETOS: Well, the letter was to him directly
11 as an official writing from the government, and there's no
12 objection to it and it's 803(8). Now he's talking about a
13 phone conversation --

14 THE COURT: Phone conversation with the FDA.

15 Ms. Brown?

16 MS. BROWN: Yes, Your Honor. He testified this is
17 part of how he does his job. This is part of information that
18 he considers in making these decisions. And at the very least,
19 Your Honor, it goes to our state of mind and our knowledge and
20 our intent. We were having conversations with the FDA and
21 being told about what would or would not make these pieces
22 misleading, and that informed how -- where our state of mind is
23 at issue, that informed what we thought.

24 THE COURT: Ms. Brown's argument is that it goes to
25 the impact of the listener, that they're not offered for the

1 truth in saying if I was told by the FDA that this was okay,
2 then why would I take any action to change the messaging.

3 MR. MARKETOS: And they're going to offer it for the
4 truth of the matter asserted that the FDA had this conversation
5 and something that we've never seen.

6 THE COURT: Well, Ms. Brown, I want to be very clear.
7 So you're making the point to me to say, look, Your Honor, we
8 believe it's admissible because we know it's a hearsay
9 statement. There's an exception, because really this is
10 dealing with the impact on the listener. This is not hearsay
11 because we're not offering it for the truth.

12 MS. BROWN: Yes, sir.

13 THE COURT: That would mean, just to be clear, that
14 when the end of trial comes and you're in closing argument, you
15 can't argue the truth of that saying you heard testimony, the
16 FDA told them it was okay. What you could say is you heard
17 testimony that the reason why -- his understanding because
18 that's why he didn't do anything. But you have to be careful
19 about arguing that the FDA approved something if you don't have
20 someone from the FDA saying it.

21 MS. BROWN: Understood, Your Honor. I think what we
22 would say is you heard from Dr. Patel that in interpreting this
23 consumer piece, he spoke to the FDA. And based on feedback, he
24 understood blah, blah, blah, blah, blah. And we continued to
25 do this with the understanding that we were complying with 2253

1 and that these pieces, that we never received enforcement, and
2 that's the way 2253 works.

3 MR. MARKETOS: That's going to be for the truth of
4 the matter asserted.

5 THE COURT: Well, let me ask you this. How does the
6 effect on the listener play out then, right? Because he has to
7 be able to say...

8 MR. MARKETOS: If they're arguing mistake, that's one
9 thing. But now they're trying to prove that the FDA approved
10 it in a phone call.

11 THE COURT: I think what they're trying to show is
12 that he may not have taken certain action because he understood
13 that there was not a problem. I mean, that's --

14 MR. MARKETOS: Right, based on a conversation that
15 he's going to relay about -- call the witness. We're in trial.
16 You want to call the FDA person who had this conversation,
17 that's an in-court statement. Now he's going to testify about
18 an out-of-court statement from some unnamed FDA bot. And we
19 have no way to test that, no way to confront the witness, and
20 it is not an official statement. Everything that's official
21 from the FDA has to be --

22 THE COURT: Is it in his deposition?

23 MS. BROWN: It is, Your Honor. He spoke about it in
24 his deposition, and he just testified this is the way he does
25 his job. He has frequent conversations with both the consumer

1 and the professional reviewer at the FDA.

2 THE COURT: So what are you establishing other than
3 he's communicating with the FDA by phone at times?

4 MS. BROWN: That he spoke specifically about this
5 piece and his understanding, based on that conversation, was
6 the critique articulated in the consumer document was that we
7 had just listed that statement standalone and we didn't include
8 any of the backup data, and that's what made it difficult for a
9 consumer audience to understand before context of that. And
10 his belief is the health care pieces, why we received 2253 is
11 they do include --

12 THE COURT: Do you have anybody from the FDA coming
13 to back that up?

14 MS. BROWN: No.

15 THE COURT: Did he ever identify the FDA in a
16 deposition?

17 MS. BROWN: He may have identified the name of the
18 reviewer, Your Honor. I think he knows --

19 THE COURT: Well, I'm trying to figure this out, too,
20 because it does sound very close to offering it for the FDA
21 approved of this.

22 MS. BROWN: Well, I think, Your Honor, it's
23 different. We get this letter, and his job is to interpret the
24 words on the page. And part of the way he does that, part of
25 the effect on the actions that he takes or doesn't take is

1 informed by what he does in the ordinary course.

2 THE COURT: I'm sorry. Didn't he already testify
3 that -- and you correct me if I'm wrong, but he testified on
4 your examination that there is no approval letter. I submitted
5 all these documents. And if there's silence, it's like
6 silence, it's acquiescence by silence.

7 MS. BROWN: Correct.

8 THE COURT: So he established that process. What
9 you're trying to do is get an unnamed third party from the
10 FDA's statements in to the jury? Why don't you call the FDA
11 guy?

12 MS. BROWN: But, Your Honor, here's why I believe,
13 you know, this is the consumer piece, right. I could have just
14 left it there --

15 THE COURT: He established that also. On your
16 examination, you elicited some testimony that there's a
17 difference between a layman and a standard for a physician, and
18 that something that may be insufficient marketing for a layman
19 because they don't have any kind of medical expertise may not
20 be the same standard for a doctor. So you've elicited that
21 testimony.

22 MS. BROWN: But what Mr. Marketos has tried to
23 establish is that, hey, the only written message you got under
24 Subpart H or the advisory method, the only information you got
25 was that minimal impact on cholesterol is misleading. So he

1 needs to understand and give the basis --

2 THE COURT: I agree. Then why didn't you call the
3 FDA?

4 MS. BROWN: -- for his understanding.

5 THE COURT: Why not call the person that he spoke
6 with?

7 MS. BROWN: Well, I don't think we need to, though,
8 Your Honor. He made this --

9 THE COURT: You do. You do. Just because they have
10 some evidence that you're looking to refute doesn't mean you
11 get to get some hearsay statement in from the FDA to refute it.
12 There is direct evidence that you can refute by having a
13 witness in court make the statement, but what you're saying is,
14 well, we need to refute this evidence, and the only way for us
15 to refute it is through a hearsay statement.

16 Well, that's not my fault. Why didn't you call the
17 person that Dr. Patel told you I spoke to this person at the
18 FDA? Why not depose that FDA person?

19 MS. BROWN: I think what's at issue, Your Honor, is
20 the decisions Dr. Patel made, and I think what's relevant is
21 what informed those decisions. And our state of mind is at
22 issue in this trial. What our intent was is at issue, and we
23 have to be able to elicit that Dr. Patel, the person in charge
24 of giving these statements, to proving these statements for the
25 sales force to take out, had a good faith basis to think that

1 this was an appropriate message.

2 THE COURT: At the end of the day, you're going to
3 put before this jury that the FDA signed off on this.

4 MS. BROWN: That's actually not what I'm going to
5 suggest, Your Honor. I'm going to have him explain what his
6 interpretation of this guidance, this is an advisory opinion
7 that came from the FDA, and what I need him to explain is how
8 he interpreted that as it relates to the consumer pieces for
9 which we didn't receive --

10 THE COURT: Here's what I'll allow you to do. I'll
11 allow you to elicit testimony that he communicated with the FDA
12 verbally, maybe not in writing. And that from those
13 communications, this is it, from those communications it was
14 his understanding that -- whatever, I'll paraphrase, there was
15 no problem. What he's not going to be able to elicit is this
16 is what the person said to me.

17 MS. BROWN: I will make that clear that he's not to
18 say that.

19 THE COURT: And then also, to be clear, once you've
20 elicited that testimony, if that's the only testimony you have
21 or only evidence you have, because I don't know your defense
22 case yet, if that's all that remains, you will not be able to
23 argue that the FDA signed off on any of this. You would only
24 be able to argue that you heard Dr. Patel testify that based on
25 his communications, his understanding is that this was okay.

1 But that's all you've got.

2 MS. BROWN: That's separate, Your Honor, from the
3 2253 process, which he just explained, and that is they don't
4 take enforcement action, that's how the process works.

5 THE COURT: You have that testimony. That's why I'm
6 not going to allow him to testify as to what the FDA told him
7 by phone. I sustained your objection, but I'm limiting -- but
8 I'm not completely prohibiting that examination, but it's very
9 limited now.

10 MS. BROWN: It's his knowledge based on that
11 conversation.

12 THE COURT: Without getting into the conversation.

13 MS. BROWN: Without getting into the details of who,
14 you know -- right?

15 MR. MARKETOS: Yes, Your Honor.

16 We are going to ask for an instruction on the case
17 law. DDMAC's silence must be in writing. There's no
18 acquiescence. It's the law. But I just want to bring that to
19 the Court's attention now, that as part of final instructions
20 we will be asking for that law to be included.

21 THE COURT: We'll get to that. If I end up giving an
22 instruction that hurts one of your presentations because the
23 law is inconsistent with something you've been trying to put
24 before the jury, that's on you all. So I'm not going to get
25 into that today. I'm going to allow Janssen to --

1 MR. MARKETOS: Yes, Your Honor.

2 (End of sidebar discussion.)

3 THE COURT: All right, folks. We're back.

4 MS. BROWN: May I proceed, Your Honor?

5 THE COURT: You may.

6 BY MS. BROWN:

7 Q. Dr. Patel, I understand that part of your work at Janssen
8 involved communicating with the FDA; is that fair?

9 A. Correct.

10 Q. Okay. I don't want you to go into the details of what
11 anybody at the FDA told you. I want to ask you some questions
12 about how your opinion was formed. Do you understand that?

13 A. Can you explain that again? It's tricky.

14 Q. Sure. It is tricky.

15 Was part of your interpretation of the FDA's comments
16 about the consumer piece informed by discussions with the FDA?

17 A. Correct.

18 Q. Without going into the details of who at the FDA said
19 what, can you share with us what your interpretation of the
20 feedback from the FDA was regarding this consumer piece?

21 A. My interpretation was these comments were applicable to
22 the consumer materials. The claims was presented without
23 disclosing all the side effects that were in the package
24 insert. The laboratory abnormalities were included in a table.
25 Based on the conversation, FDA founded minimization of risk

1 because company did not disclose all that in the draft
2 material. If we would have included all those material, FDA
3 opinion would be different.

4 Q. I just want to show you quickly that. I think counsel put
5 it up or it was attached to the exhibit counsel showed you.
6 But do you recognize this as the consumer piece that was at
7 issue in the letter counsel went over this morning?

8 A. Yes. And -- yes.

9 Q. Let me just highlight. This is -- when we say a consumer
10 piece, where does something like this appear?

11 A. This is a journal ad that -- it would appear in a
12 magazine.

13 Q. Okay.

14 A. So consumers will read it in a consumer magazine, pick it
15 up at the grocery stores, that provides them the basic
16 information and suggests them to go to the website to get more
17 information. But it's a journal ad.

18 Q. Okay. And if we go back to the letter from the FDA, the
19 statement that they were concerned about in this consumer piece
20 was Prezista had a low impact on cholesterol, right?

21 A. Yes.

22 Q. And if we go to the actual journal ad that was being
23 proposed, it said, "had low impact on cholesterol," right?

24 A. Yes.

25 Q. And below it, it says, "Prezista does not lower

1 cholesterol levels and has not been shown to provide any
2 heart-related benefits," correct?

3 A. Correct.

4 Q. What was your understanding doing your job at Janssen
5 about what about this draft statement gave the FDA concern?

6 A. Sure. So if you look at the statement above, it says had
7 low rates of diarrhea. So both diarrhea and lipid information
8 are in the same section of the label, which is the adverse drug
9 reaction. And FDA was okay with company making low rates of GI
10 side effects claim as long as you provide proper context, which
11 is what is the frequency of diarrhea reported, which you
12 disclose clearly so people understand it's not 90 percent, it's
13 6 percent, that supports the word low.

14 Q. I'm sorry, can I just interrupt you, Dr. Patel?

15 A. Sure.

16 Q. Are you saying -- when you said you have to give kind of
17 context or the rates, is that what you're referring to where
18 there's this double asterisk and then down here it says
19 reported as moderate to severe, and it gives the percentages?

20 A. Correct.

21 Q. We don't have any asterisk -- first of all, this was a
22 draft piece; is that right?

23 A. Correct.

24 Q. This was never used in this format, correct?

25 A. No.

1 Q. Because this letter that came from the FDA on the consumer
2 piece was advisory under Subpart H?

3 A. Correct.

4 Q. It was not --

5 A. Sorry, it was not Subpart H. It was advisory because we,
6 during the full approval, we proactively sought FDA feedback.

7 And that's advisory. You could do under Subpart H or not
8 Subpart. You could get advisory feedback if you want.

9 Q. Okay. And then as it relates to what we had proposed,
10 this had low impact on cholesterol, it didn't have a little
11 asterisk and additional information?

12 A. Correct. And that's the big distinction between this,
13 what was submitted to -- what was submitted on 2253 for health
14 care professional. It's a very different -- if you look at
15 side by side, the health care professional materials included
16 all the information that we similarly include here for low
17 rates of GI side effects, like diarrhea, nausea, vomiting.

18 So that's really the reason why FDA took issue with this,
19 because we didn't disclose here. And it was pretty -- when we
20 looked at the comments, a patient would not understand what's
21 lipid grade two, grade three abnormalities.

22 I think that was over -- so our attempt was to say, based
23 on the data, so in order to be claimed to be false and
24 misleading, FDA have to look at does the data is a good
25 science. The data is based on good science. It's a randomized

1 controlled trial, which is the gold standard trial that FDA
2 would want.

3 And then you look at, Are you disclosing all the facts
4 that somebody should understand if they read this statement?
5 Just like low rates of diarrhea, what is the percentage
6 patients did experience? So that was missing and that's why,
7 based on a conversation, the concern was we failed to disclose
8 material facts.

9 Q. Okay. And you said compared to the health care provider
10 piece, there was some different information provided; is that
11 right?

12 A. Correct.

13 Q. And this was one of the health care provided pieces that
14 had low impact on lipids. Do you see that, sir?

15 A. Yes.

16 Q. And there are a number of additional datapoints down here,
17 including some of the percentages that we just saw in the
18 consumer piece about GI effects, right, sir?

19 A. So, yeah. So this actually shows that patients did have
20 elevation in triglyceride levels. And this data is comparing
21 to lopinavir, which was studied in a head-to-head trial. And
22 it provides all the information for physician to know how do
23 you look at this information based on the cutoffs that are used
24 to inform clinician decision what to do if patients do have
25 elevated triglycerides, or HDL, and said there's national

1 guidelines that suggest what patients should be treated with.

2 We also disclosed next to this presentation is all the
3 laboratory abnormalities that were -- patient had experienced.
4 If you -- and in that, as you can see, we were very transparent
5 that in naïve population, if you scroll down a little bit, the
6 triglycerides, cholesterol, LDL, all the data was shared. And
7 this is pretty hard to consumerize. And that was a challenge.
8 And once we got the FDA feedback, company made a decision that
9 this is not a claim that we can pursue in the consumer
10 material. I think the health care professional materials
11 provides room to provide all this context. Because the concern
12 by FDA was just as a statement, low impact on cholesterol, may
13 consumer take it as there's no side effects of cholesterol.
14 Versus over here is you have a health care professional who can
15 understand that, and if you look at the rates, are not like
16 90 percent or it's comparable and it's lower than lopinavir.
17 And I think that was a very important context the physicians
18 were asking for this product because protease inhibitors are
19 known to cause lipid issue. They wanted to know what is the
20 Prezista effect on lipids. And this is our way to provide all
21 the facts to avoid any misleading impression.

22 Q. Okay.

23 You testified on direct examination, Dr. Patel, that you
24 were not concerned that the low impact on lipids message that
25 we approved for use by the sales reps and we provided to the

1 FDA, you were not concerned that that was false or misleading.

2 Did I hear you correctly?

3 A. Yes.

4 Q. Tell us why?

5 A. Because based on review of -- first of all, lipid

6 information is in the label. Side effects are in the label.

7 So it's not off-label. This is a characterization of what was

8 observed in clinical trial. We're not presenting clinical

9 trial that is not robust in design, it's different when you're

10 making a claim based on a study that is inadequate in design.

11 This is the trial that got FDA approval for the product. So we

12 are factually presenting what was the data between our product,

13 and we were not making any superiority claim to suggest we're

14 better than lopinavir, we're just suggesting factual data and

15 what the ADR table was also disclosing.

16 So, to me, based on the totality of the presentation, FDA

17 was okay with us using low rates of GI side effects because in

18 the same brochure, the first page before that, had the similar

19 low rates of GI side effects, and FDA had asked us to include

20 all the data if you're going to use the words low rate of GI

21 side effects. So I think it's a similar presentation of side

22 effects. They both are ADRs and they could be equally

23 presented.

24 So as you can see, we had learned through all the Subpart

25 H conversation that low rates of GI side effect was okay by

1 FDA. It's a side effect and we are saying the word "low."
2 Lipid is a side effect too. I think we're characterizing what
3 does the low impact mean. And we put all the data out for
4 health care professional to understand and make their decision.

5 Q. Did you form the opinion, Dr. Patel, based on your time
6 working at the FDA, based on your correspondence with the FDA,
7 based on your understanding of the regulations and feedback
8 from the FDA, that low impact on lipids was not a false and
9 misleading message to provide to doctors?

10 A. Yes. I would say low impact on lipid was not a false,
11 misleading message if it was presented with full context.
12 That's very important in the distinction between -- because by
13 itself, it could be false and misleading because you're not
14 giving by regulation all the context to support the word what
15 does low mean. Just like diarrhea example.

16 Q. And when you, Dr. Patel, and your colleagues at Janssen
17 approved these pieces for the sales reps to use with doctors,
18 did they provide that context that you were prescribing?

19 A. They were required by our company policy.

20 Q. And I had just started to show you before we started
21 talking about the consumer piece the fact that you also
22 provided the FDA with speaker decks; is that right, sir?

23 A. Yes.

24 Q. Okay. And this is an example, what's in evidence, 2084,
25 as one of the speaker presentations that contains data on

1 lipids; is that right, sir?

2 A. Correct.

3 Q. Does it similarly contain in the notes statements like the
4 one we just looked at, that Prezista had a low impact on lipids
5 based on the 48-week data?

6 A. Correct. And if you could see below, it's a balancing of
7 information that provides context.

8 Q. It provides the actual data to support that claim; is that
9 right?

10 A. Yeah. And disclosing what the toxicity were observed. So
11 we were very truthful in sharing everything we knew about the
12 product.

13 Q. And based on your knowledge and your time at Janssen, did
14 Janssen ever receive any feedback on these speaker decks about
15 Prezista and Intelence like the one we're looking at in 2084?

16 A. No.

17 Q. Okay.

18 MS. BROWN: Your Honor, permission to admit D-2163?

19 THE COURT: Mr. Marketos.

20 MR. MARKETOS: Sorry, Your Honor.

21 No objection. Excuse me.

22 THE COURT: All right. No problem. So admitted.

23 (Exhibit D-2163 admitted into evidence.)

24 BY MS. BROWN:

25 Q. I want to show you -- we heard a little bit about another

1 term that was used in some of the materials, "proven lipid
2 profile". Do you recall that, Dr. Patel?

3 A. I remember during the discussion today.

4 Q. Okay. And here it looks like this is 2010, and we're
5 submitting ARTEMIS 96-week lipids piece, do you see that, sir?

6 A. Yes.

7 Q. And, again, this is a professional piece like the ones at
8 issue in this lawsuit, correct?

9 A. Yes.

10 Q. All right. And, again, this is being submitted to the
11 government under Form 2253?

12 A. Yes.

13 Q. All right. And your name, again, is down here as the
14 responsible official or agent?

15 A. Yes.

16 Q. Okay. And does this refresh you, Dr. Patel, about
17 information that was provided to the FDA pursuant to this
18 process with the claim "proven lipid profile"?

19 A. Yes.

20 Q. Okay. Based on your review of this submission, does it
21 contain the contextual information that you were just
22 discussing?

23 A. Yes.

24 Q. How is that, sir?

25 A. Because we -- when somebody use the word "proven" the

1 regulation requires what is the supporting data to say you have
2 proven. So, one, we had studied this drug for 96 weeks in a
3 randomized controlled trial. So that's substantial evidence,
4 first. And second is, we are clarifying what we mean by the
5 findings that were observed on lipid parameters, which are
6 disclosed in the chart in comparison to the compared drug. We
7 also disclosed how they, based on NCEP cutoff, what does that
8 mean? Because that is what the medical input was to -- this is
9 how clinician will look at it, lipid, is how's average patient
10 in the trial perform. Of course there's always an outlier and
11 the outliers are explained on the right side, which is the
12 table that shows how many patients at 96 weeks had incidents
13 which are -- could be concern for a physician, and they should
14 appropriately manage those patients.

15 Q. Okay. I want to show you one more on proven lipid
16 profile.

17 MS. BROWN: Permission to admit D-2215?

18 MR. MARKETOS: No objection.

19 THE COURT: All right. So admitted.

20 (Exhibit D-2215 admitted into evidence.)

21 BY MS. BROWN:

22 Q. One more, Dr. Patel, on the proven lipid profile. Does
23 this appear to be another submission to the FDA that, again,
24 used the term "proven lipid profile" and provided the
25 supporting data?

1 A. I don't recall this material. Can you share with me?

2 Q. Yes, sure. This may have been, Dr. Patel -- were you
3 still in role in July 2011?

4 A. No.

5 Q. Are you generally familiar with the process that continued
6 after you moved into the compliance role?

7 A. I know there was somebody else transitioning in my role.
8 But the same process is that we submit on 2253. So I think
9 this is a final form of the material.

10 Q. Okay. And in terms of the one we were looking at that you
11 do remember, do you remember any feedback from the FDA
12 enforcing or criticizing the term "proven lipid profile" as it
13 was used in pieces with health care providers?

14 A. Since I was there 2015, never received any communication
15 informing that this presentation is false and misleading or it
16 minimizes the risk. And even today, before appearing in Court,
17 I looked at their website, it's the same claim is still there.

18 Q. And we heard some other variations of these lipid terms.
19 And what I wanted to ask you is based on your experience, do
20 sales reps need to go into a physician's office and read word
21 for word the package insert or every word that's on an approved
22 promotional piece?

23 A. When I was in compliance role and when I did field rides,
24 what I generally observed is the reps used this piece as
25 educational tool. They do cover important context and safety

1 information during the call. I think there's -- they don't
2 read word to word. They generalize, but their presentation is
3 consistent with the message that were approved here. So they
4 cannot change the claim and make the new claim on their own.
5 So that was -- homemade materials or claims not approved by
6 company cannot be used in promotional setting.

7 Q. Are sales reps, in your opinion, required to deliver
8 messages that are consistent with company-approved messages and
9 with the package insert?

10 A. That is our company policy, yes.

11 Q. And sales reps, though, are allowed to use their own words
12 that are consistent with the data and with the approved
13 message; is that fair?

14 A. Correct.

15 Q. Okay.

16 Dr. Patel, do you recall a time when we did actually get
17 feedback from the FDA about a promotional piece that was used
18 by mistake?

19 A. Yes.

20 Q. Tell us about that.

21 A. So during Subpart H review, if you guys are familiar with
22 the Google search ads, if you type in a word, a product name,
23 you get a display which allows you to click on a link to go to
24 the website to get more information. So there is called a
25 sponsor ad and then there is called organic. The sponsor ad is

1 what company sponsors. Organic is something Google searches on
2 your website and just pulls it.

3 So during a review, we had reviewed two tabs. One tab, an
4 Excel file, was related to reminder-type ads, which basically
5 just say Prezista, doesn't say this is HIV product, it just say
6 go to this website to learn more. That's it. There is no
7 representation of a product.

8 A second tab was proposed by marketing team to doing
9 claims such as Prezista is an HIV treatment, click here to
10 learn more. And during our review, we did not approve that
11 tab. So when we got FDA enforcement we did an investigation to
12 look at the root cause, and we determined that the person who
13 was responsible for that actually told agency to upload both
14 tabs. So one tab was clearly approved by company, one was not
15 approved through the promotional review committee.

16 So we submitted our findings to FDA. We definitely
17 complied with FDA, we pulled those ads immediately because, A,
18 they were not company-approved and they were violative so we
19 took action immediately. And we put a process in place to make
20 sure this never happens, that only company-approved materials
21 are used.

22 Q. If I could just understand that then, Dr. Patel, it sounds
23 like somebody at the company made a mistake and submitted an ad
24 that hadn't been approved; is that right?

25 A. Correct.

1 Q. It was a consumer Google ad?

2 A. Yes.

3 Q. And within just a couple of months did we hear from the
4 FDA?

5 A. Yes.

6 Q. And did the FDA catch the ad that we hadn't approved?

7 A. Correct.

8 Q. Did we take action?

9 A. Yes.

10 Q. What does that tell you about the FDA oversight when it
11 comes to promotional materials?

12 A. Based on my experience, typically during Subpart H FDA is
13 definitely looking at all the materials once they provide
14 feedback to make sure you're incorporating the feedback.
15 Because if you're not incorporating feedback, they will take an
16 enforcement.

17 Same thing with the launch of new indication, six months
18 to one year is typically the reviewers are very looking at all
19 your data, documentation, because that's really what -- FDA
20 just approved the drug. They want to make sure the drug is
21 approved and presented in a proper balance. So FDA does review
22 all the materials, and if they have issue, they would
23 definitely take enforcement.

24 THE COURT: Ms. Brown, sorry, I don't want to switch
25 topics, but are we at a place where we can take a short break?

1 MS. BROWN: Absolutely, yes.

2 THE COURT: If we're only going to do one break this
3 afternoon, why don't we make it 15 minutes. Then we'll see if
4 we can stretch until 5:00, and I'll let the jurors alert me if
5 we need to do a second break, all right? So let's do that,
6 let's get the jurors to stretch for 15 minutes.

7 THE DEPUTY CLERK: All rise.

8 (The jury exits the courtroom at 3:01 p.m.)

9 THE COURT: Dr. Patel, you can step out for 15
10 minutes if you want to stretch or whatever you want to do.

11 Everyone be seated.

12 Ms. Brown, how much longer?

13 MS. BROWN: Not that much longer. Maybe less than 15
14 minutes.

15 THE COURT: Then do you have some redirect,
16 Mr. Marketos?

17 MR. MARKETOS: I will, Your Honor.

18 THE COURT: We will get to the next witness at least,
19 correct?

20 MR. MARKETOS: I believe so.

21 THE COURT: All right. Real quick, any objection to
22 me -- when we get to the next witness I just want to alert the
23 jurors to one instruction that we have a witness who is
24 testifying, you know, remotely, they're not to consider that
25 any sort of way other than they should evaluate that testimony

1 no different than if the witness was sitting in the box.
2 That's the only instruction I want to give just so they
3 understand. Any objection to that instruction for the next
4 witness?

5 MR. MARKETOS: No, Your Honor.

6 MS. BROWN: No objection.

7 THE COURT: Everybody's in recess.

8 (Recess taken from 3:02 p.m. to 3:14 p.m.)

9 THE COURT: Dr. Patel, do you mind coming back to the
10 witness box since you're already in?

11 THE DEPUTY CLERK: Please rise.

12 (The jury enters the courtroom at 3:15 p.m.)

13 THE COURT: All right. Folks, everybody can have a
14 seat.

15 Just a reminder for the jurors, tomorrow we are 12:30
16 to 5:00. I believe that's my understanding. So I just want to
17 make sure counsel's aware of that too, that I may not be here
18 at 8:30 a.m. tomorrow. So we'll talk later about what time
19 maybe we should link up depending on whether there's any
20 issues. But whatever they are, I want to make sure we're ready
21 to go by 12:30. So even if we have to meet 11:00 or 11:30 just
22 to ensure that we cover any administrative issues, I'm happy to
23 do that. But I wanted the jurors now to be reminded because I
24 might forget by the end of the day.

25 So, guys, if you're ready to go by 12:30, we're good

1 to go. But don't show up in the morning because I may sleep
2 in, so that's where we are.

3 With that, Ms. Brown, if you want to continue your
4 examination.

5 And, Dr. Patel, just remind you, you're still under
6 oath from earlier.

7 MS. BROWN: Thank you very much, Your Honor.

8 BY MS. BROWN:

9 Q. Dr. Patel, I have less than ten minutes of questions left,
10 so we'll just zip through this here.

11 MS. BROWN: Your Honor, without objection from
12 counsel, I'll seek to admit D-4096, D-2078, and D-4232.

13 MR. MARKETOS: No objection.

14 THE COURT: All right. So that's admitted.

15 (Exhibits D-4096, D-2078, and D-4232 admitted into
16 evidence.)

17 BY MS. BROWN:

18 Q. Dr. Patel, just for the record, sir, we have been looking
19 at a number of 2253 submissions for Prezista messaging. Do you
20 recall that?

21 A. Yes.

22 Q. And did we similarly submit to FDA, using the same
23 process, promotional materials that we sought to use for
24 Intelence messages?

25 A. Yes.

1 Q. And I'll just show an example here of an Intelence slide
2 deck that was submitted by 2253.

3 And is this your name down here as well, sir?

4 A. Yes.

5 Q. And, similarly, for all of the promotional materials that
6 were provided to sales reps during the relevant time period in
7 this case, for Intelence, were they all reviewed internally?

8 A. Yes.

9 Q. Were they all provided to the FDA pursuant to 2253?

10 A. Yes.

11 Q. And did we ever receive an enforcement letter or action
12 from the FDA that there was a problem with any of those
13 promotional messages?

14 A. Not to my knowledge.

15 Q. During the entire time period that you worked on
16 promotional pieces for Intelence and Prezista being submitted
17 to the FDA pursuant to 2253, did the company receive an
18 enforcement action for health care provider pieces?

19 A. Never.

20 Q. Final topic, Dr. Patel. I want to talk to you quickly
21 about the Corporate Integrity Agreements that our jury has
22 heard about.

23 Are you familiar with those, sir?

24 A. Yes.

25 Q. Did you have some involvement in the work Janssen did to

1 comply with its obligations under the Corporate Integrity
2 Agreements?

3 A. Yes.

4 Q. Are you familiar with something called an IRO, or an
5 independent review organization?

6 A. Yes.

7 Q. What is that?

8 A. When the companies settle, and we -- with OIG and we got a
9 CIA, as part of the CIA settlement, OIG appointed an
10 independent review organization which is outside of Janssen to
11 oversee over our compliance program, how effective was the
12 compliance program, and how effective we were doing the
13 requirement that was stipulated, how we were implementing the
14 requirements stipulated in the CIA. So that was the role of
15 the IRO, to oversee the implementation of the CIA.

16 Q. And are you familiar with something called a RAMP?

17 A. Yes.

18 Q. What is that?

19 A. It's part of the Corporate Integrity Agreement, and when I
20 was a compliance officer we had to develop a risk assessment
21 mitigation plan, called RAMP. I can explain more.

22 Q. Yeah. Let me just ask you a couple questions. Then I'll
23 give you the chance to explain.

24 The risk assessment mitigation plan you just discussed,
25 was that something that was prepared for Prezista?

1 A. Yes.

2 Q. Was the risk assessment mitigation process something that
3 was prepared for Intelence?

4 A. Yes.

5 Q. So it was a product-specific plan?

6 A. Yes.

7 Q. Was it reviewed by the IRO?

8 A. It was provided to IRO, yes.

9 Q. And tell us what it included.

10 A. So all the pharmaceutical products that we were
11 responsible for, Janssen, each compliance officer had to work
12 with the business partners to identify what are the potential
13 activities that we might be engaging with, either promotional,
14 health care professional through speaker program, or any
15 activities that we think that might be a potential risk.

16 The word potential is we don't know there's a risk but
17 there could be a risk, and what are the mitigation efforts that
18 company has in place as of today, policy, training, oversight
19 monitoring, and if there's something missing that is something
20 we need to create new, then we work with the organization
21 including sales and marketing and the president of the company,
22 to implement the new requirements and capture that as part of
23 the risk assessment mitigation plan.

24 So it's pretty comprehensive. Covers all the off-label,
25 potential off-label use when we know that health care

1 professionals are allowed to use our product off label on their
2 own. And if there's such a high use of it, we have to capture
3 that because that's a potential exposure for the company and
4 sales reps too, so how are we helping them to comply.

5 Q. And when you say mitigation, Dr. Patel, was part of this
6 RAMP process that was reviewed by the independent organization,
7 did it deal with our policies and procedures to make sure the
8 sales force was in compliance with the regulations and the
9 policies?

10 A. Yes.

11 Q. Did you interact with the IRO, the people from the
12 independent company, to make sure that we were meeting our
13 obligations under the CIA?

14 A. Yes, compliance officers were interviewed by IRO as part
15 of the IRO activities.

16 Q. Did you ever receive feedback from the independent
17 company, the IRO, that there was something wrong or deficient
18 about the RAMP plans for Prezista or Intelence?

19 A. Not to my knowledge.

20 Q. Okay. Did you work with the IRO to make sure we met our
21 obligations?

22 A. Yes.

23 Q. And based on the feedback you received from the folks at
24 the IRO you were interacting with, was your understanding that
25 our policies and procedures were meeting our requirements?

1 A. Correct.

2 Q. Finally, Dr. Patel, I heard you say there came a time that
3 for personal reasons, you left Janssen; is that right?

4 A. Yes.

5 Q. Did you leave on good terms, sir?

6 A. Yes.

7 Q. Are you here today testifying?

8 A. Yes.

9 Q. And did you move out of the area for personal reasons?

10 A. Yes.

11 Q. Have you remained in the regulatory pharmaceutical
12 industry?

13 A. Yes.

14 MS. BROWN: All right. Thank you very much for your
15 time, Dr. Patel. I have no more questions.

16 THE COURT: All right. Thank you, Ms. Brown.

17 Mr. Marketos, any redirect?

18 MR. MARKETOS: Yes, Your Honor. Thank you.

19 Make sure my mic is on. Excuse me.

20 REDIRECT EXAMINATION

21 BY MR. MARKETOS:

22 Q. Good afternoon, Dr. Patel.

23 A. Good afternoon.

24 Q. Sir, you told me on direct examination that you're not a
25 medical doctor, right, sir?

1 A. Correct.

2 Q. You also said you're not a lawyer, right?

3 A. Correct.

4 Q. You -- you said you would have to seek legal advice even
5 for an understanding of the application of the Anti-Kickback
6 Statute.

7 Do you remember that testimony?

8 A. I have understanding -- I think your question was more
9 about the potential topic could be violation of Anti-Kickback,
10 so that's a different question.

11 Q. And you'd have to seek legal advice, legal counsel, is
12 what you told us, right, to answer that?

13 A. To get their input, yes.

14 Q. And, in fact, with respect to whether or not cholesterol
15 or lipids can lead to congestive heart failure, you told us
16 you're not a medical doctor, that would be more medical advice,
17 right, sir? Do you remember that?

18 A. Yes.

19 Q. Okay. But you just testified, as I understood it, about
20 the differences under the laws and the regulations of the FDA
21 as it relates to consumer and direct-to-physician advertising.

22 Do you recall that?

23 A. Yes.

24 Q. And you also were talking about how a doctor is more
25 capable of interpreting information in an ad.

1 Do you remember that?

2 A. Yes.

3 Q. Sir, I want to make perfectly clear, I think -- I think
4 it's your testimony that from Janssen's perspective and from
5 your perspective, Janssen received approval from the FDA for
6 these lipid messages because they didn't say anything about
7 them?

8 A. Can you repeat that question again? Sorry.

9 Q. Yeah. Let's make sure I've got this right, okay?

10 It's my understanding that it's your testimony to the
11 members of the jury that from your perspective and from
12 Janssen's perspective, the FDA -- you actually said -- was it
13 tacit approval or indirect approval? That's what it was.
14 Indirectly approved were your words.

15 They indirectly approved of these ads by not sending an
16 enforcement action; is that right?

17 A. That is correct.

18 Q. Just so we're all clear, you're saying that the Food &
19 Drug Administration indirectly or tacitly approved of Janssen's
20 lipid messaging for Prezista by not saying anything in writing?

21 A. They never took enforcement, correct.

22 Q. So you're saying that the FDA approved indirectly or
23 tacitly of Janssen's messaging by not writing to Janssen and
24 taking enforcement; is that right?

25 A. Correct.

1 Q. Okay. So they didn't do anything on specific promotional
2 materials you sent, and Janssen took that as FDA approval; is
3 that right?

4 A. That's my understanding, yes.

5 Q. All right. Just so we're clear, sir, you testified in
6 response to my questions on direct that the FDA will only take
7 official action in writing, correct?

8 A. Correct.

9 Q. And that's not just an opinion. That's not something you
10 formed from your few months being at DDMAC 20-something years
11 ago.

12 That's the regulation; that's the law, correct?

13 A. Correct.

14 Q. Okay. So it has to be in writing to be official. What
15 the FDA can also do if you submit an ad is they can respond,
16 and if they don't have an objection to your ad they could say
17 no further comment, correct?

18 A. On a draft materials only.

19 Q. To be clear --

20 A. Yes.

21 Q. -- on a draft material only, just like the one we saw
22 about low impact on cholesterol, if they don't have an
23 objection to what is being submitted to the FDA, they can write
24 back and say we have no objection at this time, correct?

25 A. I think your question is confusing me. Are you referring

1 to draft material or the final material?

2 Q. Once again, sir, the draft material. That was a draft
3 material that was submitted to the FDA that led to a response
4 from the FDA that you've called guidance that said low impact
5 on cholesterol is misleading.

6 Recall that?

7 A. Yes, yes.

8 Q. What the FDA could do in a certain situation like that is
9 respond and say no comment at this time?

10 A. That is accurate.

11 Q. What the FDA could also do is say that's false and
12 misleading in writing, right, sir?

13 A. That is accurate.

14 Q. Or the FDA might not respond at all, correct?

15 A. It's -- no. Typically for Subpart H, FDA has to either
16 respond to you, or we tell them we're not waiting for comments.

17 Q. Dr. Patel, I'm not asking about Subpart H. That's before
18 you get label approval. I'm talking about April of 2009.

19 That's after Subpart H approval when this letter was
20 received, right, sir?

21 A. That is incorrect. Label is approved during Subpart H
22 also, so I'm not understanding your question. Sorry about
23 that.

24 Q. Let me just make sure I frame it correctly, okay?

25 The FDA can take one of three courses of action in

1 response to a draft advertisement, okay? It can say this ad is
2 bad or false in writing?

3 A. Sure. Yes, correct.

4 Q. It can say no comment at this time, correct?

5 A. Correct.

6 Q. The FDA can also not respond at all, correct?

7 A. That has not been my experience.

8 Q. Well, sir, in fact, with respect to DDMAC, you were there
9 for, I think you told us, a few months right out of school,
10 right?

11 A. Out of pharmacy school, yes.

12 Q. Yes, right before you went to work for Johnson & Johnson.

13 A. Correct.

14 Q. And that was 20-something years ago that you were there,
15 right?

16 A. Yeah.

17 Q. For a few months, correct?

18 A. For nine months, yes.

19 Q. Okay. And you understand that the FDA receives a hundred
20 thousand promotional materials submitted by pharmaceutical
21 manufacturers every year?

22 A. Correct.

23 Q. And there are 40 employees, right?

24 A. Correct.

25 Q. An enforcement action is taken only if they catch you?

1 A. That is incorrect.

2 Q. Well, they have to catch you doing something. They have
3 to have reviewed an ad, right, sir? They have to have reviewed
4 it first in order the take an enforcement action, right?

5 A. When they review, they have concerns, they take
6 enforcement.

7 Q. Yes, sir. One of those 40 employees has to catch a
8 misleading or false statement in promotional materials in order
9 to take an enforcement action.

10 That's the order of operations, right?

11 A. Yes.

12 Q. And it's your testimony that the FDA implicitly or tacitly
13 or indirectly approved of ads that were sent -- marketing
14 materials sent by Janssen because they didn't say anything; is
15 that correct?

16 A. Can you repeat that again? Sorry.

17 Q. It's your testimony, with respect to promotional materials
18 that Janssen did deliver to the Food & Drug Administration,
19 that they tacitly or impliedly or indirectly approved of those
20 ads because they didn't respond to them, correct?

21 A. Yes.

22 Q. So you have nothing in writing from the FDA with respect
23 to these lipid profile messages that says no comment, true?

24 A. For health care professional materials, no, yes.

25 Q. For any materials.

1 You have nothing from the FDA in writing saying no comment
2 at this time about lipid profile?

3 A. That's correct.

4 Q. You have nothing from the FDA other than a letter that was
5 received in April of 2009 saying low impact on cholesterol is
6 false and misleading, right?

7 A. Correct.

8 Q. But it's your testimony to the members of the jury
9 nonetheless that Janssen considered its promotional materials
10 to doctors to have been approved by the FDA because they didn't
11 respond; is that right?

12 A. Can you repeat that question, because -- is it a yes-or-no
13 question?

14 Q. I thought it was, sir. Let me ask it again.

15 It's your testimony to the members of the jury that
16 Janssen believed the FDA had approved its promotional materials
17 for Prezista with lipid profile messages delivered to doctors
18 because the FDA didn't respond; is that true?

19 A. True.

20 Q. And you're aware of the fact that under the regulations
21 and the guidance manuals, that the FDA will provide comments
22 but only those in writing are considered official, right, sir?

23 A. That's correct.

24 Q. And that's been the rule. That's what they put in the
25 letters to you. That's what's in the regulations, right?

1 A. That is correct.

2 Q. And if you thought -- I'm just wondering. If you thought
3 that the FDA had approved of proven lipid profile or low impact
4 on lipids by not responding to items that you sent to the 40
5 employees that were there, why were you so worried about this
6 regulatory action against Roche?

7 A. That is our normal review. We ensure any enforcement FDA
8 issues, we look at it to see how -- what the issues were
9 identified, how is their presentation, is it similar or not, to
10 understand that so we see if we were in the same boat, we know
11 how to make changes.

12 Q. According to your testimony, sir, for four years, Janssen
13 had been delivering messages to doctors from 2006 until 2010
14 that contained messages about lipid profiles, right, sir? Up
15 until that Roche enforcement action, right? Hold on. I'm
16 sorry. Let me make sure I frame this so we don't have to go
17 off on a paragraph, okay?

18 It's your testimony, as I understand it, that between 2006
19 and 2010, Janssen had been delivering promotional materials to
20 doctors about lipid profiles with Prezista; is that true?

21 A. Not true.

22 Q. It's not true that Janssen had its sales force delivering
23 marketing messages to doctors from 2006 to 2010?

24 A. The claims were introduced in 2008, so not the 2006. We
25 didn't have any claims on lipids during Subpart H review

1 because it was in a different study design.

2 Q. You're saying that there were no lipid messages delivered
3 by the sales force between 2006 and 2008, for two years?

4 A. Correct.

5 Q. So I'm sorry, sir. I represent two sales representatives,
6 two sales reps for Janssen that were on the ground from 2006
7 until 2008 and beyond.

8 You're telling us that those sales representatives didn't
9 deliver messages to doctors about the lipid profile for
10 Prezista?

11 A. They were never approved in promotion materials. All the
12 materials, you can look at it, there was no discussion of
13 lipids in those materials. Low impact on lipids was never
14 approved until we got to the naïve indication.

15 Q. For two and a half years, if the sales representatives
16 around the country were telling doctors that Prezista had a low
17 impact on lipids or a minimal impact on lipids, that was not an
18 approved message by Janssen?

19 A. To my knowledge, that was not approved until eight. We
20 submitted on 2253 in eight, 2008, as we were looking at the
21 materials.

22 Q. So the drug was launched in June of 2006, right, sir?

23 A. Correct.

24 Q. And for two and a half years, you're saying that there was
25 no approved message that those sales representatives could

1 deliver to doctors?

2 A. Not to my knowledge. We approved any messages because the
3 studies were different.

4 Q. So if any messages were being delivered by sales
5 representatives for that two-and-a-half-year period, between
6 2006 when the drug launched and 2008, it's your testimony to
7 this jury that those were all unapproved messages?

8 A. Those were not approved by me, and I have to look at the
9 context of when you say lipid information, because there may be
10 something in a PI that they might be referring to. So you have
11 to look at the package insert to see what lipid information was
12 included.

13 Q. For two and a half years, if sales representatives were
14 saying low impact on lipids, minimal impact on the lipids, just
15 like Reyataz, similar to Reyataz, those were all unapproved
16 messages even by Janssen, according to you?

17 A. Correct.

18 Q. All right. What we do know is that if we wanted to look
19 at a piece of paper that came from the FDA saying this lipid
20 message is approved by the FDA, you don't have a piece of paper
21 for us to look at?

22 A. No.

23 Q. You mentioned, sir -- I'm trying to follow it.

24 You mentioned that there was a different standard that is
25 applied to consumers versus doctors, messages that are

1 delivered to all of us versus those that are delivered to
2 doctors; is that right?

3 A. Correct.

4 Q. Except that that standard is not recognized in the law, as
5 you testified in response to my questions.

6 Do you remember that?

7 A. I think I testified that laws are similar. It's just the
8 way you communicate to health care professional versus consumer
9 is different.

10 Q. The regulations that apply to promotional advertising for
11 pharmaceutical companies are the same for consumers and
12 doctors?

13 A. Yes.

14 Q. An advertisement that is misleading or false to a
15 consumer, you're saying it is not misleading or false to a
16 doctor?

17 A. Correct, depending on the context.

18 Q. So you testified about fair and balanced. I'm not asking
19 about something that's fair and balanced. I'm asking about
20 whether a message is true or false, okay?

21 Is it your testimony that a message that is false, when
22 it's delivered to a consumer, like low impact on cholesterol,
23 that message is true if it's delivered to a doctor?

24 A. If message is delivered with proper context, it's true.

25 Q. So something that is false could also be true?

1 A. Correct.

2 Q. I understood you to say, sir, that you were in Janssen's
3 compliance department from 2010 forward doing something, but
4 there was an IRO organization that was essentially babysitting
5 your department; is that right?

6 A. I wouldn't describe it that way.

7 Q. Okay. I'll describe it differently. They were -- there
8 was a compliance organization overseeing your compliance
9 organization overseeing Janssen's sales force?

10 A. That was appointed by OIG so --

11 Q. Yes.

12 A. -- I cannot comment on why did they appoint it.

13 Q. The Corporate Integrity Agreement required oversight of
14 Janssen for its lack of compliance, right?

15 A. That's not my understanding.

16 Q. Okay, sir. But if we were to look at -- we've seen a
17 spreadsheet of the number of speaker events that compliance
18 attended. If we were to show that spreadsheet to the jury and
19 sort for the number of times that you attended a speaker event
20 from 2010 until you left, how many speaker events do you think
21 that would show?

22 A. I don't know the number, but we were assigned by our head
23 of compliance across all Janssen pharmaceutical products how
24 many per product. We have to do speaker or rep rides, field
25 rides, to comply with the CIA requirements.

1 Q. You're talking about a number of events that Janssen,
2 company-wide, different Janssen subsidiaries had to comply with
3 in order to meet the requirements of a Corporate Integrity
4 Agreement they had entered into with the federal government,
5 right, sir?

6 A. Correct.

7 Q. That's not what I'm asking about. I'm asking about
8 Dr. Amit Patel, okay?

9 You were in compliance for Janssen, as I understand it, a
10 health care compliance officer from 2010 until 2015, correct?

11 A. Correct.

12 Q. You went to no speaker events during that time period?

13 A. I don't remember that because I had -- Catherine Kaucher
14 was my -- reporting to me. She was primarily responsible for
15 Prezista and Intelence.

16 Q. I'm going to ask this one more time, sir.

17 You, Mr. Patel, attended zero --

18 A. Okay.

19 Q. -- zero speaker events between 2010 and when you left for
20 Prezista and Intelence; is that true?

21 A. I have to look at the data to confirm that's accurate.

22 Q. Have you looked at it before today?

23 A. No.

24 Q. Have you tried to determine how many speaker events -- you
25 testified to the members of the jury in response to questions

1 from counsel for Janssen and your counsel that you attended
2 speaker events. I thought I heard that.

3 A. Yes.

4 Q. But you don't know if you attended any for Prezista and
5 Intelence?

6 A. It's been over how many years? So to know the actual
7 number, I don't know that. I don't recall that.

8 Q. Yes, sir. But Janssen has the data. It's in evidence in
9 this case. There's a spreadsheet.

10 A. Okay.

11 Q. Have you looked at it to see if you went to a single event
12 for Prezista or Intelence to determine whether they were
13 compliant?

14 A. I have not looked at that spreadsheet.

15 Q. Do you have any recollection of going to one?

16 A. I did speaker program evaluation for Janssen CNS products
17 psychiatry or Prezista/Intelence. I don't have that
18 information.

19 Q. Okay. Dr. Patel, I'm trying to be fair here. Let me just
20 frame it this way.

21 Do you recall going to one single speaker event for
22 Prezista or Intelence on the promotional speaker bureau?

23 A. Yes.

24 Q. You recall going to one now?

25 A. I mean, at least one, yeah.

1 Q. You do recall going to a speaker event?

2 A. Yes. You're asking me just do I recall going ever, yes.

3 Q. You do recall going more than zero times?

4 A. More than zero times, yes.

5 Q. Was it less than five?

6 A. I don't know that.

7 Q. Somewhere between five and zero?

8 A. I don't know the answer.

9 Q. Okay. There were almost 9,000 speaker events for Prezista
10 an Intelence that were held during this time period, 2006 to
11 2014.

12 Do you understand that?

13 A. Okay. Yes.

14 Q. Do you know that to be true? Sir, I represent the
15 Relators in this case. I'm counsel for the Relators.

16 You were the head compliance officer for Janssen from 2010
17 to 2014, right?

18 A. I think you keep referring to me as head. I was not the
19 head of compliance there. So, I'm sorry, I cannot answer your
20 questions.

21 Q. Okay. You were the compliance officer for Janssen, for
22 this unit of Janssen, for that specific time period, correct?

23 A. Catherine Kaucher was the compliance officer for
24 Janssen/Tibotec Therapeutics, and I was compliance officer for
25 Janssen CNS, which is separate from the HIV portfolio. Now,

1 she reported to me. That was my relationship. I had oversight
2 management responsibility.

3 Q. So you were actually the compliance officer for a
4 different company than the one that we're here talking about?

5 A. I had both responsibilities. She was reporting to me so I
6 had understanding of what the Janssen/Tibotec Therapeutics
7 compliance issues were.

8 Q. So Catherine Kaucher was reporting to you?

9 A. Yes.

10 Q. You were her boss?

11 A. Yes.

12 Q. So you had oversight of the compliance for this
13 organization, Janssen/Tibotec?

14 A. Yes.

15 Q. So it's fair for me to ask you if you ever went to an
16 event for Prezista or Intelence; is that fair?

17 A. Yes, fair.

18 Q. But you don't recall how many you went to?

19 A. I don't know the actual number.

20 Q. Sir, you were making some -- you had some discussions
21 about the FDA taking enforcement actions, do you recall that?

22 A. Yes.

23 Q. Actually, what Johnson & Johnson teaches all of its
24 subsidiaries, and what Janssen teaches all of its employees is,
25 if there's off-label promotion that the FDA doesn't catch, the

1 False Claims Act is a mechanism of enforcement. You understand
2 that, right?

3 A. I don't understand this. Sorry. Can you repeat again or
4 clarify?

5 Q. Yes, sir.

6 Enforcement actions taken by the government, taken by
7 whistleblowers on behalf of the government under the False
8 Claims Act, is the primary mechanism for enforcing off-label
9 promotion by pharmaceutical companies. Are you aware of that?

10 A. That's not entirely accurate.

11 Q. Okay. Are you aware of the fact that a case like this
12 brought by whistleblowers on behalf of the government is a
13 mechanism of enforcing off-label promotion under the False
14 Claims Act?

15 A. To my knowledge, that's one way, yes.

16 Q. Mr. Patel, last question for the day, sir. Are you able
17 to testify on behalf of Janssen as to the safety of Prezista
18 and Intelence as they were marketed and promoted by the sales
19 representatives to doctors around the country?

20 A. I don't understand your question. What do I testify for?

21 Q. Yes, sir. Are you familiar yourself, sir, can you testify
22 that the products that Janssen delivered to doctors to
23 prescribe to their patients were safe for their hearts?

24 A. I don't think I'm qualified to answer that question about
25 unapproved use because Prezista was never approved to treat

1 heart conditions.

2 Q. I understand it wasn't approved to treat heart conditions,
3 Dr. Patel. It had side effects that could affect those heart
4 conditions. You understand that, right?

5 A. Okay.

6 Q. Do you understand that, sir?

7 A. Yes.

8 Q. You're not testifying to the jury that those side effects
9 couldn't have caused problems for patients, are you?

10 A. As I said, that's more of a medical expertise required to
11 understand patient situation to see if it will or will not.

12 Q. That would require a medical doctor's opinion?

13 A. Yes.

14 MR. MARKETOS: No further questions. Thank you.

15 THE COURT: All right. Thank you, Mr. Marketos.

16 Dr. Patel, you're excused from the trial. Thank you.

17 THE WITNESS: Okay. Thank you.

18 (Witness excused.)

19 THE COURT: Before the next witness, Counsel, can I
20 see you for one moment, folks, just before we call the next
21 witness?

22 (Sidebar discussion as follows:)

23 THE COURT: Remind me, this is your witness?

24 MS. BROWN: Yes, Your Honor.

25 THE COURT: I should also allow them to know that,

1 look, the defense is calling a witness out of order, I
2 permitted that for witness availability issues. And he'll also
3 testify remotely. Then I'm going to say that they're not to
4 consider any of that other than they should evaluate this
5 witness as if the witness is testifying in the courtroom. I
6 think that's the only fair instruction to give. But I also
7 want them to understand that this is not Relators' witness.
8 And that you're directing now, and they're on cross. And this
9 is just being done because I made a determination to do that.
10 Does that make sense?

11 MS. BROWN: It does.

12 MR. MARKETOS: That's fine, Your Honor.

13 THE COURT: Yeah, just so they have a sense.

14 MS. BROWN: Appreciate it. Thank you, Your Honor.

15 (End of sidebar discussion.)

16 THE COURT: Folks, just briefly on the next witness.
17 So the next witness is actually being called by the defense out
18 of order. And, well, there's two issues, one is, I'm allowing
19 this witness to be called out of order because the witness has
20 an availability issue for when Janssen is calling their
21 witnesses. So I'm going to allow them to call this one witness
22 ahead of time in the Relators' case, but also I'm permitting
23 this witness to testify remotely by video. You are not to
24 consider that in any way really whatsoever other than you
25 should evaluate this witness's testimony as if the witness is

1 testifying in the witness box. So you should just consider all
2 the same factors that you would evaluate any witness that's
3 been testifying before you, but it's going to be done by video.

4 The only other thing is logistically this is a
5 defense witness being called early because there was an
6 availability issue and I made a determination to allow this one
7 witness to come early to testify.

8 So I just wanted to make sure you understand that
9 we're switching roles a bit. Janssen's counsel is going to be
10 doing direct examination of this witness. Relators' counsel is
11 going to be cross-examining. And Ms. Brown will be doing the
12 redirect. So we're reversing it. It's only for this one
13 witness. And then we go back into the regular course and the
14 Relators continue to present their case.

15 With that, Ms. Brown, do you want to call this next
16 witness?

17 MS. BROWN: We do. Thank you very much, Your Honor.
18 We call via video Dr. Ricky Hsu.

19 THE DEPUTY CLERK: Good afternoon, sir, can you hear
20 me?

21 THE WITNESS: Yes, I can.

22 (Witness sworn.)

23 THE DEPUTY CLERK: Please state your name for the
24 record.

25 THE WITNESS: Ricky Hsu.

1 MS. BROWN: May I proceed, Your Honor?

2 THE COURT: You may, Ms. Brown.

3 DIRECT EXAMINATION

4 BY MS. BROWN:

5 Q. Dr. Hsu, good afternoon. My name is Alli Brown. I'm a
6 lawyer for Janssen. Can you hear me, sir?

7 A. Yes.

8 Q. Okay. Do we need to turn up the volume or you're okay
9 proceeding?

10 A. If you could turn up the volume a tiny bit, that would be
11 very helpful.

12 Q. Dr. Hsu, I'm just going to switch to this microphone, is
13 that better?

14 A. It's much better. Thank you.

15 Q. Sure, no problem. Let me just bring my stuff over.

16 MS. BROWN: And then, Your Honor, may I proceed?

17 THE COURT: You may.

18 BY MS. BROWN:

19 Q. Okay. Dr. Hsu, I think we're ready to go. Everything
20 okay on your end?

21 A. Yes, it is.

22 Q. Okay. Sir, would you introduce yourself to our jurors,
23 tell them who you are and what you do?

24 A. Sure. So as you know, my name is Ricky Hsu. I am an
25 internal medicine physician. Been in practice in the field of

1 internal medicine with an emphasis in HIV medicine for the last
2 26 or so years. My current role is the national medical
3 director for the AIDS Health Care Foundation.

4 Q. Dr. Hsu, what is the AIDS Health Care Foundation, sir?

5 A. The AIDS health care foundation is actually the largest
6 provider of HIV care in the world. We're in over 40 countries
7 and take care of about 1.3 million people affected by HIV. In
8 the US we have roughly 50, 60 clinics that take care of about
9 60,000 people with HIV.

10 Q. And can you tell us a little bit about what you do as the
11 medical director for the AIDS Health Care Foundation?

12 A. Sure. So I am responsible for establishing the clinical
13 standards for all of the doctors, nurse practitioners and PAs
14 in the organization. I also develop some policy regarding a
15 variety of different disease states. And involved in
16 education.

17 Q. Okay. Do you treat patients, Dr. Hsu?

18 A. Yes. Actually, 70 percent of my time is in direct patient
19 care. About 20 percent is administrative. And 5 percent in
20 clinical research.

21 Q. Okay. And, sir, can you tell us just a little bit about
22 where you went to medical school and how you decided to get
23 involved in the field of HIV care and treatment?

24 A. Yes. So I did go to Harvard. And I initially was going
25 to pursue a potential MD Ph.D. program because my undergraduate

1 work as well as my after undergraduate work was in actually
2 basic -- what you call basic science, and it was always in the
3 infectious disease space, microbiology, HIV, and immunology.

4 And after my second year of medical school there was
5 clinical. I decided to abandon the Ph.D. portion and
6 concentrate on the MD portion because I really enjoyed patient
7 care and direct patient interaction.

8 In terms of HIV itself, as I mentioned, from a research
9 standpoint I was always interested in infectious disease area
10 and I've worked with people like Tony Fauci in his lab for HIV,
11 but personally this was coming around at a time in the, you
12 know, early '90s where basically HIV was still a death sentence
13 at that point, and there were not very many, I guess, options
14 for a number of our patients. And I had -- I, myself, being a
15 gay male, had a number of friends and very close people that
16 were affected by HIV and who passed away from the illness
17 itself.

18 Q. Fair to say, sir, it's an area of care that is important
19 to you both personally and professionally?

20 A. I would definitely say so, yes.

21 Q. All right. And have you devoted now more than 20 years of
22 your professional life to treating patients in this area?

23 A. Yes. My training and residency, many fellowships and
24 current practice have all been in this area.

25 Q. And you mentioned working with Dr. Fauci, was that work

1 that you did as part of a government laboratory or where did
2 you work with Dr. Fauci?

3 A. Yes, I worked in his lab -- NIH lab doing HIV research.

4 Q. And that's the National Institutes of Health, Dr. Hsu?

5 A. That's correct.

6 Q. Do you also currently hold a teaching position at NYU,
7 sir?

8 A. Yes, I do.

9 Q. And what do you teach there?

10 A. So general internal medicine and primary health care. So
11 we do have medical students. We also really invite any
12 residents who would like to come in and rotate through our
13 office. But we also let them know if anyone has any particular
14 interest in LGBTQ care or HIV care, that our facility is more
15 than happy to teach the students.

16 Q. Sir, have you published in the scientific literature about
17 issues regarding HIV?

18 A. Yes, I have, probably over 50 papers or so in the area.

19 Q. And have you similarly lectured to other doctors at
20 conferences and other professional events regarding your
21 experience and knowledge in the area of HIV?

22 A. Yes. I do attend most of the national and international
23 HIV conferences and have lectured in multiple conferences as
24 well.

25 Q. And, Dr. Hsu, final background question, and I don't mean

1 to embarrass you, sir, but have you been recognized with awards
2 and recognition for your work in the area of HIV?

3 A. Yes, I have. I've gotten a few honors and currently help
4 evaluate and review journal articles for a number of potential
5 publications in the field.

6 Q. Dr. Hsu, the reason we asked you to come testify here in
7 this case, do you understand that this is a lawsuit being
8 brought by sales representatives who worked at Janssen, and the
9 time period at issue is about 2006 to 2014?

10 A. Okay. Yes, I do.

11 Q. And there are claims being made in this case, Dr. Hsu,
12 about Janssen's speaker bureau and about claims that sales reps
13 were making off-label promotion claims to doctors like you. Do
14 you understand that, sir?

15 A. Okay. Yes, I do understand that.

16 Q. Okay. And I want to start by talking with you first about
17 Janssen's speaker bureau, okay, sir?

18 A. Sure.

19 Q. You, Dr. Hsu, were a member of Janssen's speaker bureau
20 for a period of time; is that correct?

21 A. That's correct.

22 Q. Okay. And was Janssen the only company for whom you
23 served on a speaker bureau?

24 A. No. I actually served in all the speaker bureaus for all
25 the companies. I think the number of patients I see gave me a

1 | broad exposure to a number of different drugs, and I think a
2 | lot of the speaker bureaus are -- speakers are chosen in a
3 | speaker bureau because of their ability to convey information
4 | in a short and concise and understandable way to providers. So
5 | I also spoke for Glaxo ViiV, Merck, Abbott, and Bristol-Myers,
6 | Gilead and Serono and Thera.

7 | Q. Dr. Hsu, why did you make the decision to serve on the
8 | speaker board of Janssen as well as some of these other
9 | companies?

10 | A. So a few things. I mean, I think one of the things I
11 | really do enjoy and I actually find it not, shall I say -- I
12 | would judge for myself. It would not be a good program if I
13 | present a program and people don't go home with some type of
14 | learning point that they gained from me. So I do like,
15 | obviously, education -- it's my current role -- and I do like
16 | providing education to others.

17 | I have to say, being part of the different speaker bureaus
18 | also really forces you to be up to date with the latest data
19 | for almost all of the products that are out there, including
20 | those products in development. So having that knowledge, also
21 | just kind of, I would say, kept me on my toes in terms of just
22 | my understanding of HIV and its multiple aspects of use.

23 | Q. It sounds like, Dr. Hsu, it was both a benefit for you
24 | professionally, but you also hoped to educate some of your
25 | colleagues; is that right?

1 A. Absolutely.

2 Q. Okay.

3 A. And I won't be mistaken about it. You know, it's also
4 nice, of course, getting compensation for the work, but it is
5 hard work that you spend a lot of hours, you know, plodding
6 through slides and trying to get them ready for hopefully an
7 interesting discussion at the lecture.

8 Q. And we heard, Dr. Hsu, that some of the speaker programs
9 lasted a couple of hours. Is that consistent with the programs
10 that you did, sir?

11 A. Yes. So oftentimes, especially the dinner programs, do
12 last a couple hours. Most of the times the slides themselves
13 roughly would be 45 minutes and you always want to leave at
14 least 15 minutes for questions. But usually, as questions went
15 on, sometimes we'd extend to two hours if people were
16 interested in the topic area.

17 Q. Dr. Hsu, do you have to spend time preparing to give your
18 presentation at these events?

19 A. Absolutely. You know, I mean, I think a good amount of
20 time oftentimes was utilized on personal hours after general
21 work where we would -- you know, where I would go through the
22 slides, try and really understand them, try and figure out how
23 to present it in a manner that could be clinically useful for a
24 provider and to also understand the competitive landscape
25 should that information get brought up.

1 Q. Do you recall, Dr. Hsu, signing a speaker contract with
2 Janssen prior to your engagement on the speaker program?

3 A. Yes. Every year we are required to sign a speaker
4 contract.

5 Q. Okay. And I'm going to move that into evidence right now,
6 sir. And I'm going to try to do it without slowing us down
7 here. Just a minute.

8 MS. BROWN: Your Honor, counsel indicated no
9 objection to D-4187.

10 MR. MARKETOS: No objection, Your Honor.

11 THE COURT: So admitted.

12 (Exhibit D-4187 admitted into evidence.)

13 BY MS. BROWN:

14 Q. And, Dr. Hsu, I have what we've admitted into evidence now
15 as one of the contracts that you signed with Janssen. I
16 understand you would have done this every year, sir, is that
17 about right?

18 A. That's correct.

19 Q. And one of the things you agreed to in the contract was to
20 undergo speaker training, is that accurate?

21 A. Yes, every year there was a speaker training.

22 Q. Yes. And you also agreed, sir, that you would be of
23 course compensated for your time preparing and presenting,
24 correct, sir?

25 A. Yes, that is correct.

1 Q. And did you understand and agree that that compensation
2 would be set at fair market value?

3 A. Yes.

4 Q. And did you understand and agree in the contract that that
5 compensation was not meant to obligate you, sir, to use our
6 medicines?

7 A. Absolutely. I actually would not. There was actually a
8 situation where there was one company that I did speak with
9 that actually broached that topic area and actually asked and
10 told me that I was part of the speaker bureau, however, my
11 prescriptions were not on par with the usual speakers on the
12 speaker bureau. And I actually found that extraordinarily
13 offensive and did report that to the company's manager. That
14 was not Janssen. Different company.

15 Q. I understand, sir. You're telling a story about another
16 company's speaker bureau; is that right?

17 A. That is correct.

18 Q. And you understood that company to be suggesting that your
19 participation in their speaker bureau was tied to how much you
20 prescribed of their drug?

21 A. Yes. And pretty much all the other companies have not
22 tied speaking to prescriptions. It was just this one company
23 that I was rather shocked that they actually brought it up.

24 Q. And did you say you reported that, sir, to the company?

25 A. Yes, I did.

1 Q. Did you ever have that experience with Janssen?

2 A. I did not.

3 Q. Okay. Would you have continued to serve on Janssen's
4 speaker bureau if you believed your participation was dependent
5 on how much of Prezista or Intelence you were prescribing?

6 A. If it was dependent, I would have severe reservations in
7 being part of the speaker bureau. I would try and discuss this
8 with whoever is making that comment, and if that was
9 definitively the case, I would probably feel it went beyond my
10 line of ethics.

11 Q. Do you understand, sir, that the allegations in this case
12 are that Janssen paid speakers like you to prescribe more
13 Prezista and Intelence?

14 A. I am not aware and have not ever experienced feeling any
15 pressure to prescribe a particular drug to be part of the
16 speaker bureau. Except for that one company I mentioned.

17 Q. Do you understand, sir, that the amount of money Janssen
18 compensated you was set at fair market value pursuant to the
19 contract that you signed?

20 A. Yes, I am.

21 Q. And do you understand that pursuant to the open payment
22 regulations, that payment was made public on a website that
23 anybody could access?

24 A. Yes, I am. I am aware of it.

25 Q. Okay. Did you agree, sir, in the contract that you signed

1 with Janssen, to present information at these speaker events
2 that was consistent with the approved slide decks the company
3 provided?

4 A. Yes, that is part of the training that Janssen provided
5 and so that is what we indeed followed.

6 Q. Did you understand you had the ability, if someone asked
7 you a question outside of that slide deck, to answer it, but
8 then you had to return to the approved slide deck?

9 A. Yes, I am aware of this.

10 Q. And based on those speaking engagements that you did for
11 Janssen, did you follow those policies?

12 A. Yes. I think a lot of providers naturally I think, people
13 in the field of HIV generally are pretty passionate about
14 figuring out what the optimal drugs are for the patients to
15 help them adhere and maintain their drug therapies. So in the
16 early years, even up to the early 2000s, in this period came
17 about there were a lot of, I guess, innovative or off-label
18 methodologies of treatment that would naturally come up in
19 discussion because of, you know, what was presented at the
20 conferences. The conferences -- at every conference there was
21 something pretty significant or new or interesting that came
22 about. So these topic areas did oftentimes come up. I, like
23 we were trained, would state that this is an off-label issue.
24 It's an off-label indication for the drug. Making that quite
25 clear. Address the question with whatever data or experience

1 we had, and then return to the original slide deck.

2 Q. Were you, Dr. Hsu, visited in your office or at your
3 institution by Janssen sales reps regarding Prezista and
4 Intelence?

5 A. Yes.

6 Q. And do you understand the claims in this lawsuit are that
7 our sales reps, when they visited doctors, including you,
8 promoted those medicines off-label? Do you understand that,
9 sir?

10 A. That's the claims in this lawsuit.

11 Q. Yes, sir.

12 A. That's what I understand.

13 Q. Yes. Do you, based on your memory and your experience,
14 believe that Janssen sales reps came to your office and
15 promoted Prezista and Intelence to you off-label?

16 A. I do not think so. They were -- I think the sales reps
17 have been very good in discussing just on-label information.
18 What the provider talks about in his or her office on their own
19 is up to that provider. And so if the provider brings up
20 off-label information, they, you know, would just ask that
21 provider's experience and why they would not actually promote
22 it themselves.

23 Q. Did you recall receiving visits from a Janssen sales rep
24 named Nancy Bartnett?

25 A. Yes, absolutely. Nancy, honestly, is one of, in my

1 | opinion, this one provider's opinion, an extraordinarily bright
2 | representative who knew the information regarding her drug as
3 | well as multiple other competitor's drugs and some of the
4 | latest data at the conferences better than a lot of providers
5 | knew information.

6 | Q. What about a Janssen sales rep named Tim Mcsherry, do you
7 | recall receiving visits from him?

8 | A. Yes. Also extremely nice. And, yes, we did get along.

9 | Q. And in terms of any Janssen sales rep that visited your
10 | office, do you recall them promoting Prezista and Intelence to
11 | you for use in off-label ways that were not indicated in the
12 | label?

13 | A. The Janssen representatives themselves did not promote
14 | that. They may have asked me how I utilized it and how I felt
15 | the drugs were useful and I may have volunteered on my own
16 | off-label information. But I usually do say, you know, in my
17 | own office that I know this is off-label, but this is why I
18 | think this is supported based on so and so study.

19 | Q. Do you, Dr. Hsu, and did you during the time period in
20 | this case make decisions in your own medical judgment to use
21 | Prezista or Intelence in an off-label manner for your patients?

22 | A. Yes. On my own clinical judgment, I did use Prezista and
23 | Intelence in an off-label manner.

24 | Q. And why would you, as an HIV expert and doctor, why would
25 | you make that decision, sir?

1 A. So I think it's really mainly because of what we've
2 learned from other drugs that have been in development. For
3 example, one of the reasons why I use a good amount of Prezista
4 is because, unlike many providers, a lot of my patients have
5 been with me 25 -- some 20, 25 years from the beginning, and
6 they've gone through a number of different medicines and have
7 become resistant to them so have few options. And it's a
8 protease inhibitor that is utilized for those patients who have
9 a good amount of resistance.

10 Kaletra is a protease inhibitor that was the first
11 protease inhibitor that really showed that a protease inhibitor
12 that's very potent could still be utilized in a patient who
13 wasn't so good at adherence, yet not have resistance be
14 developed. And Kaletra was approved, I think, around 2000 or
15 so, first for highly experienced patients, and then a few years
16 later it was approved once a day for first-line therapy for
17 treatment-naïve patients.

18 Very similarly, Prezista was compared to Kaletra and it
19 showed the same results, if not even superior results to
20 Kaletra, and also similar showed extraordinarily good efficacy
21 in experienced patients. And having that ability potentially
22 to use in naïve patients did indeed make sense because naïve
23 patients are generally much more easy to treat than experienced
24 patients.

25 And regarding the use of Prezista occasionally in naïve

1 patients to help preserve treatment options was off-label early
2 on, 2006 when I think Prezista got approved, later it was
3 approved in that indication. But I did consider using it
4 earlier on in that manner before it got officially approved.

5 Q. Dr. Hsu, would you ever allow a sales rep's promotional
6 message to hijack or override your independent medical judgment
7 about what's best for your patients?

8 A. No, I wouldn't. I would definitely not feel comfortable
9 and would not want that person in the office if they couldn't
10 at least understand or listen to some things I was saying to
11 influence and unfairly try to pressure me to practice a certain
12 way.

13 Q. If sales reps from Janssen were in your office regularly
14 promoting Prezista and Intelence off label, would you report
15 that to the company or to somebody?

16 A. If they actively promoted it without someone bringing it
17 up, yes, I would potentially do that.

18 Q. Do you recall a Janssen sales rep named Jessica Penelow?

19 A. I knew Jessica with a different last name.

20 Q. Jessica Finkelstein?

21 A. Yes, I knew her as Jessica Finkelstein.

22 Q. Okay. And similarly, sir, do you have any memory of
23 Ms. Finkelstein, now Ms. Penelow, coming into your office and
24 promoting these medicines for Janssen in an off-label way?

25 A. No, she did not come to my office and promote these

1 medicines in an off-label way.

2 Q. Just a few final questions, sir.

3 One issue that has been a big topic for us in this trial
4 is lipids as they relate to the use of protease inhibitors.

5 Is that a topic you generally have some knowledge about,
6 sir?

7 A. Yes, I do.

8 Q. Do you, Dr. Hsu, as an expert in the area of HIV,
9 understand that all protease inhibitors can have an impact on
10 lipids?

11 A. Yes, yes, I do.

12 Q. How did you, Dr. Hsu, view Prezista's lipid profile in
13 your medical view?

14 MR. MARKETOS: I'm sorry, Your Honor, objection.

15 THE COURT: Sidebar.

16 MS. BROWN: I'll withdraw.

17 THE COURT: No, I need to see you guys anyway.

18 MS. BROWN: Dr. Hsu, we just have to run up and speak
19 to the judge. We'll be right back.

20 THE COURT: They can walk. They don't have to run.
21 Don't give the doctor the wrong impression about judges.

22 (Sidebar discussion as follows:)

23 THE COURT: Just remind me, though, is he testifying
24 as an expert?

25 MS. BROWN: No, he's testifying as a doctor who may

1 --

2 THE COURT: But you're saying in your questioning "as
3 an expert in HIV." It sounds like he's testifying as an expert
4 witness in the case. I thought he was a fact witness.

5 MS. BROWN: I apologize. He is a fact witness, Your
6 Honor. I meant just because he has such impressive
7 credentials, but I'll rephrase.

8 THE COURT: Credentials is one thing, but he's not an
9 expert. So you're going to have to clarify that.

10 MS. BROWN: I will do that.

11 MR. MARKETOS: He's not disclosed as an expert.

12 MS. BROWN: I can rephrase the questions.

13 THE COURT: Guys, slow down.

14 MR. MARKETOS: I want to be clear, Your Honor. She's
15 trying to elicit an opinion about a lipid profile from him as a
16 medical doctor. She's trying to get an expert opinion in.
17 That's not allowed.

18 THE COURT: Let me hear from you, Ms. Brown, because
19 it sounds like that's exactly what you were doing.

20 MS. BROWN: Not meaning to do that, Your Honor. I
21 will rephrase the question and make clear --

22 THE COURT: What is the question?

23 MS. BROWN: That he had an independent understanding
24 in his medical judgment of the medicines he was prescribing and
25 their lipid profiles. That's it.

1 THE COURT: Is he going to go into lipid-friendly is
2 not off label and this is --

3 MS. BROWN: No, no. I just am establishing that
4 doctors like him who treat these patients understand generally
5 the lipid profile of this class of medicines. They have
6 independent knowledge that every medicine in this class can
7 raise lipids.

8 THE COURT: And that's it?

9 MS. BROWN: Yes, sir.

10 THE COURT: And you're going to also fix the expert
11 issue.

12 MS. BROWN: Right now.

13 THE COURT: So your objection is sustained, but
14 you're going to clear it up. Okay.

15 (End of sidebar discussion.)

16 BY MS. BROWN:

17 Q. We're back, Dr. Hsu. One thing I want to make clear. I
18 was calling you an HIV expert, but to be clear, you're
19 participating here not as a, quote, expert witness for Janssen.
20 You are a fact witness, and you were on our speaker bureau.
21 Do you understand that, sir?

22 A. I do understand that.

23 Q. Okay. And when we left off, sir, we were talking about
24 physicians' knowledge generally about protease inhibitors and
25 their lipid profiles.

1 Do you remember that, sir?

2 A. Yes.

3 Q. And is that -- I apologize, sir. Go ahead. Let me just
4 rephrase the question to make sure I keep us on track.

5 Is that something, sir, when you make a prescribing
6 decision, you consider your independent medical knowledge and
7 experience when prescribing medicines in that class?

8 A. Yes. So prescribing protease inhibitors, always, you
9 know, there are advantages and disadvantages with each and
10 every drug that's out there for HIV, similarly to other non-HIV
11 drugs. But with the protease inhibitors, a number of them have
12 caused some elevations in lipids, both in total cholesterol,
13 triglycerides, and the LDL, bad cholesterol.

14 In comparison to some of the earlier protease inhibitors
15 like Kaletra and Crixivan, there seems to definitely be some
16 advantage of Prezista very similar to one of the, what we call,
17 second generation protease inhibitors called Reyataz, where
18 both of them had more favorable lipids than the first
19 generation of protease inhibitors; however, it still causes
20 mild elevations in lipids.

21 Q. Finally, Dr. Hsu, just from your point of view, sir, as a
22 doctor who was visited by Janssen sales reps, based on your
23 experience, did the Janssen sales reps who visited you promote
24 these two medicines, Prezista and Intelence, to you
25 affirmatively off-label?

1 A. No, they did not, not that I recall at all.

2 Q. Finally, sir, based on your participation in Janssen's
3 speaker bureau, were you of the understanding that Janssen was
4 paying you to increase your prescriptions of Prezista and
5 Intelence?

6 A. I was and am not at all aware that my being involved with
7 the speaker bureau had anything to do with my prescription
8 volume.

9 MS. BROWN: Dr. Hsu, thank you very much for your
10 time. I'm going to sit down, and the lawyer for the other side
11 will come up.

12 THE COURT: All right. Thank you, Ms. Brown.

13 MS. BROWN: Thank you.

14 THE COURT: Mr. Marketos.

15 MR. MARKETOS: Thank you, Your Honor.

16 CROSS-EXAMINATION

17 BY MR. MARKETOS:

18 Q. Dr. Hsu, good afternoon, sir.

19 A. Good afternoon.

20 Q. My name is Pete Marketos. I represent the Relators,
21 Jessica Penelow and Christine Brancaccio. You understand that
22 they were representatives for Janssen during the time period
23 from 2006 to 2014? Were you aware of that?

24 A. Okay. I knew they were part of the Janssen sales force.
25 I don't recall the time period.

1 Q. Thank you, Dr. Hsu.

2 And you actually, as I understand it from your testimony,
3 you recall Ms. Jessica Penelow, but you knew her as
4 Ms. Finkelstein; is that right?

5 A. That is correct.

6 Q. And, sir, I never have had a chance to speak with you.

7 You've had a chance to speak with Janssen's lawyers about
8 this case; is that right?

9 A. That is correct.

10 Q. Okay, sir. And did Janssen's lawyers tell you what this
11 case is about, Dr. Hsu?

12 A. Yes, they did.

13 Q. Okay. Dr. Hsu, were you aware of the fact that Janssen's
14 promotional speaker bureau during the time period from 2006 to
15 2014 held almost 9,000 speaking events?

16 A. No, I'm not aware of that.

17 Q. Were you aware, Dr. Hsu, that during that time period,
18 Janssen paid more than 335 different doctors to give speeches
19 on that promotional speaker bureau?

20 A. No, I'm not aware of marketing practices. I would expect
21 that to be fairly similar to other companies.

22 Q. You would? You would expect other companies to have held
23 almost 9,000 programs during that same time period?

24 A. I would think so.

25 Q. Okay, sir.

1 A. Just a guess.

2 Q. I understand, sir.

3 You mentioned, Dr. Hsu, that you had one experience with
4 another company, and you found it offensive because that
5 company was suggesting that your participation on the bureau
6 was tied to your prescriptions.

7 Do you recall that testimony?

8 A. Yes. Yes, I do.

9 Q. Now, I understand that you, sir, would sign a contract on
10 an annual basis to speak with a number of companies, and
11 Janssen was one of them, correct?

12 A. That is correct.

13 Q. And at the end of each year, you would then sign another
14 contract, including nine years in a row for Janssen, correct?

15 A. Correct.

16 Q. And that was, of course, for both Prezista and Intelence?

17 A. For myself -- I don't recall exactly when we started
18 talking about Intelence, the exact time period, but I did sign
19 yearly contracts to speak on behalf of both.

20 Q. Understood, Doctor.

21 And like you said, it's nice money; is that fair?

22 A. Yes.

23 Q. And to be clear, sir, Janssen paid you, in cash money in
24 the form of checks \$300,000 during that time period, right,
25 sir?

1 A. In nine years, yes, I guess so. I'm not aware of how much
2 they paid me absolutely.

3 Q. Well, Janssen has continued to pay you, sir, money over
4 the last eight years as well, which is available under the
5 Sunshine Act, correct?

6 A. That is correct.

7 Q. And since 2016, Janssen has paid you an additional
8 \$300,000; is that right?

9 A. If that's what the Sunshine Act states, that's correct. I
10 did not look at the reports myself.

11 Q. All right, sir. And to be clear, that's separate and
12 apart from the amount of money that you get paid to be on a
13 speaker bureau. Janssen has paid you for items of, like,
14 consulting fees and other source of payments not related to a
15 promotional speaker bureau, correct?

16 A. Yes. That does include research, and I am part of the
17 Janssen's presidential advisory board while Janssen had that
18 process. So they had selected -- they select about ten, I
19 guess, influential providers in the area to help them
20 understand their medicines, to help guide their research, and
21 to actually help do the research.

22 Q. Yes, sir. So Janssen has paid you to be on advisory
23 boards, correct?

24 A. Yes, and research as well.

25 Q. And I'll go through them one by one if you bear with me,

1 Doctor.

2 They paid you to be on advisory boards, correct?

3 A. Yes.

4 Q. They've paid you for research, correct?

5 A. That's correct.

6 Q. They've paid you for consulting, correct?

7 A. I think that is part of the advisory boards, but maybe it
8 might be separate.

9 Q. Is the amount of money that you have received directly
10 from Janssen, sir, over \$1 million?

11 A. I do not think so.

12 Q. All right. Somewhere between 600,000 and a million; is
13 that right?

14 A. I would be a little surprised, but possibly. I think a
15 lot of that money also is reimbursement for all of the expenses
16 of, you know, hotels, flights --

17 Q. Yes, sir.

18 A. -- car services.

19 Q. I'm sorry. I don't mean to speak over you, sir. I just
20 want the jurors to understand.

21 You get paid money directly from Janssen in the form of
22 honoraria is what they call it? That's --

23 A. Yes.

24 Q. -- checks directly to you for speaking, right?

25 A. That's correct.

1 Q. And those amounts have totaled more than \$300,000.

2 Do you agree?

3 A. In nine years, possibly, yes. I'm not keeping track of
4 it.

5 Q. And since, right, sir? It wasn't just for that nine-year
6 time period.

7 You've been paid by Janssen several hundred thousand
8 dollars since 2014, correct?

9 A. If that's what your records do show, that is correct.

10 Q. And I don't want to misrepresent anything, sir. I'd like
11 to know if you're aware of the fact that the Janssen that is in
12 this courtroom has paid you more than \$300,000 since 2014?

13 A. Since 2014?

14 Q. Yes, Dr. Hsu.

15 A. As honoraria, I do not think that's correct.

16 Q. In any form or fashion since 2014, sir, they have paid you
17 more than \$300,000, correct?

18 A. I do not think it was honoraria for speaking, and I think
19 they gave me, I'm guessing, for research. We don't -- you
20 know, all the research funds just go back into our company, the
21 health care foundation company. So I don't know. And I also
22 thought this case was about the years 2008 to 2014.

23 Q. Yes, doctor.

24 A. I'm just curious why we're talking about beyond 2014.

25 Q. I was just wondering if Janssen was paying you today, sir,

1 if you're receiving checks from Janssen even today.

2 A. I am not being paid by Janssen. Janssen disbanded their
3 HIV group, including all of their promotional talks, their
4 research, as well as their advisory boards, roughly two years
5 ago.

6 Q. Thank you, Dr. Hsu. I appreciate that. It's important
7 that we know. One of the reasons, Dr. Hsu, that you found it
8 offensive that one company had tied your speaking and getting
9 paid to speak on a bureau to their prescriptions was because
10 that's unethical.

11 Would you agree?

12 A. I would say so, yes.

13 Q. It's unethical because if somebody is -- if a company, a
14 pharmaceutical company is paying a doctor to speak on a speaker
15 bureau and they tie those payments to the level of
16 prescriptions for that doctor, it seems like a kickback.

17 Do you agree?

18 A. I would agree with that, yes.

19 Q. Are you aware of the fact, Dr. Hsu, that Janssen was
20 tracking your prescriptions after it paid you to be on the
21 promotional speaker bureau for Prezista and Intelence?

22 A. I do -- I am aware that all pharmaceutical companies track
23 doctors' prescriptions. I can't remember the name of the
24 program, but there is a program where all pharmaceutical
25 company representatives do know -- actually, I think Viiv

1 | stopped that process maybe ten years ago where the reps are not
2 | aware of prescription practices of the provider, but for all
3 | other companies, they do do that. I am aware of that. Yes.

4 | Q. I'm sorry, Dr. Hsu. Let me take it back to Janssen for
5 | the time being.

6 | Are you aware of the fact that Janssen the company was
7 | tracking your prescriptions for Prezista and Intelence after it
8 | started paying you to be a speaker?

9 | A. I think that like all other pharmaceutical companies,
10 | whether it be Janssen or not, all our prescriptions are being
11 | monitored and tracked.

12 | Q. And were you aware, Dr. Hsu, that during that time period,
13 | the sales force for Janssen was tracking the amount of
14 | prescriptions of Prezista and Intelence that you wrote, sir?

15 | A. Yes, I think I was aware of that. And as I was saying,
16 | I'm aware that all companies, with exception of ViiV, have
17 | their representatives know how many prescriptions the doctor is
18 | writing.

19 | Q. All pharmaceutical companies do that; is that right?

20 | A. That I'm aware of, yes.

21 | Q. All right, sir. And were you aware of the fact that
22 | Janssen would remove speakers from their promotional speaker
23 | bureau if they didn't prescribe enough Prezista and Intelence?

24 | A. I am not aware of that policy. It could have happened,
25 | but I was not aware of it.

1 Q. You weren't aware of it, sir, because you had a high level
2 of prescriptions of Prezista and Intelence during the time
3 period from 2006 to 2014, so with you, that issue was never
4 raised, fair?

5 A. Yes, but it's hard to jump to the conclusion, at least in
6 my mind, that because I wasn't dropped from the bureau that
7 someone else was dropped from the bureau because of their
8 prescription.

9 Q. Yes. I understand, sir. You might have wanted to hear
10 the testimony of the president of the company stating that
11 speakers were removed from the program if they didn't prescribe
12 enough of the drug; is that fair?

13 MS. BROWN: Your Honor, I object. That misstates
14 Mr. Mattes's testimony. It also lacks foundation here.

15 THE COURT: I'll sustain the objection.

16 MR. MARKETOS: I'm sorry, Your Honor.

17 BY MR. MARKETOS:

18 Q. Dr. Hsu, are you aware of whether or not the president of
19 the company in this case has attested to the fact that the
20 company Janssen would remove speakers if they didn't prescribe
21 enough drug? I'm just asking if you're aware of that.

22 MS. BROWN: I object as misstating the testimony.

23 THE WITNESS: No.

24 THE COURT: Do you have the transcript?

25 MS. BROWN: We can get it, Your Honor.

1 THE COURT: Let me see it.

2 MS. BROWN: Okay.

3 THE COURT: I'll sustain the objection for now. Why
4 don't you continue with your examination.

5 MR. MARKETOS: Thank you.

6 BY MR. MARKETOS:

7 Q. Let me just ask it this way, sir.

8 If, in fact, that were happening, if, in fact, it were
9 true that the company Janssen were removing speakers from the
10 speaker bureau if they didn't prescribe enough drug, that would
11 concern you enormously, wouldn't it?

12 A. It would concern me if the reason why they were removed --
13 not because of the number of drugs that, you know, they
14 prescribed. It would be unethical in my mind to directly link
15 being part of the speaker bureau to direct the number of
16 prescriptions a provider writes.

17 I think if a provider does not have experience with the
18 drug -- so let's just say hypothetically they may be writing
19 one or two or five prescriptions of Intelence so had very
20 little experience with it or do not know the data regarding it,
21 that drug, then I could understand why that person wouldn't be
22 on the speaker bureau, because they wouldn't be able to convey
23 the information.

24 However, if you have two cases of two providers that wrote
25 the same amount of drug, one who was on the speaker bureau, and

1 one that was not on the speaker bureau and one was removed
2 because their prescriptions dropped, that would be of concern
3 and would be ethically, in my mind, concerning.

4 Q. Thank you, Dr. Hsu.

5 It would be in your view unethical for a company like
6 Janssen or any pharmaceutical company to remove a speaker from
7 a speaker bureau because they weren't writing enough
8 prescriptions for the drug, fair?

9 MS. BROWN: Objection, Your Honor. Asked and
10 answered.

11 THE COURT: I'll overrule it because it's a long
12 answer. I need him to clarify.

13 THE WITNESS: I'm sorry. Should I answer that?

14 THE COURT: Yes, you should, Dr. Hsu. This is the
15 judge. You can answer it.

16 THE WITNESS: Okay. So I think it would be unethical
17 if a provider -- if Janssen removed someone from a speaker
18 bureau because they -- I guess their prescriptions -- how
19 should I put this. This is an interesting question.

20 If we had adequate -- if a provider had adequate
21 experience with the drug and was able to convey that
22 information and they were taken off the speaker bureau because
23 they had a drop in their prescriptions, I would have problems
24 with it ethically.

25 BY MR. MARKETOS:

1 Q. Yes, Dr. Hsu, because then it would seem like the payment
2 of money was being made in exchange for prescriptions, right?
3 That's why you would have a problem with it?

4 A. Potentially, yes. Yes, I would think so.

5 Q. Now, you attested to the fact, sir, that as I understand
6 it, off-label conversations came up with some frequency during
7 the speaker engagements that you hosted; is that right?

8 A. Yes.

9 Q. All right. And as I understand it, sir, that would be
10 because somebody from the audience asked a question --

11 A. That's correct.

12 Q. -- that prompted an off-label response, right, sir?

13 A. Yes.

14 Q. Because in order to speak off label at a promotional
15 speaker event, you're not permitted to do so unless an
16 unprompted question comes from the audience, right, sir?

17 A. That is correct.

18 Q. Okay. Do you know whether or not Janssen was using plants
19 in the audience at the speaker engagements that you attended in
20 order to prompt discussions about off-label prescriptions for
21 Prezista and Intelence?

22 A. I'm not aware that was a tactic used.

23 Q. If that were, in fact, a tactic that was deployed by the
24 sales force nationwide in order to prompt off-label discussions
25 about these two drugs, that would be enormously concerning to

1 you, would it not?

2 A. Yes, it would.

3 Q. That would be an unethical way to obtain and spread
4 off-label information about a drug in violation of the law,
5 right, sir?

6 A. I would think so, yes.

7 Q. And, sir, you mentioned that you remember Nancy Bartnett.
8 Do you recall testifying about her?

9 A. Yes.

10 Q. And do you recall that she was very -- I think you said
11 she was bright and had lots of data; is that right?

12 A. Yes.

13 Q. And Nancy Bartnett had a lot of data and so did Tim
14 McSherry, right, sir?

15 A. I think they both did, but Nancy was particularly -- she
16 particularly knew the data from all the conferences better than
17 a great majority of people.

18 Q. From all the conferences and all the studies that she
19 shared with you, right, sir?

20 A. That we talked about, yes.

21 Q. Do you know how many of those conversations that you had
22 with Ms. Nancy Bartnett included discussions about off-label
23 studies?

24 A. Well, with myself she oftentimes would ask me what my
25 experiences were and why I felt or thought the way I did. And

1 so, you know, we would discuss that.

2 Q. Yes, sir. And you said, as I understood it, that
3 Janssen's sales representatives, including the Relator in this
4 case, Ms. Penelow, never marketed to you or promoted their
5 drugs to you off-label. Do you remember having that
6 conversation?

7 A. Yes.

8 Q. Sir, you were actually on the early access program for
9 Janssen's drug Prezista. Do you recall that?

10 A. I actually do not, but thank you for reminding me.

11 Q. Do you remember that now, you were part of an early access
12 program to evaluate the long-term safety and tolerability of
13 Prezista back before the drug was even launched? Do you recall
14 that?

15 A. Honestly, I do not. I'm usually part of almost every
16 extended access drug, if it's available.

17 Q. I'm sorry for interrupting, sir. Sorry, it's a little bit
18 difficult.

19 A. Go ahead.

20 Q. You actually learned during the course of your training
21 and being on the early access program that Prezista did not
22 have a good lipid profile, do you recall that?

23 A. It has a decent lipid profile, but there are some
24 downsides to it. It's not as good as other drugs, some other
25 drugs.

1 Q. Yeah, it's not as good as other drugs that were available
2 on the market. And Prezista's label stated that there were
3 adverse and serious adverse reactions with respect to
4 hypercholesterolemia and hyperlipidemia, right, sir?

5 A. Yes.

6 Q. And, in fact, at one point at Cabrini Hospital, Ms. Nancy
7 Bartnett told you that Prezista had great lipids and that it
8 was the same as Reyataz, and you found that odd because you
9 were -- you had learned that Prezista did not have a good lipid
10 profile like Reyataz. Do you recall that?

11 A. I actually do think it had similar lipids like I mentioned
12 in my last testimony. I put them together as the second
13 generation protease inhibitors. So significantly better than
14 the first generation protease inhibitors like Kaletra and
15 Crixivan, but still with some lipid elevations. And it does
16 depend on the person, some people are more predisposed than
17 others for lipid elevations.

18 Q. I apologize for interrupting, sir. I asked a different
19 question. Would you like me to restate it?

20 A. Yes, please.

21 Q. Yes, sir.

22 You were actually in a conversation with Ms. Nancy
23 Bartnett at Cabrini Hospital, do you recall that, where she
24 stated at the time that Prezista had great lipids and were the
25 same as Reyataz; and you stated in front of Ms. Penelow that

1 | you found that odd. Do you recall that conversation?

2 | A. I do not recall that conversation now, sorry.

3 | Q. You don't recall finding that conversation or that

4 | statement by Ms. Bartnett to be odd because you had learned

5 | through the early access program that Prezista had lipid issues

6 | associated with that drug? You don't recall that?

7 | A. No, and it's not through the early access program. I

8 | think through the clinical studies it shows a mild elevation in

9 | lipids that is very similar to Reyataz and certainly better

10 | than a lot of the prior -- pretty much all the prior protease

11 | inhibitors. I would be surprised if she said it was great

12 | because I think she would be aware that there is some

13 | elevations very similar like there are some elevations to

14 | Reyataz.

15 | Q. So is the answer to my question, Dr. Hsu, you don't recall

16 | that conversation taking place?

17 | A. I do not recall that conversation specifically.

18 | Q. One of the reasons that the sales representatives who

19 | called on you from Janssen would not promote the drug off-label

20 | as having a good lipid profile is because you were educated on

21 | the drug and knew that it did not have one at the time. Do you

22 | recall that?

23 | A. The company's -- the representatives have been very good

24 | to not promote things off-label. So I don't think any -- I'm

25 | not aware, at least that comes to memory, of any representative

1 that was promoting things off-label.

2 Q. All right. Sir, one of those people you said was not
3 promoting the drug off-label was Ms. Jessica Finkelstein, now
4 Ms. Penelow, right, sir?

5 A. Yes.

6 Q. It's your testimony that Ms. Penelow has not promoted
7 Prezista and Intelence off-label; is that right?

8 A. Not that I recall. I do not think she did.

9 Q. At least not to you, that's what you can tell us?

10 A. Yes, not to me.

11 Q. There were 335 other doctors on that speaker bureau, and
12 thousands of attendees, you're aware of that, right, sir?

13 A. Sure.

14 Q. All right. And to the extent that off-label information
15 was shared during those speaker bureaus, that off-label
16 information would have reached hundreds or thousands of other
17 doctors, right, sir?

18 A. I'm trying to figure out which off-label information.

19 Q. Well, any off-label information that was discussed during
20 those bureaus would necessarily reach the audience, do you
21 agree?

22 A. Not unless it was actively discussed from the audience
23 members and it was a reactive discussion. But as I was
24 mentioning, a lot of people go to these conferences, especially
25 during this period of time, in the early 2000s, where --

1 Q. I'm sorry, Dr. Hsu, do you remember my question, sir? I'm
2 sorry to interrupt but we've got five minutes left before
3 letting the jurors go. If you wouldn't mind, sir, I just have
4 some questions that I need you to answer, okay?

5 A. Sure.

6 Q. All right. If off-label discussions were held, took place
7 at these speaker bureaus, they reached thousands of audience
8 members. I'm not asking about how or why the conversations
9 started. If off-label discussions took place, they reached
10 thousands of audience members. Do you agree?

11 A. Yes, I do.

12 Q. Is it my understanding, sir, that you are currently
13 serving on a -- what did you call it? What board are you
14 currently serving on for Janssen?

15 A. The Presidential Advisory Board is a group of ten
16 physicians in the US that evaluate studies and drugs in
17 development. That was disbanded about a year and a half, two
18 years ago.

19 Q. All right. Sir, that was a paid position?

20 A. Yes, it was.

21 MR. MARKETOS: If we take a look at RX-376.

22 We're going to offer RX-376, Your Honor. My
23 understanding, there's no objection. This is the MedForce
24 data.

25 THE COURT: Ms. Brown, do you have that before you?

1 MS. BROWN: I don't. Can I see it on my screen? I
2 don't know what it is.

3 THE COURT: Mr. Marketos.

4 MR. MARKETOS: Yes, I don't know if you can see it on
5 the screen.

6 THE COURT: We have Dr. Hsu on the screen.

7 MS. BROWN: I'll just reserve, Judge. I don't want
8 to hold us up, Judge. No objection, it's fine.

9 THE COURT: Do you have something over there?

10 MS. BROWN: It's okay. No objection.

11 THE COURT: All right. It's admitted.

12 (Exhibit R-376 admitted into evidence.)

13 MR. MARKETOS: I'll also offer the AHM data,
14 Defendants' Exhibit 4533, and 1039, Relators' Exhibit, which is
15 the 902 affidavit.

16 THE COURT: Is there some way you folks can show
17 these folks what those exhibits are without the monitors?

18 MR. MARKETOS: Yes, Your Honor. It's actually a
19 defense exhibit. It's called the AHM data, and it's just a
20 business records affidavit attendant to it.

21 THE COURT: It's their exhibit.

22 MS. BROWN: That's fine, Your Honor.

23 THE COURT: So admitted.

24 (Exhibit D-4533 admitted into evidence.)

25 BY MR. MARKETOS:

1 Q. I'm going to show you a demonstrative, Dr. Hsu. If you
2 can see the screen, just let me know if you can see that, sir?

3 A. No, I cannot.

4 Q. It's going to come on. This is going to be Demonstrative
5 Number 1.

6 MR. MARKETOS: If you could share that.

7 BY MR. MARKETOS:

8 Q. There we go, sir.

9 Sir, what I'm showing you is a demonstrative that shows
10 the accumulative amount of payments that you, Dr. Hsu, received
11 from Janssen during the time period from 2006 to 2014 on the
12 speaker bureau. Do you see those amounts increasing over time
13 from 2006 to 2014?

14 A. Yes, I do.

15 Q. Okay. We'll take a look at Demonstrative 2, if we could?

16 MS. BROWN: Is it possible to get a copy of your
17 demonstratives, Counsel?

18 MS. WENDEL: Yeah.

19 MS. BROWN: Thank you.

20 BY MR. MARKETOS:

21 Q. Dr. Hsu, what I'm showing you here, sir, is this is the
22 amount of money that you were paid by Janssen during the
23 speaker bureau. And then in blue we have the cumulative
24 reimbursements for prescriptions that Janssen received from the
25 prescriptions that you wrote for Prezista and Intelence. Do

1 you see that, sir?

2 A. Yes, I do.

3 Q. As you see, sir, Janssen got a significant return on the
4 amount of money that it paid you to speak on the speaker
5 bureau?

6 MS. BROWN: I object, Your Honor, argumentative.

7 THE COURT: Overruled. I'll allow it.

8 BY MR. MARKETOS:

9 Q. Janssen obtained a return on investment from
10 reimbursements from the government compared to the amount of
11 money that it paid you to speak on its bureau. Can you see
12 that, sir?

13 A. Yes. I do have to dispute that in the sense that my
14 practice has grown. In 2006, I was in private practice as a
15 solo practitioner, along being with St. Vincent's, NYU, I can't
16 remember which one. And as the years have gone by, my practice
17 now has doubled in size. So I don't see a doubling in scripts.

18 Also, in terms, if you look at anyone's prescriptions of
19 the drug, as any drug comes about, it increases exponentially
20 as we get more and more experienced and as it gets -- as it,
21 you know, replaces the older generation of medicines that were
22 inferior to it.

23 So all the Kaletra drugs, all the Crixivan, and many of
24 the other drugs are being switched to Prezista because Prezista
25 is a new drug, first in 2006 when it's approved, but of course

1 | it's going to grow as people get more experience with it, and
2 | of course the indication from a twice a day experienced drug to
3 | people who are on first line therapy --

4 | Q. Dr. Hsu, do you remember my question, sir? I'm sorry.

5 | A. Sir, you're showing data that is completely irrelevant.
6 | It's not related to how much I'm being reimbursed. It's
7 | completely related to. One, a new indication for the drug from
8 | experienced to naïve. And as I find offensive in that Gilead,
9 | that other representative who tried to tie prescriptions to
10 | profit that they get from a company, I find your allegations to
11 | be extraordinarily offensive as well because you have no idea
12 | and no practicing concept of our wanting, as HIV providers,
13 | needs to take care of our patients as best as possible. We're
14 | in it not to -- because we're being paid by a company. We
15 | choose the right drug for the right person because it's the
16 | best for them. And you're trying to correlate me being paid,
17 | which doesn't -- which includes reimbursement and everything
18 | else, and research, expanded access, everything else, you're
19 | trying to insinuate --

20 | Q. Dr. Hsu, I'm sorry.

21 | THE COURT: I'm going to let him finish.

22 | THE WITNESS: -- brand-new indication. It's
23 | offensive. It's ridiculous. And you should know that
24 | yourself.

25 | BY MR. MARKETOS:

1 Q. Thank you, Dr. Hsu.

2 A. I'm sorry to be weird about this, but think about it, new
3 indications and prescriptions go up. You're going to have to
4 get your logic in better order.

5 Q. Thank you, Dr. Hsu.

6 MR. MARKETOS: Objection, Your Honor, nonresponsive,
7 I'd move to strike.

8 THE COURT: I'm not going to strike that response,
9 denied.

10 BY MR. MARKETOS:

11 Q. Dr. Hsu, I have a question for you, sir, I'm not asking
12 you about your receipt of money. You know that Janssen was
13 tracking its return on investment based on the amounts of money
14 that it paid you?

15 MS. BROWN: I object, Your Honor, misstates the
16 facts.

17 THE WITNESS: I am not aware of any of that.

18 THE COURT: Overruled.

19 BY MR. MARKETOS:

20 Q. Thank you, sir.

21 As I understand it, sir, you would take the tracking of
22 the return on investment that a company paid doctors for their
23 prescriptions, you would find that to be offensive? That's
24 what you just told us; is that right?

25 A. Yes, if it was a return on investment I would find it

1 offensive in terms of it being related to why they're on the
2 speaker bureau.

3 Q. I understand, Dr. Hsu. And you have no idea what Janssen
4 was actually tracking because you haven't seen any of the
5 return on investment calculations that it was performing while
6 you were speaking on its bureau, fair?

7 A. That's fair.

8 THE COURT: Mr. Marketos, on that one, is that a good
9 place to stop?

10 MR. MARKETOS: Yes, Your Honor.

11 THE COURT: We have more to go, I presume?

12 MR. MARKETOS: Yes, Your Honor.

13 THE COURT: Folks, it's 5:00, we're going to adjourn
14 for the day. Just a reminder, tomorrow at 12:30. Folks, I
15 appreciate your patience and the time you've been putting in.

16 Counsel, remain, I do want to speak with you briefly
17 before tomorrow. And we're going to be ready to go at 12:30
18 with Dr. Hsu.

19 THE DEPUTY CLERK: Please rise.

20 (The jury exits the courtroom at 5:04 p.m.)

21 THE COURT: All right. Folks, have a seat. Do we
22 need a sidebar?

23 MS. BROWN: I was just going to ask if we could
24 excuse Dr. Hsu from the video.

25 THE COURT: Sorry. I didn't realize that we still

1 had him on the screen. Why don't we temporarily excuse
2 Dr. Hsu.

3 Dr. Hsu, we're going to be starting at 12:30 sharp,
4 so I presume that counsel will make sure that you're available,
5 set this VTC up at that time.

6 MS. BROWN: Thank you, Dr. Hsu.

7 THE WITNESS: Thank you.

8 (Witness excused.)

9 THE COURT: All right. Let's go off the transcript.

10 (Discussion held off the record.)

11 (Proceedings adjourned at 5:05 p.m.)

12
13 CERTIFICATION

14
15 I certify that the foregoing is a correct
16 transcript from the record of proceedings in the above-entitled
17 matter.

18
19 /S/Shannan Gagliardi, RDR, CRR 5/30/24

20 Court Reporter/Transcriber
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