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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

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, ET AL.,
Plaintiffs,
v.
JOHNSON & JOHNSON, JANSSEN PRODUCTS, L.P.
Defendants

CIVIL ACTION NUMBER:
3:12-CV-7758-ZNQ-JBD

JURY TRIAL VOLUME 13

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

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

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

REESE MARKETOS
BY: PETE MARKETOS, ESQUIRE
JOSH RUSS, ESQUIRE
ANDREW WIRMANI, ESQUIRE
ADAM SANDERSON, ESQUIRE
WHITNEY WENDEL, ESQUIRE
750 N. Saint Paul Street, Suite 600
Dallas, Texas 75201
For the Relators

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP
BY: ALLISON M. BROWN, ESQUIRE
GEOFFREY M. WYATT, ESQUIRE
BRADLEY A. KLEIN, ESQUIRE
One Rodney Square
920 King Street
Wilmington, DE 19801
For the Defendants

Proceedings recorded by mechanical stenography
Transcript produced by computer-aided transcription

Shannan Gagliardi, Official Court Reporter
shannan_gagliardi@njd.uscourts.gov

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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		

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

THE DEPUTY CLERK: All rise.

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

MR. MARKETOS: Good morning, Your Honor.

THE COURT: Good morning.

MR. MARKETOS: Pete Marketos for Relators.

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

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

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

THE COURT: Good morning, everybody.

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

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

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

THE COURT: Good morning to you folks as well.

Ms. Brown, what did we learn?

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

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

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

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

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

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

The first investigation is in 2011?

MR. WYATT: Early 2011.

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

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

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

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

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

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

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

THE COURT: Those were separate allegations?

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

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

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

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

MR. WYATT: Correct.

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

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

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

information regarding the initial investigation by your clients?

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

THE COURT: Of these drugs?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. WYATT: Yes, Your Honor.

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

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

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

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

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

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

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

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

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

MR. WYATT: Understood, Your Honor.

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

MR. WYATT: I'm not --

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

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

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

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

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

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

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

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

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

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

THE COURT: I'll take it, yeah.

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

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

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

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

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

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

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

THE COURT: But she connected them to her conclusion.

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

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

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

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

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

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

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

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

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

at least get some of the information now.

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

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

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

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

MR. WYATT: I do.

THE COURT: How many is the total?

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

16, 17 documents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. WYATT: I believe there's four.

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

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

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

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

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

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

MR. MARKETOS: Yes, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE COURT: Was there a response that you received

from Janssen regarding that follow-up letter?

MR. MARKETOS: Yes.

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

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

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

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

THE COURT: How long is the report?

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

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

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

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

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

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

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

THE COURT: There are parts of this report that

substantiate some of the allegations?

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

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

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

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

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

Would they want to have seen the document?

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

MR. WYATT: I do.

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

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

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

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

What is said in this allegation finding is not only

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

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

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

MR. WYATT: That is my position.

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

MR. MARKETOS: No problem, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

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

THE COURT: No, I get it.

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

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

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

not a part of this case?

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

THE COURT: But either way --

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

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

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

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

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

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

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

THE COURT: Is it relevant, though?

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

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

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

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

gives me time to review the documents.

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

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

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

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

MR. WYATT: Yes, Your Honor.

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

MR. MARKETOS: Absolutely, Your Honor.

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

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

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

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

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

THE COURT: I think it's Thursday.

MR. MARKETOS: Thank you.

THE COURT: Monday?

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

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

Mr. Wyatt, Monday works for defense?

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

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

MR. WYATT: We do.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. WYATT: Thank you, Your Honor.

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

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

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

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

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

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

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

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

withheld these documents, not some tactic by an attorney.

MR. MARKETOS: We know how this works.

THE COURT: I got it.

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

THE COURT: I appreciate that clarification.

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

THE COURT: I appreciate that. I understand that.

All right, folks, the jurors are here.

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

MR. WYATT: I do.

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

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

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

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

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

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

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

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

MR. WYATT: Or at the next break.

THE COURT: What else, folks?

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

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

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

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

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

THE COURT: Perfect.

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

THE COURT: And the follow-up letter.

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

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

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

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

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

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

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

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

MR. MARKETOS: Yes, Your Honor.

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

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

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

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

jurors.

MS. BROWN: Thank you.

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

THE DEPUTY CLERK: Please remain seated.

THE COURT: Ms. Brown, do you want this back? Actually, I marked it. Can I keep it?

MS. BROWN: Sure.

THE DEPUTY CLERK: All rise.

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

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

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

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

MR. RUSS: I am, Your Honor.

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

THE WITNESS: Yes.

THE COURT: You may proceed.

MR. RUSS: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. RUSS:

Q. Good morning, Mr. Grooms.

A. Good morning.
Q. Just to kind of reorient ourselves. I know were going pretty quickly at the end of yesterday.
You were a sales representative in Kansas City for Janssen from 2006 to 2010?
A. Yes, sir.
Q. Okay. We talked about some of the individuals that you reported to. Just a reminder on some of those names.
Denise Levere?
A. Correct.
Q. Doyletta Minix was a KAM at some point?
A. Yes, sir.
Q. Mark Wilhelm was a boss of yours at one point?
A. Yes, sir.
Q. Scott Libby?
A. Regional director.
Q. So he was?
A. Two levels up.
Q. Two levels up?
A. Yes, sir.
Q. Okay. When we left off talking yesterday, we were talking a little bit about some speaker programs.
Do you recall that?
A. Yes, sir.
Q. We talked about a Dr. Bellos, and then you were talking

about a gentleman named Dr. Verstraete?
A. Yes, sir.
Q. Remind the jury who Dr. Verstraete was.
A. He was one of my larger-targeted customers in the Kansas City area for HIV patients.
Q. Again, if you could just get a little closer to the microphone.
A. Sure.
Q. Thank you, sir.
When you say one of your larger-targeted doctors, what does that mean?
A. For potential -- for potential patients. So he saw between, like, five and 700 HIV patients. So it was like decile rating of 1 to 10, he would have been a 7.
Q. Is this your first time testifying in court?
A. Absolutely.
Q. I know I was going fast yesterday. We only had 20 minutes. So we'll go a little bit slower for the court reporter.
A. I'll take a breath.
Q. Okay. Was one of the ways that you and Ms. Levere determined who was going to be a large target was the prescription potential of a doctor?
A. That is correct.
Q. Were these doctors, were their prescriptions tracked?

A. Yes, sir.
Q. And we talked a little bit yesterday about some of the speakers who you believe also were tracked as far as their prescriptions; is that right?
A. That's correct.
Q. One of the doctors that you told us about was Dr. Dietz?
A. Yes, Dr. Craig Dietz.
Q. Is he the doctor that you provided these off-label lipid messages about Prezista in order to get him to switch to Prezista?
A. Yes. I would have the messaging myself, and then Doyletta Minix would come in before Denise Levere, and then I had to produce MIR forms. So Tiffany Surles was my medical science liaison. She would come in -- she came in twice to cover I believe it was a MONET study, which showed a correlation of starting Prezista with the NNRTIs and then dropping them, and then you looked at the difference between the cholesterol on both arms.
Q. Was that an off-label study?
A. Yes.
Q. So is it fair to say that there was a sort of targeted approach by multiple Janssen employees to Dr. Dietz on the lipid profile for Prezista?
A. Yes, because he would have been a decile 10. He had about a thousand patients. He was my largest target.

Q. What is a decile 10?
A. Decile 1 to 10, so it's a ranking, 10 being the highest of potential for patients, for HIV patients.
Q. Decile 10 is the --
A. The highest, yes.
Q. So the company and some of your coworkers were targeting him to get him to switch to Prezista?
A. Correct.
Q. That included using off-label lipid messages?
A. Correct.
Q. Did Dr. Dietz at some point tell you he switched because of those messages?
A. Yes.
Q. Explain that to the jury. How did that conversation occur?
A. It would be -- would boil it down to a particular patient, like if a patient was -- could be a hairdresser, somebody that's a bus driver, somebody that's in the community more. Because Reyataz would cause some jaundice, so if we could say we have the same lipid profile, which we showed, and not the jaundice, it would be a better option for that patient. And then we would also draw a correlation of dosing symmetry again. So that's where the MONET study comes in, that you potentially would draw the conclusion you could potentially use Prezista monotherapy.

Q. What is monotherapy?
A. On its own with no other regimen behind it.
Q. Without ritonavir?
A. It would still have ritonavir, but you wouldn't have any non-nucleosides or nucleosides with it.
Q. Okay. Was that another off-label message?
A. Yes, to my knowledge. I don't know of anything that was at the time -- I don't know if there is now -- but that was approved for monotherapy.
Q. Did Dr. Dietz tell you that those messages caused him to switch to Prezista?
A. Yes.
Q. Tell us about that conversation.
A. I would go back in, and he would say have you checked my numbers lately. So he was always wanting to know if I saw what his numbers had done, if he had moved. Did you see how many I've written? And it was specific again to patients that I targeted for Reyataz as far as lipid-neutral and the jaundice issue.
Q. You were able to target particular patients?
A. A patient type. Not a name, but a patient type.
Q. So you would work with Dr. Dietz on a patient type?
A. Correct.
Q. Give him, with your coworkers, the off-label lipid message, and then he would say have you seen my numbers?

A. Correct.
Q. Were they going up?
A. Yes.
Q. Did you have similar conversations with Dr. Verstraete as to either Prezista or Intelence?
A. Yes.
Q. Tell the jury about that.
A. Dr. Verstraete was a lot more of a -- I'd say amiable doctor. He's a lot more open-minded to try different things and more, I guess, off-label, if you will. He was not as structured as some of the other physicians. So I'd call him a maverick. He would just try out anything you kind of recommend to him.
Q. Did he ever tell you that he tried Intelence once-a-day or Prezista because of the messages that you were providing to him?
A. Yes. He'd use Intelence once-a-day especially in the slurry where you'd just drop the pill in, because it would be no pills at that point. So it was very convenient for some of his patients.
Q. So explain to the jury what the slurry is.
A. So you can take Intelence and actually dissolve it in water and then drink it, so you would get the medication just as a liquid as opposed to swallowing a pill.
Q. On a package insert, is there a method of how you're

supposed to take the medication, like dosage for instance?
A. Yeah. The dosage is on the pack insert, correct.
Q. Is there anything on the package insert for Intelence that you should dissolve it in water and take it once a day?
A. Not to my knowledge.
Q. But you and your coworkers were providing QD dosing for Intelence messages to doctors like Dr. Verstraete?
A. Correct.
Q. He told you he was trying it?
A. Yes.
Q. How did that conversation happen? Was it similar to Dr. Dietz where he would say have you seen my numbers, or would he just flat out tell you I'm trying this?
A. It was over lunch. He would just tell me, hey, that really works well for some of my patients.
Q. Okay. Again, that was based off of off-label information that you and your coworkers were providing to these doctors?
A. Yes.
Q. And that message was coming from Ms. Levere?
A. As far as directed down to me?
Q. Yes, sir.
A. Yes.
Q. And then I think you talked a little bit about this yesterday, but you had reason to believe that it didn't start with Ms. Levere?

A. No, I don't believe any of the marketing messages started with her.
Q. Why do you believe that?
A. Because she would always say we just got off a call, like a regional call with Scott Libby, or we had a managers call, and this is the direction that we're given. It would change quite often, very targeted.
Q. Is the Dr. Verstraete that you and I just discussed the same doctor that we ended the day yesterday where you told the jury he frequently went to -- attended speaker programs?
A. Yes, sir.
Q. Was that a common occurrence for some of the same doctors to attend multiple speaker programs?
A. Yeah, I would say so.
Q. Remind us about how many speaker programs you attended personally.
A. During my whole time at Tibotec?
Q. Yes, sir.
A. I know I was required to do three to four per quarter, so about 12 a year times however many times I was there or how many years I was there, five. And then also if Doyletta Minix would do a program in my area, because she would do programs too, I would go to hers as well. So maybe 30ish, I'm guessing, something like that or more than that.
Q. You were there for four years?

A. 2005 through 2010, I think, or 2006 through 2010. Yeah.
Q. At those programs, do you recall off-label information being discussed?
A. Yes.
Q. Okay. Describe how that would generally work for the jury.
A. Usually I would prep somebody in the audience, a Pharm.D, a pharmacist, Dr. Verstraete, Dr. Dietz, Dr. Ha Ta, to ask the question to get to the information that we wanted to get out.
Q. We've heard some other testimony in this case about plants in the audience?
A. Correct.
Q. Is that the similar concept that you would ask an attendee to ask an off-label question?
A. Absolutely, yeah. That's what we were directed to do. That's what I was directed to do.
Q. By who?
A. Denise and Doyletta.
Q. How would that process work? Walk us through step by step how would you get somebody in the audience to ask a specific question.
A. I would meet with Dr. Verstraete or maybe the Pharm.D from Walgreen's the day of or day before, go over a couple of the questions that I wanted them to ask to lead the speaker to the information we wanted to get out.

Q. Mr. Grooms, you never worked as a sales representative with Ms. Brancaccio or Ms. Penelow, did you?
A. Same company but not in the same area, no.
Q. You didn't work in the New York district?
A. No, no, sir.
Q. Would it surprise you to learn that there were similar tactics being used in other districts within Janssen?
A. No, because I talked to people around the country. We all talked as reps, and we all had the same direction.
Q. Give us an idea of some of the names of representatives that you would talk to about these types of tactics.
A. Bob Foote was in Michigan. Russ Moyer was in the Boston area. Kim Betty was in the Tennessee area. Brendan Snyder was in Houston. Melissa Wade was in St. Louis, which was close. So yeah, everybody that was around me I would talk to.
Q. What were they telling you was happening in their districts across the country?
A. It was the same message, the same concern as far as the message goes, and same thing as far as plants on speaker programs. We wanted to get to a certain -- get certain information out if we could.
Q. Did other sales representatives from different districts tell you that they were selling Prezista as lipid-neutral or lipid-friendly?
A. Absolutely.

Q. Did other sales representatives from across the country tell you they were selling Prezista as appropriate for treatment-naïve patients before 2008?
A. I don't recall that one specifically.
Q. Okay. But we do recall the lipid message?
A. Yes, that was a big message, yes.
Q. Did other representatives across the country tell you how they were selling Intelence off label?
A. Yes, the slurry, and then once-a-day -- leading to once-a-day dosing because of half-life, absolutely.
Q. Were there concerns being shared in these phone calls with other sales reps?
A. Yes.
Q. Give the jury a sense of some of the concerns that were being raised and how frequently those concerns were being raised.
A. Well, we would speak daily, because for me, for instance, I'd drive to Wichita or Omaha, which is a three-hour drive, so you had time to talk. And we would talk daily about the concerns of is this the right direction that we're going here, is this correct, is this accurate, should we be doing this.
There's a really big amount of pressure and fear for everybody for their role, so we would just go along with it, but we definitely discussed it.
Q. Was there a general concern at the company at that time of

people being put on performance improvement plans or fired?
A. Yes.
Q. Give the jury a sense for what your day-to-day pressure was like to make these sales and what would happen if you didn't.
A. If my recollection is right, the first six months, there was it seems like at least 10 or 12 people out of only 70 that were on a performance plan for not hitting numbers or not using messaging correctly. So it was -- every day was a check-in or get checked on by your manager. What are you doing? What messages are you delivering? Are you delivering all pieces of the sales aid?

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

Q. So let's talk about some of those metrics. We talked about the hub and some of the off-label studies yesterday.
A. Uh-huh.
Q. This was a hub that sales reps could go on and actually have off-label studies delivered to their homes?
A. Go on and order marketing materials, off-label studies. Sometimes they were just drop-shipped directly to you.
Q. This was, I believe you testified yesterday, one of the metrics that Ms. Levere was calling you to check in on whether or not you were ordering enough of these?

A. Correct.
Q. Was that happening with other sales representatives?
A. Yes, everybody in my district.
Q. And you mentioned MIRs, and I know this jury has heard a ton about MIRs.
What was the company doing as to your medical information requests as a metric for your sales performance?
A. We had, like, a contest where we had to have 12 -- I think it was 12 MIRs per district per week, so about threeish per person per week for MIRs. Then if we didn't hit that, we had a call about it, why we weren't asking the right questions to generate an MIR.
Q. Is there something that struck you as curious or inappropriate of how you were supposed to actually obtain something that was supposed to be unsolicited?
A. Yeah, because it's supposed to be unsolicited, exactly.
Q. Did you push back on that practice?
A. Yes.
Q. Tell the jury about that.
A. That was one of the real big reasons that Kim Betty, for instance, in Tennessee got reprimanded, because she pushed back really hard to Denise about unsolicited MIRs, and she wasn't producing and going to produce three to four a week.
Q. Okay. Let's focus on that instance because I think it's important.

How do you know Ms. Betty pushed back?
A. It was on a conference call.
Q. So you were on a conference call.
Who was on it?
A. My whole district, the seven of us and Denise.
Q. Seven sales representatives and Ms. Levere?
A. Yes.
Q. Were MIRs being discussed as a metric on that call?
A. Yes.
Q. What did Ms. Betty -- is it Betty?
A. Yes, B-E-T-T-Y.
Q. What did she say?
A. It was inappropriate to unsolicit MIRs -- or go get unsolicited MIRs -- solicit MIRs, excuse me, for unsolicited reasons. It's supposed to be the doctor is supposed to ask you and then you respond to it, not you ask the question leading the doctor to the information and say, oh, that's an MIR.
Q. How did Ms. Levere respond to that pushback?
A. Not well. That was the direction we were given as far as how many we need to get. We're behind the Florida district. We're behind the Chicago district. We need to up our game.
Q. Was Ms. Betty reprimanded on that call?
A. Yes, on the call.
Q. How?
A. Just scolded. This is our direction. You need to hit it.

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

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

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

A. Correct.

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

A. Yes.

Q. Tell the jury about that.

A. Just everything. Any kind of emails or anything, handwritten notes, nothing to be left behind in writing. That's why we didn't leave our business card, anything in handwriting left on a provider's desk.

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

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

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

A. Yes.

Q. Tell the jury about that.

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

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

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

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

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

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

A. No.

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

A. Yes.

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

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

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

discussed for Prezista and Intelence?
A. Of all 35, it would be hard to say all, but I would say everybody -- at least 90, 95 percent, if I got a chance to get in front of them, yes, I would cover the message.
Q. You would cover the message with anybody you got in front of?
A. Correct.
Q. So if you were able to get in front of your doctors, they heard that message?
A. Yes.
Q. Multiple times often?
A. As often as possible, because my fear would be that if Denise or Doyletta would ride with me and they'd ask the questions that the physician didn't have the answer to or didn't know that message, that would be -- I would fear that they didn't think I was relaying the message. So I did that as often as possible.
Q. So Ms. Minix or Ms. Doyletta would actually quality check, so to speak, whether or not your doctors were getting these off-label messages?
A. Yeah, that's a good way to say it. Quality check, yeah.
Q. Now, Mr. Grooms, we talked a little bit yesterday about this event at the selling dome.
A. Uh-huh.
Q. Describe for us -- I think you briefly described it as

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

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

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

A. Yes.

Q. Who pushed back?

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

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

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

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

A. Yes.

Q. What happened to Ms. Betty?

A. She was no longer at the company. I don't know for sure.
Q. Soon thereafter she was no longer employed?
A. Yes.
Q. Were there other individuals that you just named that soon after this selling dome instance were no longer employed?
A. Yeah. I don't know how long it was, but Melissa Wade was gone, Joyce Arellano was gone. There was another gentleman, Preston, in the Arkansas area that was gone. I think it was myself and Brendan were the last two left after that.
Q. Was that sort of the culture at Janssen at that time, that you couldn't push back and keep your job?
A. It definitely seemed that way.
Q. Had you ever worked before or since your time at Janssen at an organization that had that type of culture?
A. No.
Q. Mr. Grooms, at some point, did you yourself go to human resources, or sometimes what's called HR, to voice your concerns?
A. I did.
Q. Tell the jury what you did as far as your concerns and who you spoke to?
A. I spoke to a woman named Dolores, I don't remember her last name, probably three, four times. With regards of Denise's, my interactions with her were getting more like -- were getting more harsh or hostile. And I was not comfortable

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

Q. The off-label messaging?

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

Q. Were these phone calls?

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

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

A. Yes.

Q. With Dolores?

A. Yes.

Q. You think that was Dolores Smith?

A. Sounds right.

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

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

Q. And she didn't say, oh, my goodness, come to home office, let's get an investigation started and figure out what's going on?
A. No.
Q. She said what again?
A. She said -- she just continually said we stand behind our management team and the direction you're given.
Q. Johnson & Johnson stands behind its management team?
A. She just kept repeating that.
Q. Multiple times?
A. Multiple times.
Q. Did anything ever get fixed?
A. No.
Q. Mr. Grooms, I want to talk to you about a couple additional topics. At some point, did you learn that our clients, Ms. Brancaccio and Ms. Penelow, had filed this lawsuit?
A. When I was first contacted I think in like 2019 maybe, '18 or '19.
Q. Somebody contacted you and asked you -- to interview you and figure out about your experience while you were at Janssen?
A. Yeah.
Q. Did you talk to that person and give an interview?
A. I did.
Q. Truthful information?

A. Yes.
Q. Was that truthful information then written up and provided to you to review?
A. Yes.
Q. Did you review it?
A. I did.
Q. Did you make sure it was accurate?
A. Yes.
Q. That's a declaration that you ultimately signed?
A. Correct.
Q. Did anybody make you sign the declaration?
A. No.
Q. Do you have any financial interest in this case?
A. No.
Q. Do you have any stake in any recovery or potential verdict in this case?
A. No.
Q. The jury's heard a little bit about some friends in this case, and I want to see if you are, in fact, close friends with some individuals that have testified in this case, okay?
A. Okay.
Q. Are you close friends with Ms. Brancaccio?
A. No.
Q. Tell the jury, before this trial, this week, when was the last time you saw Ms. Brancaccio?

A. 2007 or '08 maybe. Probably a national meeting, the last one I was at.
Q. Are you close friends with Ms. Penelow?
A. No.
Q. Before this trial, and this week, when was the last time you saw Ms. Penelow?
A. Would have been the same national meeting, probably 2007 or '08.
Q. And when you were working at Janssen, you were in Kansas City, Missouri and they were in New York or New Jersey?
A. Yeah, up here somewhere.
Q. Fair to say you didn't see them very frequently when you worked there?
A. No.
Q. That is fair to say?
A. Yes, that's correct, sorry, fair to say.
Q. Bad question, sorry.
A. Sorry.
Q. You do know a gentleman you used to work with named Mark Wilhelm?
A. Yes, he was my manager.
Q. You kept in touch with him?
A. I did.
Q. Tell the jury about your relationship with Mr. Wilhelm?
A. Just friends. He lives in Denver. He's a Broncos fan,

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

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

A. No.

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

A. That would be 2007 or '08 probably.

Q. Seventeen years ago?

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

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

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

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

A. No.

Q. Did you work in the same district?

A. No.

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

A. Correct.

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

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

the last time I had seen any of them.
Q. So the last time you had seen Mr. Holshoe was, conservatively, 15 years ago?
A. Correct.
Q. Did you talk to any of these individuals that I just mentioned -- oh, forget to ask, are you close friends with Sara Strand?
A. No.
Q. When was the last time you saw Ms. Strand?
A. I actually interviewed with her, she was with Tourig or Turing Pharmaceuticals, but that was probably ten or 12 years ago, so probably ten years ago.
Q. About a decade ago?
A. Yes.
Q. Have you talked to any of those individuals, Ms. Strand, Mr. Wilhelm, Ms. Graham, Ms. Brancaccio, Ms. Penelow, Mr. Holshoe, to coordinate your testimony here in front of this jury?
A. No.
Q. Mr. Grooms, you agreed to come here to testify?
A. Yes, sir.
Q. Why?
A. I felt like it was the right thing to do after -- I kind of suppressed everything that happened. And then whenever I did the interview in '18 or '19, it brought up a lot of just

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

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

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

Q. Understood, sir.

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

Pass the witness.

THE COURT: Thank you, Mr. Russ.

Ms. Brown.

MS. BROWN: Thank you, Your Honor.

May I proceed, Judge?

THE COURT: You may.

MS. BROWN: Good morning, everyone.

CROSS-EXAMINATION

BY MS. BROWN:

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

A. Good morning. Thank you, good.

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

A. Correct.

Q. I understood your testimony to give us a list of the items that you recall reporting to HR, correct, sir?
A. A specific list?
Q. Well, sir, I heard you say you went to HR to report the off-label marketing, correct?
A. Correct.
Q. I heard you say you went to HR to report concerns you had with Ms. Levere's management style, correct?
A. Correct.
Q. I heard you say you reported to HR concerns you had with the company's culture and marketing correct, sir?
A. Correct.
Q. Well, when we asked you in your deposition, sir, what you reported to HR, you said you couldn't recall the conversation at all. Do you know that?
A. No, I don't remember that.

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

MR. RUSS: No objection.

THE COURT: All right. You may play it.

(Video playing.)

BY MS. BROWN:

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

Q. And since that time, you had the opportunity to meet with the lawyers for the Relators to prepare for your testimony, correct, sir?
A. Met with them, I think it was Monday night briefly when I got in.
Q. Sure.
A. Correct.
Q. Today, I'm losing track of the days, it's Thursday, correct?
A. Yes. Maybe it's Tuesday. I'm sorry, I can't remember with the holiday.
Q. Fair, Monday was a holiday?
A. Correct.
Q. Did you fly into town on Monday, sir?
A. No, ma'am, Tuesday, I believe.
Q. Tuesday, okay.
A. Yes.
Q. And did the lawyers pay for your expenses to come out here for the trial?
A. Not yet.
Q. Do you expect they will, sir?
A. I hope so.
Q. Your understanding is they'll reimburse you for your travel here, correct?
A. Correct.

Q. And you're staying at the hotel with them; is that correct?
A. I think some are at a different hotel, I'm not sure. Some of them are at that hotel, correct.
Q. And you had the opportunity to meet with some of these lawyers to prepare for your testimony, correct, sir?
A. Just one really.
Q. Mr. Russ?
A. Correct.
Q. Okay. And one of the things you and Mr. Russ discussed was that he was going to ask you about this conversation with Dolores in HR, correct?
A. Multiple things. It could have been, yes. There was multiple things.
Q. That was the same question we had asked you at your deposition that we just saw, correct?
A. I don't know if it was the exact same question, but, yes.
Q. At least at your deposition you couldn't recall what you talked about, correct?
A. At that time I did not, no.
Q. But after speaking with Mr. Russ today you have a different memory, correct?
A. No, not correct.
Q. Today you had a memory of that conversation, correct?
A. Yeah, I didn't sleep good last night, I had a lot of

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

Q. They came back to you all last night?

A. A lot of it.

Q. Yes, sir.

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

A. Yes.

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

A. Sounds right, yes.

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

A. That's correct, he hired me.

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

A. Correct.

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

A. I do not.

Q. Okay.

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

D-6063?

MR. RUSS: No objection.

THE COURT: So admitted.

(Exhibit D-6063 admitted into evidence.)

BY MS. BROWN:

Q. Mr. Grooms, what I'm showing you here, is that your signature down there at the bottom in March of 2006?

A. Yes, ma'am.

Q. Okay. And do you recognize this at least as a document titled The Professional Sales Representatives Pledge of Ethics?

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

Q. Sure. And we've gone through this with several witnesses before, I don't want to belabor the point, but do you recall agreeing, when you came to Janssen to work for us as a sales rep, that you would follow the company policies?

A. I recall agreeing to, yes, with every company I would try to follow the ethical policies.

Q. Right. And those policies included promoting our medicines on the FDA label, correct, sir?

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

Q. Of course. And I know it was a long time ago, 2006, but you read this pledge before you signed it, right?

A. No idea if I read it or not.

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

ethics without reading it?
A. It's typical for every single health care company, so yeah, I would have signed it.
Q. Yes, sir. But do you think you read it when you signed it?
A. I don't know.
Q. All right. Did you understand that your job responsibility was to promote the medicines within the appropriate regulations and policies?
A. That's, yes, that's what I would have -- yes.
Q. Okay. And I understand your testimony here in this lawsuit, sir, is that you did not abide by this pledge of ethics, correct?
A. No.
Q. Right. But, sir, what you tell the public when you write about your experience at Janssen is that you did promote the product within the FDA indication, correct, sir?
A. No.
Q. You have a LinkedIn page, right, sir?
A. Yes.
Q. And your resume is available through that LinkedIn link, right, sir?
A. It could be, yes.
MS. BROWN: All right. Your Honor, Tab 22, D-9180.
MR. RUSS: No objection.

THE COURT: All right. So admitted.

(Exhibit D-9180 admitted into evidence.)

BY MS. BROWN:

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

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

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

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

A. It shouldn't be.

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

A. Yes, ma'am.

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

A. Correct.

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

Do you see that, sir?

A. I do.
Q. Used clinical studies to exhibit product experience.
Do you see that, sir?
A. Expertise, yes.
Q. Expertise, yes.
So your resume available on LinkedIn talks about the proper usage and the indication of the medicine, correct, sir?
A. Yes.
Q. When you got to Janssen, Mr. Grooms, you went through compliance training, correct, sir?
A. I don't recall compliance training necessarily. We could have, I just don't remember it.
Q. All right. Do you remember we asked you that question in your deposition, sir?
A. I don't. I remember sales training. It's probably in there, I just don't recall it specifically.
MS. BROWN: All right. Permission to play 154 through 9?
MR. RUSS: No objection.
THE COURT: You may.
MS. BROWN: Thank you.
(Video playing.)
BY MS. BROWN:
Q. You recall at the time of your deposition that your training included health care compliance, right, sir?

A. Yes.
Q. All right. And you were also trained on proper promotional practices, right, sir?
A. I believe so, yes.
Q. And that training you told us you recall happening at least once a year, correct?
A. I think so, yeah. Most companies have it once a year, correct.
Q. Okay. And you don't recall ever being instructed or directed by any of the trainers at Janssen to promote off-label, correct?
A. Not correct.
Q. All right.
MS. BROWN: Your Honor, permission to play 47, 12 to 23?
MR. RUSS: Sorry, Your Honor, just one moment.
THE COURT: That's all right.
MR. RUSS: No objection.
THE COURT: All right. You may publish.
MS. BROWN: Thank you.
(Video playing.)
BY MS. BROWN:
Q. At the time of your deposition, sir, you didn't recall that trainers had given you direction to promote off-label; is that correct?

A. Yeah, I didn't recall then.
Q. Okay. And, in fact, you testified at your deposition and again on direct examination that you were expected to, I think your term was, "show up and throw up," meaning regurgitate the approved messages from the company; is that correct?
A. Regurgitate messages from the company, yes.
Q. And I want to talk to you about one of those approved messages that you were asked about in your deposition.
You, sir, as a sales representative, were provided with company-approved materials to use when you were speaking to physicians, correct, sir?
A. Yes.
Q. All right. And I want to show you one that you were asked about in your deposition.
MS. BROWN: It's Tab 21, D-9179.
MR. RUSS: No objection.
THE COURT: All right.
BY MS. BROWN:
Q. I'll try to zoom in on this, I know it's a little small. But you were asked about this Prezista approved promotional piece in your deposition. Do you recall pieces like this that the sales force were provided to use when meeting with doctors?
A. I don't recall the specific piece, but I know they gave us stuff to use, correct.
Q. Do you recall being shown this and asked about it in your

deposition, sir?

A. I do not recall.

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

Do you see that, sir?

A. I see that.

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

Do you see that, sir?

A. I do.

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

A. I am not.

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

A. I don't recall.

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

A. I don't recall that.

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

MR. RUSS: No objection.

THE COURT: All right. You may play it.

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

BY MS. BROWN:

Q. You were asked in relation to this promotional piece: Sir, do you see the promotional message on this page that Prezista is lipid-neutral or lipid-friendly?

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

Do you see that testimony you gave, sir?

A. I do.

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

Do you recall that?

A. Yes.

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

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

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

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

yes.
Q. And you talked a bit about accessing studies from the hub as well, right, sir?
A. Correct.
Q. And you know that there was a policy and an FDA procedure that allowed sales reps to provide providers with off-label studies in some limited circumstances, correct, sir?
A. I don't recall that.
Q. Okay. Do you recall being trained during the time period you were at the company on an FDA guidance that allowed sales reps to give out reprints of studies?
A. I don't recall. I'm not sure it happened. I don't remember that.
Q. All right. Let me see if I can refresh your recollection.
MS. BROWN: Your Honor, just for the witness and counsel, permission to display tab 26, 9211.
THE COURT: Just for the witness, right?
MS. BROWN: Yeah, to see if I can refresh his recollection, Your Honor.
THE COURT: Mr. Russ?
MR. RUSS: No objection. Maybe potentially an objection to admission.
THE COURT: I'm just talking about showing it to the witness.
You may.

MS. BROWN: Thank you.

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

BY MS. BROWN:

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

A. I do.

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

A. Yes, ma'am.

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

Do you see that slide, sir?

A. I do.

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

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

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

A. No.

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

A. I don't recall that specifically.
Q. All right. Do you recall if the studies that you told us you were accessing on the hub were made available pursuant to this FDA regulation we were just looking at?
A. I don't know that.
Q. All right. Sir, you were trained when you were at Janssen on the various ways that the company had for employees like you to report potential noncompliance; is that right, sir?
A. I'm sorry. Repeat that. Trained for what?
Q. Sure. You were made available, for example, when you worked at Janssen of the anonymous hotline where employees could report potential issues, correct?
A. I don't recall specifically. It's possible. I don't know.
Q. Okay. You didn't report any of the concerns that you've raised in this case to health care compliance, correct, sir?
A. Not in the beginning, no.
Q. Okay. And you said -- I think I heard you testify that one of the reasons that you're testifying here is in retrospect, you wish you would have pushed back more; is that right, sir?
A. Yes, that's correct.
Q. All right. One of the things you told us in your deposition, sir, is that someone, one of your superiors, Bill Weatherford, do you recall him, sir?

A. Yes. He wasn't a superior. He was an equal.
Q. He was an equal.
He was a KAM or a fellow sales rep?
A. I believe he started as a sales rep and then became a KAM, if I recall right. Yes.
Q. And one of the things you told us is that he was thrown out of one of your doctor's offices because he was promoting off-label, right, sir?
A. That's correct.
Q. Okay. And you don't have or know of any documents that would substantiate that that happened, correct, sir?
A. I do not have any documents.
Q. All right. And you're not aware -- you didn't report that incident, correct?
A. I spoke to Denise Levere about it.
Q. Dr. Sweet was the doctor that you claimed this happened with, correct?
A. No, that's not correct. It was Dr. Ha Ta. It's in Dr. Sweet's office. Dr. H-A-T-A.
Q. All right. Sir, there was actually one document -- Mr. Weatherford accompanied you on a sales visit one time, correct, sir?
A. Correct.
Q. And there's actually a coaching document that he filled out that reported the events of that visit, correct, sir?

A. Yes. He filled that out.
Q. All right. And, actually, on that form, there's a place for you to add your own comments, correct, sir?
A. Correct.
Q. And none of Mr. Weatherford's comments reflected any doctor throwing him out of the office, correct?
A. No.
Q. And you in the employee comment section didn't add any comments to suggest that had happened either, correct, sir?
A. Absolutely not.
Q. You know, Mr. Grooms, that many different factors go into a doctor's decision to prescribe HIV medicine, correct?
A. I'm not a doctor. I don't know what they use wholly. It's up to the physicians' discretion.
Q. What you've told us before is that even though you're not a doctor, you believe that many different factors go into their decision to prescribe an HIV medicine, correct, sir?
A. It should, yes.
Q. All right. For instance, doctors consider individual patients they're prescribing to, correct?
A. I would hope so, yes.
Q. Their experience informs their decision to prescribe, correct?
A. I'm not sure on that.
MS. BROWN: Permission to play 166:24 to 167:5.

MR. RUSS: No objection.

THE COURT: You may.

(Video playing.)

BY MS. BROWN:

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

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

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

A. No. That statement?

Q. Yes, sir.

A. I don't recall that, no.

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

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

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

MR. RUSS: No objection.

(Video playing.)

BY MS. BROWN:

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

As a sales representative at the time that you worked at

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

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

Q. Yes.

A. Yes, ma'am.

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

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

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

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

Q. To recommend, correct, sir?

A. Correct.

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

A. Correct.

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

A. Correct.

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

A. I did not -- like, identified as far as someone I'd recommend, but it wasn't up to me.
Q. And you don't know of any speakers that were removed from the bureau because they didn't write enough prescriptions, correct?
A. I wouldn't have that information.
Q. You don't know of any doctors that were removed from the speaker bureau because their prescriptions didn't increase after being selected, correct?
A. I wouldn't know that.
Q. And you don't know of a single doctor who told you that they increased their number of Prezista prescriptions because of lipid messages they heard at a speaker program, correct?
A. That's not correct.
MS. BROWN: Your Honor, permission to play 244:2 to 8.
MR. RUSS: No objection.
THE COURT: All right. You may play it.
(Video playing.)
BY MS. BROWN:
Q. You don't recall, Mr. Grooms, a single doctor telling you that they increased Intelence prescriptions because of once-daily dosing messages that they heard at an Intelence speaker program, correct?
A. No, I don't agree with that.

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

MR. RUSS: No objection.

THE COURT: All right. You may play it.

(Video playing.)

BY MS. BROWN:

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

Do you remember that, sir?

A. Yes, ma'am.

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

A. From what I recall at the time.

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

MR. RUSS: No objection.

THE COURT: All right.

MS. BROWN: Thank you, Your Honor.

BY MS. BROWN:

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

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

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

That was during the time period you were working at the

company, right, sir?
A. Yes, ma'am.
Q. All right. And if you turn, in fact, to dosage and administration, do you see some information provided in the label right there, sir?
A. I do.
Q. All right. And it says here: Patients who are unable to swallow Intelence tablets whole may disperse the tablets in a glass of water.
Do you see that?
A. I do.
Q. And once dispersed, they could stir it up and drink it immediately, correct, sir?
A. Correct.
Q. And that was actually an on-label way to take Intelence, correct, sir?
A. For twice-a-day, it was.
Q. Sir, the emails that you wrote at the time you were working at Janssen were focused on making sure you were complying with the company policies, correct, sir?
A. The emails? I'm not following you on that. Sorry.
MS. BROWN: Okay. Let's take a look at Tab 15, D-9165, please.
THE COURT: Ms. Brown, is this admitted, not admitted? Are you looking to show just the witness?

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

MR. RUSS: No objection.

THE COURT: Okay. So admitted.

(Exhibit D-9165 admitted into evidence.)

MS. BROWN: Thank you.

BY MS. BROWN:

Q. Mr. Grooms, this is an email from you in March of 2009. Do you see that, sir?

A. Yes, ma'am.

Q. All right. And the title is journal club articles for your review. Do you see that?

A. I do.

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

A. Correct.

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

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

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

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

A. Yeah. I would say so.

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

Do you see that, sir?

A. I do.

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

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

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

Did you know that, sir?

A. I was aware that he came, yes.

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

Would you agree with that?

A. No.

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

A. Yes.

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

sales performance was not meeting expectations?
A. Yes.
Q. All right. And as I understood your direct testimony, you disagreed with that feedback, sir?
A. Correct.
Q. All right. You felt that people like Mr. Wilhelm or others were putting feedback in the coaching reports that in your view was not accurate?
A. Mark had told me that he had to put things in the coaching report because it was being looked at from above.
Q. Okay. And your view was what he put in those coaching reports wasn't fair, correct?
A. Correct.
Q. And that's the same with Ms. Levere. You did not feel she was fairly evaluating your performance, correct, sir?
A. Not completely correct. Sometimes she was very, very fair.
Q. All right. I heard you say on direct that she wrote things in the field coaching report that you took issue with, true?
A. Correct.
Q. All right. And, in fact, ultimately, at the very end of your time at Janssen, you were put on a performance improvement plan; is that right, sir?
A. Correct.

Q. And you resigned from Janssen in January of 2010 to pursue a different opportunity, correct?
A. I got a severance to resign. I guess it was a mutual agreement.
Q. When we asked you why you left Janssen, sir, you indicated it was to get experience in managed care, a different experience.
Do you recall that testimony?
A. I don't recall.
MS. BROWN: Can we play 265:22 to 266:1, please?
MR. RUSS: No objection.
THE COURT: You may.
(Video playing.)
BY MS. BROWN:
Q. Sir, I understand your testimony that you have not remained in contact with Ms. Penelow and Ms. Brancaccio, correct?
A. Correct.
Q. But at one point, you did receive outreach from their lawyers, correct?
A. Attorneys. I don't know whose they were, but yes.
Q. And they asked you to sign a declaration in this case, which you did, correct, sir?
A. Correct.
Q. And they prepared that declaration for you, correct?

A. I did not type it, correct.
Q. And they actually -- I think they came out to Kansas City to meet with you; is that right, sir?
A. Yes.
Q. And I heard you say you weren't really in contact with Ms. Penelow, right, sir?
A. Not to my knowledge.
Q. But she actually called you to see if you were going to answer questions from her lawyer, correct, sir?
A. I don't remember that.
Q. Okay. She actually called you after you submitted your declaration, correct?
A. I don't recall that either.
MS. BROWN: Your Honor, permission to play 125:23 to 126:07, please.
MR. RUSS: No objection.
THE COURT: All right. You may proceed.
(Video playing.)
BY MS. BROWN:
Q. Sir, you mentioned a number of names of individuals that you were on calls with when this off-label direction, you allege, was coming from Ms. Levere.
Do you remember that?
A. Which specific call or example? I'm sorry.
Q. I understand you listed a number of your colleagues that

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

A. We had weekly calls in our district.

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

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

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

A. I have no idea.

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

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

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

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

Q. Who was that, sir?

A. Russ Moyer.

Q. How do you know he was contacted?
A. Because I work with him.
Q. Where do you guys work together?
A. Argenx.
Q. That's a pharmaceutical company?
A. Correct.
Q. What did Mr. Moyer tell you about the outreach?
A. He just said he got contacted. That was it.
Q. Do you know if Mr. Moyer signed a declaration?
A. I have no idea.
Q. Do you know if Mr. Moyer is coming into this trial?
A. I do not.
Q. One of the people you referenced during your testimony was Joyce Arellano?
A. Arellano.
Q. Okay. And as I understood your testimony, you believe Ms. Arellano was fired from Janssen for pushing back on this?
A. I don't recall if she was fired specifically for that. I know she was gone not too much longer after, if I recall right.
Q. Do you know if she still works for the company today, sir?
A. I have no idea.
Q. What made you think she had been fired?
A. Because she was gone. She was no longer there. Out of the district.
Q. Do you know she moved to a different department at Johnson

& Johnson?

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

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

THE COURT: You may.

(Sotto voce discussion.)

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

THE WITNESS: Thank you.

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

Mr. Russ.

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

THE COURT: You may.

REDIRECT EXAMINATION

BY MR. RUSS:

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

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

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

Q. How long would that resume be?

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

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

A. No.
Q. Because you didn't list out all the illegal conduct that you witnessed at Janssen on your resume, does that mean it didn't happen?
A. No.
Q. I want to talk to you about some of the deposition clips.
And by the way, Mr. Grooms, your deposition was fairly lengthy, wasn't it?
A. Yes.
Q. I want to take a look at this sales aid discussion that you had with Ms. Brown.
MR. RUSS: If I could have the ELMO, please.
BY MR. RUSS:
Q. Mr. Grooms, do you remember Ms. Brown going over this sales aid with you for Prezista just now?
A. Yes. That's the one she put up, I believe.
Q. Do you recall in your testimony in your deposition that you were actually testifying that you believed that that information in there was showing an off-label lipid-friendly message, and you were asked where is it? Do you remember that?
A. Yes. Yes, sir.
Q. When Ms. Brown put your testimony in front of you, she asked you do you agree that this actually proves it's lipid-friendly.
A. Correct.

Q. You were saying in your deposition -- we can take a look at it -- that you believed it reflected a lipid-friendly message that was not approved by the FDA?
A. Correct.
Q. So you weren't agreeing that Prezista was lipid-friendly at all, were you?
A. No.
Q. In fact, let's just take a look at it.
Do you see your deposition at the top, Matthew Grooms?
A. Yes, sir.
Q. You were being asked by counsel for Janssen about this sales aid and why you thought it was actually an inappropriate lipid-friendly message for Prezista.
Do you recall that?
A. Yes, sir.
Q. You were asked: This document, the sales aid, have any promotional messages in it that Prezista is lipid-neutral, right?
A. Correct.
Q. Then you had trouble reading the page. We can see maybe why.
A. It was tiny, yes.
Q. Right?
A. Correct.
Q. And you said: I'm not trying to be difficult. I'm having

trouble seeing it.

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

Do you see that?

A. Yes, sir.

Q. You said yes at page 14?

A. Correct.

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

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

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

MR. RUSS: 193.

BY MR. RUSS:

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

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

A. No, they're just guidelines.

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

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

A. Correct.

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

A. No.

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

A. No, sir.

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

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

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

Then, when you were using the message.

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

Is that still your testimony today?

A. Yes, sir.

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

A. Correct.

Q. Still the same today?

A. Yes, sir.

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

Do you see that?
A. Yes, sir.
Q. Again, what's false and misleading about the statement that Prezista is lipid-friendly?
And you said: Lipid-friendly to me would mean the same. It's not going to -- it's lipid-friendly, lipid-neutral. It's somewhere to me the same. In my opinion, it means that you're safe to use this, and it's not going to increase lipids or cause any more issues. It's not going to cause any lipid issues to your patient.
Correct?
A. Correct.
Q. So when Ms. Brown showed you that one little clip, you weren't saying Prezista is lipid-friendly?
A. No.
Q. In fact, in your deposition, you were saying that sales aid was inappropriate?
A. Yes, sir.
Q. While we're at it, let's talk about the deposition testimony from -- about your HR meetings.
Ms. Brown showed you one question, again, from your deposition.
You told our jury that you had multiple conversations with Dolores in HR?
A. Yes, sir.

Q. Okay. Let's see what you said in your deposition back in 2019.
A. Yes, sir.
MR. RUSS: This is on page 176.
BY MR. RUSS:
Q. Did you ever report your concerns to anyone else in the company?
Do you see that, sir?
A. Yes, sir.
Q. Could you please read your answer from your deposition five years ago that Ms. Brown did not show you?
A. I reported a lot to Dolores in human resources about Denise Levere and how she was portraying and asking me to do illegal stuff, illegal information, yes.
Q. And you said she was the head of HR over at the Tibotec division, correct?
A. That's what I remember, yes.
Q. You said you did it multiple times approximately a year before you left?
A. Yes, sir.
Q. You specifically told Janssen's counsel you reported the illegal information?
A. Yes.
Q. To Dolores?
A. Yes, sir.

Q. Ms. Brown didn't show you that portion of your testimony, did she?
A. No, sir.
Q. Did you report to Dolores all the unlawful stuff they were having you do?
A. Yes. On multiple occasions, I had discussions with Dolores.
Q. And her response was?
A. We stand behind Janssen's management. Or Johnson & Johnson's, excuse me.
Q. Let's be accurate. Let's be detailed.
A. We stand behind Johnson & Johnson's management.
Q. We stand behind Johnson & Johnson's management?
A. Yes, sir.
Q. You were also showed some deposition testimony about whether or not a doctor told you that they increased their prescriptions after speaker programs.
Remember that?
A. Yes, sir.
Q. I believe you said you disagreed?
A. Correct.
Q. Why did you disagree?
A. Because I remember specifically Dr. Verstraete, Dr. Dietz talking to me after programs about increasing their prescriptions. Actually, the first time Dr. Dietz had written

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

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

Did they tell you in these words?

A. Correct. I believe so, yes.

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

A. Correct. I was watching the TAR reports.

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

Do you remember some conversation with Ms. Brown about that issue?

A. Yes, sir.

Q. And you said back in 2019 -- and, again, I don't remember Ms. Brown showing you this. Correct me if I'm wrong.

Did you see your doctors' prescriptions increase after delivering the lipid-neutral messages or that Prezista is comparable to Reyataz?

And you say what?

A. Yeah, for sure. It had some key physician market shares had changed.

Q. And would you happen to remember the names of those key

physicians?
A. Yeah. Dr. Craig Dietz. Dr. Ha Ta. Middle name is T.
Q. So the same doctors you told this jury yesterday and this morning that their prescriptions were increasing after you delivered an off-label lipid-friendly message to them, correct?
A. Correct.
Q. You were also asked -- and I believe some deposition testimony was played about this -- about remembering if your physicians that you called on increased their Intelence prescriptions for once-a-day dosing.
Do you remember that?
A. Yes, sir.
Q. This is on page 67 of your deposition. Correct me if I'm wrong.
I don't think this clip was played either, Mr. Grooms, was it?
A. I don't believe so.
Q. Mr. Grooms, you were asked five years ago: To the extent you can remember, do you remember any of your physicians that you called on increasing their Intelence prescriptions after hearing your once-a-day message?
And what did you say?
A. Yeah. Dr. Dietz and Dr. Ta, both.
Q. You were asked some questions about dissolving Intelence into a slurry and then drinking, and then you were showed the

Intelence label.

Do you remember that?

A. Yes, sir.

Q. When you were asked that's on label, you said for twice-a-day?

A. Correct.

Q. What did you mean by that?

A. We promoted it for QD, for dosing symmetry once a day.

Q. And tell the jury how you would promote swirling and dissolving the drug and taking it once a day.

A. So, for example, Intelence would be twice a day. The regimen you put with it would be once a day, so it would be confusing for a patient. So I would say you can drop the Intelence in the water, swirl it, drink your one pill with Intelence, and now you only have a one-pill regimen essentially. So it would be QD.

Q. Mr. Grooms, you were also shown an email that you wrote back in 2009 about journal club.

Do you remember this?

A. Yes, sir.

Q. I think you testified yesterday that journal club was one -- maybe this morning, journal club was one of the ways that salespeople would talk about off-label marketing and off-label studies; is that right?

A. Yes, sir.

Q. And I circled there in all caps the word "compliant."
A. Yes, sir.
Q. And you were asked -- well, you wrote compliant, so you must have been compliant, right?
A. Correct.
Q. Why did you write that and why did you put it in all caps?
A. Because I'm not going to put anything in writing that is not compliant. I'm not going to allude to using and talking about our off-label messaging.
Q. Is that similar to the way you wouldn't put all the fraud you saw at Janssen on your resume?
A. Exactly.
Q. Is that similar to the way that Ms. Levere taught you to be careful about what you put in writing?
A. Exactly.
Q. At some point in your career at Janssen, you were actually fairly highly ranked on your sales?
A. Yes, sir.
Q. You started reporting to HR some of the allegations that you saw, including what we just saw. All the illegal stuff, I believe, is what you said in your deposition.
A. Correct.
Q. You weren't fired, were you?
A. It was not fired. It was a mutual, like, a parting, I guess you would say.

Q. But it wasn't well received, was it?
A. No.
Q. In fact, they didn't say your performance is so bad, you're out of here. They gave you a severance, didn't they?
A. Yes. From what I remember, three months.
MR. RUSS: May I have one moment, Your Honor?
THE COURT: You may.
(Sotto voce discussion.)
BY MR. RUSS:
Q. One more topic, Mr. Grooms.
A. Yes, sir.
Q. Do you know whether the FDA itself ever took a position about Janssen's use of the phrase "low impact on cholesterol or lipids" as we sit here today in this courtroom?
A. I do not know.
MR. RUSS: No further questions, Your Honor.
THE COURT: All right. Thank you, Mr. Russ.
Mr. Grooms, you're excused from trial.
THE WITNESS: Thank you, sir.
(Witness excused.)
THE COURT: Folks, it's that time. Let's take a break before the next witness to make sure who you're calling next, folks, is lined up. We'll take ten minutes, and then we'll proceed.
THE DEPUTY CLERK: All rise.

(The jury exits the courtroom at 10:51 a.m.)

THE COURT: All right. Folks, remain seated. We're on recess for ten minutes.

(Recess taken from 10:51 a.m. to 11:01 a.m.)

THE DEPUTY CLERK: Please remain seated.

THE COURT: By the way, who is the next witness?

MR. MARKETOS: Your Honor, it's Mr. Amit Patel.

THE COURT: Right, okay. And then we're going to do the doc.

Are you guys ready? Should I get the jurors?

MR. KLEIN: Your Honor, we had just one issue to raise.

THE COURT: Yeah.

MR. KLEIN: Something that may come up with Dr. Patel. We anticipate that Relators' counsel may want to show him documents relating to direct-to-consumer marketing and correspondence with the FDA on those issues. We would object to that. They're not relevant. There are no direct-to-consumer claims in this action, and totally different standards apply to direct-to-consumer --

THE COURT: When you say "may" -- who is handling this witness? Is that an issue, Mr. Marketos?

MR. MARKETOS: Oh, yes, Your Honor. This is the witness on the DDMAC letter, and they've made a relevance objection to it. And as I told Your Honor, it's an artificial

distinction, and this is the witness that we're calling. They filed no motion in limine on this issue. They just made a relevance objection at trial.

And in my opinion, Your Honor, that was so that we could siphon this testimony to this witness instead of asking Mr. Mattes about it, asking other witnesses about it. But this is the witness.

THE COURT: Mr. Klein, you're handling this witness?

MS. BROWN: I am, Your Honor.

THE COURT: Ms. Brown, you're handling this witness?

MS. BROWN: Yes, Your Honor.

THE COURT: Let me get this straight. Mr. Patel is from compliance?

MS. BROWN: Your Honor, regulatory and compliance, correct.

THE COURT: All right. So he knows the difference between marketing to consumer and marketing to physicians?

MS. BROWN: Yes, Your Honor.

THE COURT: So if you want to establish the limited probative value of this, can't you establish that in your examination of the witness? Because relevance -- my point is simply that this is a relevance objection, right?

MS. BROWN: I think it's also prejudicial, Your Honor, and I think the problem is the fear that it becomes confusing for the jury to distinguish and there is prejudice

that they conflate the two when we know there are two very, very separate regimes for what is appropriate in a direct-to-consumer marketing versus what is appropriate in a direct-to-health care marketing regime.

And we've argued this at sidebar a couple of times throughout the trial, which is why we wanted to raise it in advance. But they know that that's true because they asked Dr. Patel about this at his deposition, and he explained the different regimes and the fact that different reviewers at DDMAC consider the pieces under different guidelines.

THE COURT: All right. So let me ask Mr. Marketos. Again, I'm not understanding. Where are you going with this? I don't have the documents in front of me, and I don't want to spend a lot of time on this, because I want the witness in the witness stand.

MR. MARKETOS: Your Honor, that's not true. What they just said is not true. There's no distinction between the two. They're governed by the same laws, and you're going to see exactly why it's relevant and what they did with it as it relates to their health care provider sales and marketing.

This goes to the heart of the case, and that's why they didn't file a brief on it, they didn't file a motion in limine on it. It's just evidence they don't want to come in.

THE COURT: All right. Well, here's what I'm going to do. I'm going to wait to hear what the question is and what

the anticipated response is. If there's an objection, I'll have to deal with it in real time.

By the way, why wasn't this briefed? With all the amount of paperwork you've all filed with me prior to trial and during the trial, how is this being brought up, you know, the morning of when the witness is going to testify?

MS. BROWN: It's come up a couple of times, Your Honor. I thought it was resolved at sidebar actually. The Court had agreed that direct-to-consumer marketing is not relevant and the two times they tried to use the piece sustained the objection.

So our view is that it's a different scheme. It's not appropriate here for at least two reasons. And we thought this was resolved at sidebar twice.

MR. MARKETOS: I'm sorry, Your Honor. I disagree. I specifically, when they raised this when I was trying to get into it with Mr. Mattes, pointed out the fact that this is a false distinction, it was going to fall flat, but we would then address it with this witness.

THE COURT: I recall some of that response from Mr. Marketos. So I don't think he withdrew any objection or revisiting this issue at a later date. I don't have the transcript of that sidebar in front of me, but I do recall that Mr. Marketos walked back a bit, but that it was going to come up again. So here it is.

So, look. Like I said, I'm going to get the witness in the witness stand. We're going to hear the examination. If there's an issue, I'll see what the witness says, and we'll deal with an objection in real time.

What else?

MR. MARKETOS: That's all, Your Honor.

THE COURT: Okay. Kim, do you want to get the jurors?

THE DEPUTY CLERK: Sure.

THE COURT: Did we call him yet?

MR. MARKETOS: No, Your Honor.

THE COURT: Sorry, Mr. Patel. You got to go back, only because they're going to be, like, who are you, why are you sitting in the witness box. Once you're in, you're in, but until then...

THE DEPUTY CLERK: All rise.

(The jury enters the courtroom at 11:07 a.m.)

THE COURT: All right. Folks, everyone be seated.

Mr. Marketos, do you have the next witness?

MR. MARKETOS: I do, Your Honor. The Relators call Mr. Amit Patel.

THE COURT: Mr. Patel, I'm just going to have you sworn in when you come in, and then you can proceed.

THE DEPUTY CLERK: Please raise your right hand.

(Witness sworn.)

THE DEPUTY CLERK: Please state your name and the spelling of your last name.

THE WITNESS: Amit Patel, P-A-T-E-L.

THE COURT: You may be seated.

Mr. Marketos, whenever you're ready to proceed, you may.

MR. MARKETOS: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. MARKETOS:

Q. Mr. Patel. Good morning, sir.

A. Good morning.

Q. My name is Pete Marketos. I represent the Relators in the lawsuit that's been filed in a whistleblower action against Janssen.

Are you aware of that, sir?

A. Yes.

Q. You and I have not had an opportunity to speak before today, true?

A. True.

Q. You, sir, are represented today by counsel for Janssen, correct?

A. Yes.

Q. Now, you have lawyers who have represented Janssen, and they're also representing you, correct?

A. Correct.

Q. And you have also given a deposition in this case, sworn testimony under oath, right, sir?
A. Yes.
Q. That was actually very recently.
That was this year, correct?
A. Yes.
Q. And you used to work at Janssen, right, sir?
A. Yes.
Q. For a number of years within the Johnson & Johnson family of companies, correct?
A. I worked primarily in the pharmaceutical business of Johnson & Johnson.
Q. Yes, sir. You worked for Johnson & Johnson pharmaceuticals, including involvement with the Janssen subsidiaries, correct?
A. Yes.
Q. And as I understand it, sir, before you gave your deposition testimony in this case this year, you had prepared for that testimony for approximately 30 hours, correct?
A. Correct.
Q. And since that time, since you gave that testimony, you've had further opportunities to prepare for your testimony today with the lawyers who are representing Janssen in this case, correct?
A. Yes.

Q. And when did you arrive in this state, Mr. Patel, in order to prepare for your testimony?
A. I arrived on Tuesday night, and Wednesday I met with my lawyers to prepare for the testimony.
Q. Thank you, sir.
So -- and prior to arriving in town physically on Tuesday, you had a number of preparatory sessions after your deposition for your testimony today, correct?
A. No, I didn't have any conversation after testimony.
Q. Okay. So as I understand it, you provided your deposition testimony in this case and had prepared approximately 30 hours for that deposition testimony, correct?
A. Approximately, yeah.
Q. And since that testimony -- that was in or about March of this year, correct?
A. I think so.
Q. All right. And then since then, you came into town on Tuesday, and then you met with lawyers for Janssen who are representing Janssen in this trial, correct?
A. They're representing Janssen and me also.
Q. You met with them for a number of hours, correct?
A. Yes, yesterday.
Q. All right. Approximately how many hours did you meet with them yesterday?
A. Five hours.

Q. About five hours?
A. Yeah.
Q. Okay. So it's fair to say that you have, for the purposes of the testimony that you've offered in this lawsuit brought by the Relators, Ms. Brancaccio and Ms. Penelow, you've put in about 35 hours of your own time; is that right?
A. Correct.
Q. How about -- now, specifically, that's with respect to meeting with lawyers and preparing.

How about on your own time, sir? Have you been reviewing deposition testimony on your own time?
A. No. I was asked to confirm my deposition written testimony was accurate, so that -- you can add a few hours to that to make sure the written testimony -- written document reflected my deposition testimony. So I reviewed that. So you can add two more hours to that.
Q. Okay, sir. And how about with respect to the time in between? Were you able to review documents provided to you by Janssen in order to prepare for your deposition without lawyers?
A. No.
Q. All right. Sir, you have a degree in biochemistry and a degree in pharmacology; is that right?
A. I have a degree in biochemistry, and I'm a Doctor of Pharmacy. Pharmacy degree, not pharmacology.

Q. So you have a bachelor's degree in pharmacy, right?
A. I have a Doctorate degree in pharmacy.
Q. I'm going to get to that. Sorry.
A. Sorry.
Q. You do have a bachelor's degree in pharmacy; is that right?
A. Right.
Q. And you have a doctorate in pharmacy?
A. Correct.
Q. So two bachelor's degrees and a doctorate; is that right?
A. Correct.
Q. As I understand it, you received that Doctorate in pharmacy in 2003, right?
A. Yes.
Q. And then you began a fellowship where you worked for nine months at the Food & Drug Administration, correct?
A. As part of my fellowship, yeah, training.
Q. As part of your fellowship training, you worked at the Food & Drug Administration itself, right, sir?
A. Yes.
Q. Specifically, you spent time with the Division of Drug Marketing, Advertising, and Communications, what's also known as DDMAC, correct?
A. Correct.
Q. And that is the division of the food and drug agency that

actually looks at marketing and promotional materials that pharmaceutical companies share with patients, with consumers, and with health care providers, correct?

A. Correct.

Q. And then you spent nine months, as I understand it, during that fellowship at Johnson & Johnson?

A. Correct.

Q. In 2005, sir, you became a manager of regulatory advertising and promotion at Johnson & Johnson, correct?

A. Correct.

Q. And your main responsibility was reviewing Janssen's marketing materials and helping them comply with the FDA's regulation on marketing in this country, right, sir?

A. Correct.

Q. And your job was, as you've explained it to us, was to interpret FDA regulations pertaining to prescription drug promotion, right?

A. Correct.

Q. And then you would guide Janssen and help it with its marketing messages to ensure Janssen complied with the FDA's laws, right?

A. Correct.

Q. And in 2006, you were promoted to the director of regulatory advertising and promotion, correct?

A. No.

Q. Okay. I understood that in 2006 you were promoted to a director. Are you saying that's not true?
A. It would be associate director.
Q. I'm sorry?
A. Associate director.
Q. Associate director. Okay. And that was in 2006 as well?
A. I believe that sounds right.
Q. All right, sir. And you had the similar job responsibilities as we've just described, fair?
A. Fair.
Q. And then except that you worked closer with senior executives on matters relating to regulatory and transactional promotion, right?
A. Yes.
Q. Now, in both of those jobs that you held with Johnson & Johnson, you yourself, Mr. Patel, communicated with the FDA, specifically with DDMAC, correct?
A. I was a liaison between the company and the FDA and communicated, yes.
Q. Okay. So when I say you communicated with DDMAC, you communicated with DDMAC, fair?
A. Yes.
Q. All right. And again, just as a reminder, that's the specific subdivision within the FDA that looks at marketing messages that pharmaceutical companies are spreading throughout

the United States, correct?
A. Correct.
Q. Now, in 2010, as I understand it, you made a lateral transfer to become the head compliance officer of Janssen; is that right?
A. That's not correct.
Q. Okay. Did you become a compliance officer for Janssen/Tibotec in 2010?
A. No.
Q. No. Were you ever a compliance officer for Janssen?
A. Yes. I was a compliance officer for Janssen CNS and as part of my responsibility also I had Tibotec Therapeutics, but I had somebody reporting to me who was the primary responsible for day-to-day function of compliance.
Q. Sorry, sir, you said Janssen CNS, that's a different Janssen company?
A. It's within Janssen, Janssen CNS focused on psychiatry products.
Q. One more time, I just need to make sure I get this right.
THE COURT: Mr. Patel, can you put the microphone a little bit closer to you so it's a little louder? Thanks.
BY MR. MARKETOS:
Q. Have you ever served as a compliance officer? To be sure --
A. Yes.

Q. To be clear, sir, let me make a distinction here. We talked about your original job with Johnson & Johnson as a manager of regulatory advertising and promotion and associate director of regulatory advertising and promotion, right, sir?
A. Uh-huh.
Q. Is that correct?
A. Yes.
Q. I'm sorry. The court reporter --
A. Yes, that's correct.
Q. Sorry, Mr. Patel, I apologize. The court reporter's taking down my questions and your answers, so we'll try not to speak over one another.
A. Okay.
Q. And if you would, sir, we can't really say uh-huh, because that doesn't translate to a transcript, okay, sir?
All right. So as I understand it, sir, you did become a compliance officer for the Janssen entity that we're talking about in this trial; is that true?
A. Yes.
Q. Was that in 2010?
A. Yes.
Q. And you were in that position until 2015 when you resigned, right?
A. Correct.
Q. And that was due to personal reasons?

A. Yes.
Q. So from 2006 through the first half of 2010, you were not performing a compliance officer role for Janssen/Tibotec?
A. Correct.
Q. At that time, 2006 through 2010, your role at Janssen was in the product and advertising department, correct?
A. Regulatory advertising and promotion department.
Q. And then you became a compliance officer in 2010, which is a different role, correct?
A. Correct.
Q. Before 2010, you did not give compliance advice at Janssen because that was the job of the compliance officers, not you, right?
A. On -- that's correct, and I can further explain.
Q. Before 2010, your role relating to compliance was only about giving advice relating to advertisement, not speaker programs, correct?
A. Can you repeat the question, sir? I didn't understand your question.
Q. Before 2010, your role relating to compliance, if at all, was about advice relating to advertising, not speaker programs?
A. That's incorrect.
Q. Okay. Before 2010, you had no role in compliance with respect to hiring speakers for the Prezista/Intelence speaker programs, correct?

A. That's incorrect.
Q. Okay.
If we could, sir, I'm going to play a deposition transcript.
MR. MARKETOS: I'm going to play lines 23 and 13. This is page 65, 23 through 66, 13.
THE COURT: Ms. Brown, any issue?
MS. BROWN: No, Your Honor.
THE COURT: All right. You may play it.
(Audio playing.)
BY MR. MARKETOS:
Q. Before 2010, Mr. Patel, you had no role in compliance with respect to hiring speakers for the Prezista/Intelence speaker program, true?
A. That's not true.
Q. Okay. Is there a different answer than you gave during your deposition? That's all I want to know for now.
A. No. I was involved as part of a SAFE committee to review speaker program, so I did have involvement. Your question is was I involved or not, so that's why I'd have to say no.
Q. Okay. Sir, you were part of the SAFE committee?
A. Yes.
Q. Okay. We'll come back to that.
A. Okay.
Q. Before 2010, you had no personal knowledge whether Janssen

tracked speaker prescriptions. Do you recall that?
A. I don't remember.
Q. You have no personal knowledge as we sit here today as to whether Janssen was tracking prescriptions of the speakers that it was paying to speak on the speaker bureau, true?
A. Correct.
Q. And before 2010, you don't recall attending any speaker programs for Prezista and Intelence, correct?
A. I don't recall. I have to look at the -- if I did, it would be documented.
Q. You don't remember attending any speaker programs for Prezista or Intelence, the promotional speaker bureau, before 2010, correct?
A. I don't remember.
Q. You also don't remember attending speaker programs for Prezista or Intelence after 2010, correct?
A. No, that's not correct.
Q. You do recall attending, is that what you're saying?
A. Yes, yes.
Q. Okay. So let's just take it from there. From 2006 to 2010, you don't recall attending any speaker programs for Intelence or Prezista; is that right?
A. Correct.
Q. Sir, you understand what the allegations that the Relators have brought forward in this lawsuit, correct?

A. Yes.
Q. You understand that the Relators have alleged that Janssen was engaged in the off-label marketing of Prezista and Intelence from the time period of 2006 through 2014, right?
A. Yes.
Q. And that Janssen was using speaker programs, promotional speaker bureaus, as a vehicle to pay kickbacks to doctors so they would increase their prescriptions of those two drugs. You understand those are the allegations, right, sir?
A. I understand those are the allegations, yes.
Q. One of those allegations involves messaging that Janssen was delivering to health care providers relating to its lipid profile. You understand that?
A. Yes.
Q. And you understand it's one of the allegations in this case that Janssen was giving messages for its sales force to deliver nationwide with respect to Prezista's lipid profile, right, sir?
A. Yes.
Q. And it's the Relators' allegations in this case that those messages were false and misleading. Do you understand that?
A. Yes, I understand those are the allegations.
Q. Specifically as it relates to the lipid profile, that those messages were intended to minimize the side effects associated with Prezista, right, sir? Those are the

allegations?
A. Yes, those are allegations.
Q. You also understand the allegations brought by the Relators includes that Prezista was marketed to naïve patients through health care providers before it had a label for naïve patients. Do you understand that's another allegation?
A. Yes.
Q. And also, that Intelence was marketed to doctors as suitable for once a day QD dosing, right, sir? That's an allegation in this case?
A. Yes.
Q. And, finally, sir, that the drug Intelence was marketed to doctors for their patients who were naïve when Intelence was only labeled on label for treatment-experienced patients, do you understand that that's another allegation that's been made in this case?
A. Yes.
Q. Now, I'd like to turn your attention to the promotional materials that Janssen provided to its sales force and that they would share with health care providers, okay, sir?
A. Sure.
Q. And your involvement in those marketing materials was to review materials that were provided to you from the marketing department within Janssen, correct?
A. I was part of a multidisciplinary team to review those

materials, yes.
Q. But I'm just asking about your role, sir, not the multidisciplinary team. I'm asking about your role, okay?
A. Okay.
Q. Your role, how you were involved from 2006 to 2010, was reviewing promotional materials that were going to be used by the sales force to help sell the drug to doctors, right, sir?
A. Yes, I was involved, yes.
Q. And the way that you were involved, sir, was you would review the materials and you would determine or help Janssen determine whether they were compliant with FDA laws and regulations, correct?
A. Correct.
Q. And then you would serve as the liaison between Janssen and the Food & Drug Administration, the FDA, correct?
A. Yes.
Q. One of the ways you would do that, sir, was you would take a promotional material from Janssen and you would submit it to the DDMAC with what's called a Form 2253, right, sir?
A. There is a step before that, but what you mentioned is accurate for final materials that are submitted on 2253.
Q. Yes, sir, I thought I went through the process, but let me make sure I got it right, okay?
First, you would review the material itself internal to Janssen, right, sir?

A. Correct.
Q. All right. When you believed that that material was in final form ready to send to the Food & Drug Administration, you would send it with a form, right, sir?
A. So Prezista and Intelence, both products, were put under subpart H. And per regulation, you had to submit all your draft materials. So based on draft label, you submit to FDA prior to approval or during the approval for advisory feedback. Once you receive the feedback, you incorporate all the feedback into the final material. And that's the material you submit on Form 2253. So the step was there was advisory requirement by regulations.
Q. Thank you, Mr. Patel.
Prezista was actually approved by the Food & Drug Administration and it received a specific label, right, sir?
A. That is correct.
Q. And then when marketing takes place in the United States by a pharmaceutical company, it is required to market only on label; that is, on the label that the Food & Drug Administration had approved, correct?
A. Correct.
Q. And after a label is approved, now you're out of subpart H, you can submit promotional materials to DDMAC going forward, correct?
A. Can you rephrase the question?

Q. Sure. Let me just turn your attention to the November 2008 time frame. November 2008 time frame was approximately two and a half years after Prezista had received its FDA label, correct?
A. 2006, yeah, that's right.
Q. If we go with June 2006?
A. Yeah.
Q. And November 2008, that's approximately two and a half years, right, sir?
A. Sure.
Q. All right. So during that time period, if you're submitting something to DDMAC, you're submitting it with a Form 2253, correct?
A. I think you're not correctly describing the process.
MR. MARKETOS: All right. Let's take a look for the witness, please, at DX-2088. For the witness and counsel only, please, Ms. Johnson.
BY MR. MARKETOS:
Q. Sir, I'm showing you Defendants' Exhibit 2088, do you recognize that as a Form 2253 document?
A. Yes.
Q. And so that we're clear, this is essentially a cover sheet where information is provided about what type of promotional materials are attached and being sent to the government, correct?

A. Correct.

MR. MARKETOS: Your Honor, we'd offer Defendants' Exhibit 2088.

MS. BROWN: No objection, Your Honor.

THE COURT: So admitted.

(Exhibit D-2088 admitted into evidence.)

MR. MARKETOS: Now, let's turn to Defendants' Exhibit 2089, please. This has been previously admitted.

BY MR. MARKETOS:

Q. What you can see here, sir, and we can publish it, this has been admitted, do you see in front of you, sir, materials that were sent with the Form 2253 that we just looked at?

A. Yes.

MR. MARKETOS: And if you turn to the second page.

BY MR. MARKETOS:

Q. Do you see there's a reference here to the promotional material for Prezista, low impact on lipids?

A. Yes.

Q. Again, this is information that Janssen is providing because it wants to use these marketing materials out in the field to market to doctors, correct?

A. Yes.

MR. MARKETOS: If we look at Exhibit 2100, DX-2100.

BY MR. MARKETOS:

Q. This is a February 25, 2009, Form 2253. Do you see that,

sir?
A. Yes.
Q. And you actually signed it yourself, that's your signature on it, correct?
A. A representative of Janssen signed on behalf of me.
Q. Somebody signed your name?
A. Yes.
Q. Okay. You recognize this document?
A. Yes.
MR. MARKETOS: We'd offer Defendants' Exhibit 2100, Your Honor.
MS. BROWN: No objection, Your Honor.
THE COURT: So admitted.
(Exhibit D-2100 admitted into evidence.)
BY MR. MARKETOS:
Q. And what was attached to this form has previously been admitted as Defendants' Exhibit 2101. Can you see, sir, this is Prezista once daily promotional materials that Janssen was sending to the Food & Drug Administration?
A. Yes.
MR. MARKETOS: If we take a look at page 15 of this document.
BY MR. MARKETOS:
Q. Do you see the reference there, sir, to low impact on lipids?

MR. MARKETOS: Turn to the next page. Sorry, the prior page, ma'am, I'm sorry.

Thank you, Ms. Johnson. Would you go to page 15? I apologize.

BY MR. MARKETOS:

Q. All right. Sir, do you see there's a reference here to the mean low-density lipoprotein LDL and total cholesterol values?

A. Yes.

Q. And in this marketing material Janssen was also promoting Prezista as having low impact on lipids, correct?

A. Correct. Based on the document, yes.

Q. Now, sir, given your experience with working for DDMAC, given your role in regulatory compliance with Janssen, you knew that any marketing materials for pharmaceutical drugs must contain true statements, correct?

A. Correct.

Q. And the Food & Drug Administration, you know, requires that in order for a statement to be true, it cannot minimize side effects, right, sir?

A. I don't understand your question, sir.

Q. Yes. Not minimizing side effects is one of the regulations?

A. Correct.

Q. Thank you. Let's make sure that we're clear here. You

understand that minimizing side effects is against FDA regulations, right, sir?
A. Correct.
Q. And that's part of what would make a statement not true, if you were to minimize side effects, that would make a statement that is promotional about a drug not true, correct?
A. I disagree.
Q. I'm sorry, let me make sure I do this in order. You understand that it is a requirement of the Food & Drug Administration that you cannot minimize the side effects of a drug, correct?
A. Correct.
Q. And if a promotional material does, in fact, minimize the side effect of the drug, that would make it not true, correct?
A. That would make it false and misleading.
Q. Okay. So that's what I meant by not true. So let me just go ahead and define not true. If it's not true, it's false, right, sir?
A. Correct.
Q. Okay. So if a pharmaceutical manufacturer is marketing a drug and it's minimizing the side effects, that would make that promotional material false and misleading, correct?
A. It may be false and misleading.
Q. Well, if you are minimizing the side effects, that is false and misleading under FDA regulations, correct?

A. It's if. If you minimize, then it is false and misleading.
Q. Yes, sir. I'm sorry. I thought that was my question. If a pharmaceutical company minimizes the side effects of its drugs in its promotional materials, that is false and misleading, correct?
A. That is correct.
Q. And that is not permitted in this country, correct?
A. That is against FDA regulations.
Q. I'm sorry?
A. That is against FDA regulations.
Q. Yes, sir, the Food & Drug Administration, which is in this country, right?
A. Yeah.
Q. Okay.
What you also know that you can't do if you're a pharmaceutical manufacturer, you can't omit material facts about a drug in your promotional materials, correct?
A. That is a requirement of the regulation, correct.
Q. It is a requirement of the regulations that pharmaceutical companies not omit material facts about their drugs in their promotional materials, correct?
A. Correct.
MR. MARKETOS: Let's turn to Defendants' Exhibit 4263.

BY MR. MARKETOS:

Q. Defendants' Exhibit 4263 is compliance guidelines for promotional speakers. Do you see that, sir?

A. Yes.

Q. And you wrote this document?

A. Yes.

MR. MARKETOS: We'd offer Defendants' Exhibit 4263, Your Honor.

MS. BROWN: No objection.

THE COURT: So admitted.

(Exhibit D-4263 admitted into evidence.)

MR. MARKETOS: If we could publish that? Thank you, Ms. Johnson.

BY MR. MARKETOS:

Q. Now, Mr. Patel, this is October 2010 compliance guidelines for promotional speakers. And this is a document that we can see on the cover page that you authored, correct?

A. Yes.

Q. And this is after you've become a compliance officer within Janssen, correct?

A. Correct.

Q. And if we turn to page 9 of this document, you were providing guidelines within the organization as to what makes something on label and what would make it false or misleading. Do you see that?

A. Correct.
Q. And with respect to false or misleading, product claims not consistent with the FDA-approved package insert, PI is the label, right, sir?
A. Yeah.
Q. Product claims not consistent with the FDA-approved label, or not supported by substantial evidence or substantial clinical experience, that would make a promotional material false and misleading, correct?
A. That's, yes, accurate.
Q. Sir, just so we're clear, that would include minimizing side effects, correct?
A. Minimizing side effects is one example of false and misleading.
Q. Yes, that's what I meant by including, Mr. Patel.
A. Yeah.
Q. Minimizing side effects is an example of something that is false or misleading, right, sir?
A. Yes.
Q. And that would be considered off-label promotion, correct?
A. That is incorrect.
Q. Okay, sir. I understand you're not aware of this, sir, you're saying something can be false and misleading in terms of minimizing a side effect that is on a drug's label and that would not be considered off-label promotional; is that your

testimony?
A. That is, right, correct.
MR. MARKETOS: If we turn to page 10.
BY MR. MARKETOS:
Q. These are examples that you were giving to other employees at Janssen, right, sir?
A. These are based on regulations, yes.
Q. All right. But that wasn't my question.
These were examples that you were providing to other employees at Janssen, correct?
A. Based on the document, this sounds like a speaker training, so I was explaining to the speakers what is the FDA regulations.
Q. Okay. And you provide examples of what's false and misleading, and that includes the number of bullet-pointed items that you, I guess, provided to doctors; is that right?
A. Correct.
Q. Now you're telling doctors what's false or misleading; is that fair?
A. That's part of the speaker training, yes.
Q. And that includes broadening of the product indication, right? Making the labeled drug broader than what was actually approved by the FDA, correct?
A. Yes.
Q. Data taken out of context, that's false and misleading,

right?
A. Yes.
Q. Minimization of safety issues, that's false and misleading, right, sir?
A. Yes, sir.
Q. Omitting material information, that would be false and misleading, correct?
A. Yes.
Q. Or comparing the efficacy or safety claims without substantial evidence, like two well-controlled head-to-head trials. That's what you were telling the doctors --
A. Correct.
Q. -- right?
Are you saying that this -- as I understand it, sir, are you saying that this actual program was not also delivered to the employees of Janssen itself?
A. Can you rephrase the question?
Q. Yes, sir. You said earlier that this was a training, you believe, of doctors for the speaker program.
This was also used to train those who were implementing the program at Janssen, correct?
A. They were always part of the process, so people responsible for speaker program were participating in training also. So they will get the same training. And this is part of our compliance program about what speakers should and should

not do.
Q. Thank you, sir.
So the people who implemented the speaker bureau programs at Janssen, that was the sales force, right, sir?
A. It was a marketing responsibility.
Q. Marketing owned the program, and the sales force implemented it.
You know that, right?
A. Execution, yes, correct.
Q. Execution, that's what I meant by implemented. I apologize.
A. Okay.
Q. The sales force executed on, they implemented the program, right, sir?
A. Sure.
Q. So this training was provided not just to the speakers but also, as I understand it, to the marketing and sales force who were implementing the program, correct?
A. What I can testify is this particular document is focused on speaker program training. There are other trainings that cover similar principles, but the reps go through different training on company policies on speaker program related.
Q. These policies were delivered to the sales force as well, correct?
A. Yes.

Q. And to the marketing department as well since it owned the promotional speaker bureau program, correct?
A. Yes.
Q. Another thing you're not permitted to do because it would make your promotional materials false or misleading is overstating the safety, efficacy or safety, right, sir?
A. Yes.
Q. Superior to, more effective, better than, safer than, more tolerable. You can't do that. You can't compare two drugs to one another in terms of safety and efficacy that have not been compared in a clinical trial that was approved by the FDA, correct?
A. Correct.
MR. MARKETOS: If we take a look at page 11.
BY MR. MARKETOS:
Q. Another example of something that would be false and misleading, sir, you were teaching doctors and the sales force and marketing, was that efficacy or safety claims based on healthy volunteers in vitro or other nonclinical information with unknown clinical relevance, that would be false and misleading, correct?
A. Correct.
MR. MARKETOS: Let's take a look quickly at Relators' Exhibit 74.
BY MR. MARKETOS:

Q. Relators' Exhibit 74 is already in evidence, sir. This is a document that we looked at earlier in the trial. This is an email from Mr. Tim McSherry that was circulated within the Janssen sales force.

Have you ever seen this email, Mr. Patel?

A. Can you give me a minute to look through it?

Q. Sure. Absolutely.

A. I was not copied on the email, so I have no knowledge of this email.

Q. Okay. Sir, I've just got some questions for you about it.

What is attached to this document, this email that's already in evidence, that Mr. McSherry was referring to was called a DART study, D-A-R-T.

Do you see that attachment referring to Lipid Prezista vs. Reyataz.doc at the top?

A. Yes. From this document, yes, I do see it.

Q. You know Tim McSherry, right, sir?

A. I don't recall.

Q. You don't remember him; is that right?

A. No.

Q. Do you remember that he was part of the sales force?

A. I don't recall.

Q. You can see at the top there he's actually copying one of the Relators, Ms. Christine Brancaccio.

Do you see that?

A. Okay.
Q. Okay. And he's attaching what is an off-label study known as the DART study.
Have you seen the DART study before, Mr. Patel?
A. Not to my knowledge.
Q. Okay. Well, if we take a look at the attachment, this is a study that looked at TMC114. That was Prezista, right, sir?
MR. MARKETOS: You can blow up the top half for now, please, Ms. Johnson.
BY MR. MARKETOS:
Q. A study of the metabolic changes in healthy volunteers compared to Reyataz.
Do you see that?
A. Yes, I do.
Q. TMC114, just for the benefit of the members of the jury, that was Prezista, right, sir?
A. Yes.
Q. And this study was looking at healthy volunteers and in comparison to Reyataz, correct?
A. Correct.
Q. If we go down to the actual description, you can see the methods -- Ms. Johnson, thank you.
This was a study that was performed in 49 HIV-negative healthy male volunteers, right, sir?
A. Sure.

Q. And it was screening for lipids, and it looks like they were on a drug for about seven days and then they were tested for 21 more days, right, sir?
A. According to the document, yes.
Q. Okay. And as I understand it, you've not reviewed the DART study before today?
A. No.
Q. All right, sir. So just to summarize, 49 patients, they're healthy, they're taking a drug for 28 days, right, sir?
A. This is a clinical study, so according to the protocol, that's what it sounds like.
MR. MARKETOS: Okay. So if we go back to exhibit -- well, let's take a look at the email if you would, please.
BY MR. MARKETOS:
Q. This is what Mr. McSherry is sharing with other members of the sales force.
Do you see that?
A. Yes.
Q. He even says to himself, one side note, the study design had patients on ritonavir alone for seven days before going on boosted Prezista or boosted Reyataz for 21 additional days. I don't understand my -- I think he meant why -- why the investigators did this besides just trying to improve the results.
Do you see that?

A. I do see it.

MR. MARKETOS: All right. Let's go back to 4263, please, Ms. Johnson, and we'll turn to page 11.

BY MR. MARKETOS:

Q. Based on what your role was, Mr. Patel, and the guidance that you were providing to employees of Janssen and to doctors, it would be false and misleading for any member of the sales force to use a DART study like the one we just looked at to promote Prezista to doctors, agreed?

A. Agree. It was never approved.

Q. And if, in fact, a study like the DART study, which was off label in healthy patients comparing to Reyataz and was not FDA approved, if a study like that were being used to promote the drug to doctors, that would be false and misleading.

You would agree?

A. According to FDA regulation, yes.

MR. MARKETOS: We'll take a look at page 12.

BY MR. MARKETOS:

Q. You gave further examples of what is considered off-label information in your own slide, right, sir?

A. Yes.

Q. Any information about a drug's use or safety not found within the label is considered to be off label, right, sir?

A. That is not a correct definition according to what current standards are by FDA. So this is probably, I don't know, in

2010.

Q. Yes, sir. It's the relevant time period for this lawsuit, and it's a document that you wrote in 2010.

A. Yes. What I wrote is what you see here, yeah.

Q. Of course we're talking about a time frame in this lawsuit from 2006 to 2014, correct?

A. Okay.

Q. And I assume that what you wrote at the time was true, correct?

A. That's my understanding of the regulation, yes.

Q. That's your understanding about the regulation.

That was your job, right, Mr. Patel?

A. Yes.

Q. Any information about a drug's use, administration, or safety not found within the label is considered to be off label.

That's what you wrote, fair?

A. Fair.

Q. And then you gave examples of what that might include. Examples of off-label information include a different use or indication for the drug, correct?

A. Yes.

Q. Different patient population or age group, right?

A. Yes.

Q. For instance, if something is on label for

treatment-experienced patients but it's marketed to treatment-naïve patients, that would be a different patient population?

A. Correct.

Q. A different dosing schedule was considered off label, correct?

A. Yes.

Q. For instance, if something is on label for twice-a-day dosing, BID, and it's marketed or promoted as once-a-day dosing, QD, that would be considered off-label marketing, correct?

A. Correct.

Q. A different stage of the disease is also off label. For instance, if an on-label requires two mutations or more, resistance to two types of drugs or more, and it's marketed to patients with less than two mutations, that would be considered off label, correct?

A. I have to look at the label, the indication, to answer that question.

Q. If, for example, Mr. Patel, a drug were approved for use in two or more, right, treatment-experienced patients with two or more resistance to protease inhibitors, and it were marketed to other patients who did not have two or more resistance to protease inhibitors, that would be a different stage of the disease, correct?

A. I'm having a hard time to answer that question. To my knowledge, different stage of disease is if you're second line therapy and you're marketing a product as a first-line therapy, in oncology, that would be a different stage of disease.
Q. Okay, sir. A different route of administration and a discussion of drugs in development, those are what you were telling people at Janssen was considered off label, correct?
A. To our speakers, yes.
Q. And you also told the sales and marketing department as well who were implementing that program, correct?
A. Yes.
MR. MARKETOS: And if we look at slide 26, please.
BY MR. MARKETOS:
Q. You made one point that you wanted to emphasize here, sir, in the summary of this slide.
Never minimize any potential safety information, right?
A. Correct.
Q. Since 1985, Mr. Patel, the FDA has regulated prescription drug advertising to health care providers and to consumers under the same laws, correct?
A. Yes.
Q. And a prescription drug advertisement or promotion must contain true statements regardless of its intended audience, correct?
A. Correct.

Q. With respect to approval by the Food & Drug Administration, ads that are directed at health care professionals must be fairly balanced and include not just major indications but also major adverse effects, correct?
A. Correct.
Q. And those are the same rules that apply to direct-to-consumer and to health care professionals, correct?
A. Correct. Correct.
Q. When it comes to the FDA's approval of promotional materials for a pharmaceutical manufacturer, notification of the FDA's approval must be in writing whether or not those materials are considered to be in violation or not in violation, correct?
A. Can you repeat the question?
Q. It was not a good one. I'll try another one.
A. Okay.
Q. With respect to the FDA's approval process, for the FDA to formally approve any marketing materials that a pharmaceutical company wants to use to market to consumers or to health care providers, that notification to the advertiser must be in writing, true?
A. That is not correct.
Q. Notification to the advertiser that a proposed advertisement is or is not considered to be in violation shall be in written form.

That is a regulation of the Food & Drug Administration, correct?

A. That's the violation. You used the term "approval." So there's two distinction. If the advertisement is false and misleading, FDA will issue enforcement in writing. So that is the regulation, and that is correct.

Q. The only official communications from DDMAC are those in writing?

A. Correct.

Q. The FDA may provide comments on a pharmaceutical company's marketing and promotional materials, but only those in writing are considered official, correct?

A. Correct.

Q. Sir, there came a time in January of 2009 that you, on behalf of Janssen, provided materials to the FDA relating to Prezista having a low impact on cholesterol.

Do you recall that?

MS. BROWN: Objection, Your Honor. May we approach?

THE COURT: You may.

(Sidebar discussion as follows:)

MS. BROWN: Your Honor, this piece that was provided, low impact on cholesterol, was never provided for a -- was only provided direct-to-consumer, not for the health care provider.

THE COURT: So what? Your witness just testified that there's no difference between the two, exactly the

opposite of what Janssen's been representing to me throughout this trial.

How do you feel about that testimony that we just heard?

MS. BROWN: Your Honor, I don't believe that's what --

THE COURT: That's exactly what he said. I've been reading the transcript, literally staring at it.

MR. KLEIN: I think, Your Honor, he'll explain certainly throughout the course of the day that the standards that are applied for the two -- there's a stricter standard for direct-to-consumer because the ads are --

THE COURT: He didn't say that now. Are you watching what I'm watching? So you want me to presume he's going to testify differently than what he just said? If he wants to say something different later, so be it. But what he's testified to right now is absolutely consistent with what Mr. Marketos represented to me today and not consistent with what you all have been representing.

MS. BROWN: Your Honor, we can all look at the deposition transcript. And I have spoken with him and read his deposition testimony and he --

THE COURT: I'm not talking about his deposition transcript. I'm talking about his testimony over the last 20 minutes.

MS. BROWN: I understand, Your Honor. I don't believe he's been able to contextualize it. We know what the testimony is. We also know what the regulations are. They are different. There is different requirements because when you detail --

THE COURT: You have to establish that on cross.

MS. BROWN: I understand, Your Honor, but I think there is prejudice to allowing something that comes in with a different standard on a consumer piece because -- and I just want to say why, Your Honor, it's not guidance is that when you detail a health care professional, the standards assume two things. One, there is more information, more detailed information being given to a doctor, and two, you're also given the label. As a result, the critique of this particular statement that Mr. Marketos is about to go in was that it didn't have any of the backup information with it because it was one line in a consumer piece.

THE COURT: And you've spoken with Dr. Patel, so he knows this issue was coming, right?

MS. BROWN: Well, I mean, he knows what the law is, so it's his experience. He spoke about it in the deposition.

THE COURT: So far he spoke about the law. He said there's no difference.

MS. BROWN: Well, Your Honor, I did not see that question.

THE COURT: I'm confident that's his testimony so far.

MS. BROWN: I understand. I think he wasn't able to contextualize it.

THE COURT: That may be true.

MS. BROWN: I think there's prejudice allowing the consumer piece to come in.

THE COURT: Then you'll have to correct it on cross-examination.

MS. BROWN: I understand.

THE COURT: But the Janssen witness who is in compliance at least for now hasn't contextualized anything.

MS. BROWN: I understand.

THE COURT: And what's even, I think, more relevant to this discussion is this isn't blind to him. He knows this issue was coming.

MS. BROWN: Well, he's been deposed on it. We are telling you truthfully what his deposition testimony was, Your Honor, so --

THE COURT: Well, then why isn't he testifying to that now?

MS. BROWN: I think he's trying to answer yes or no and he's not contextualizing the question, Your honor.

THE COURT: Dr. Patel has not been answering yes or no. I mean, this is taking much longer than it should be

because there were certain questions that we had to continue to feed him the same question multiple times.

MS. BROWN: Trying to be very precise, Your Honor. I mean, the question -- I understand, Your Honor.

THE COURT: If you're telling me that if he were to contextualize it, there's going to be some established difference, then you can do that when you have the witness.

MS. BROWN: I understand.

THE COURT: But based on his testimony, which I've been -- I'll be candid. I've been carefully reviewing his testimony because I knew this issue was coming up because I appreciate counsel putting this before me earlier this morning.

Based on his testimony, it has come out the rules are pretty much the same.

Now, if you're going to clean that up in your examination, then you can clean up before the jury. And don't get me wrong. Any piece of evidence that is admitted in a trial is prejudiced against one party or the other. So that's not my analysis. I mean, I absolutely think right now it sounds prejudicial. If you all clean it up, maybe it will be a wash. I don't know the answer to it.

But I'm going to proceed with this line of questioning and this document based on the testimony that Mr. Marketos has elicited. That's the best I can do because that's the testimony that's before me.

MS. BROWN: I understand.

THE COURT: Thanks.

(End of sidebar discussion.)

THE COURT: You may proceed, Mr. Marketos.

MR. MARKETOS: Thank you, Your Honor.

BY MR. MARKETOS:

Q. Mr. Patel, there was a time in January of 2009 that you, on behalf of Janssen, submitted certain promotional materials to the FDA relating to Prezista having a low impact on cholesterol, true?

A. I need to understand the context of what types of material you're referring to to answer the question.

MR. MARKETOS: Why don't we take a look at RX-1720. You can just show that for the witness.

BY MR. MARKETOS:

Q. Sir, you can see that Relators' 1720 is an FDA consumer package, and, if you flip through, there you can actually see where you sent the UPS label.

A. Okay.

Q. See the label, UPS, to Aline Moukhtara, and it was a consumer package sent by Ms. Sylvia Lee.

Do you see that?

A. Yes, I see.

Q. She worked for you, right?

A. She didn't report to me.

Q. She worked with you at Janssen?
A. Yes.
Q. All right. And if we take a look, you can flip through the documents, and you can see what's attached thereto. There's a fax cover sheet that comes back --
MR. MARKETOS: Turn to the next page, please. Keep going, ma'am. Thank you, Ms. Johnson.
BY MR. MARKETOS:
Q. You can see that there's a package at 1720 of communications between Janssen and the Food & Drug Administration, right, sir?
MR. MARKETOS: Go back one page, please.
THE WITNESS: Yes, sir. You scrolled through too fast, so can you -- can I look through the package quickly, if you don't mind, to refresh my memory?
BY MR. MARKETOS:
Q. Yeah, sure. I'll refresh your memory right now, sir.
If you take a look at the screen in front of you, there's a letter from you to --
THE COURT: Mr. Marketos, have him review it. It's not admitted yet.
MR. MARKETOS: Okay, Your Honor. Sure.
MS. BROWN: Can I provide him with my hard copy, Your Honor -- it's many pages -- so he can review?
THE COURT: Dr. Patel, would that be easier -- is it

Dr. Patel?

THE WITNESS: That would be great.

THE COURT: Is it easier if you see a hard copy?

THE WITNESS: Yes, that would be great.

THE COURT: Why don't you approach Mr. Marketos, and he can hand it to the witness.

MR. MARKETOS: May I approach, Your Honor.

THE COURT: You may.

BY MR. MARKETOS:

Q. Here you go, sir.

A. Thank you.

Q. Sure.

THE COURT: Hold on. Is it marked up?

MS. BROWN: I had started to --

THE COURT: Mr. Marketos, grab it. If he's going to review a document, it's got to be clean.

BY MR. MARKETOS:

Q. I believe we asked you if you prefer doctor or mister during your deposition, and you said either.

A. Either is fine.

Q. You're a Ph.D. You're not a medical doctor?

A. I'm not a medical doctor, correct. Just a doctor of pharmacy.

Q. Okay. sir.

A. Okay. I reviewed it, yes. I remember this package.

Q. Thank you, sir. This was actually discussed with you at your deposition.

Do you recall?

A. Correct.

MR. MARKETOS: All right. We'd offer RX-1720, Your Honor.

MS. BROWN: Subject to the same objection, Your Honor.

THE COURT: So the objection is overruled; but it's preserved, and I'll allow it in.

MR. MARKETOS: Thank you.

BY MR. MARKETOS:

Q. Take a look, sir, at page 1. This is a consumer package.

And then if we take a look at page 2, you see the UPS label with certain materials being sent to DDMAC at the Food & Drug Administration.

And then we can turn to page 11, and there is a submission letter from you, right, sir?

A. Yes.

Q. All right. That's -- just so that we all have our bearings here, what we're looking at is a letter that you, Mr. Patel, put in writing and sent to DDMAC with a consumer package that contains three proposed ads for Prezista.

Do you recall that?

A. Yes.

Q. And if we take a look at, you know, one of those ads, page 13, one of those promotional materials referred to, it was called Belief. This was a Belief campaign.

Do you recall this?

A. Yes.

Q. And it referred to having a low impact on cholesterol, right, sir?

A. Correct.

Q. Now, we'll get a cleaner copy. There is a response that came to Janssen in April of 2009 pertaining to this material, correct?

A. We receive advisory feedback on draft materials, correct.

Q. I'm sorry. There was a response from DDMAC, the federal agency responsible for reviewing promotional ad materials for pharmaceutical manufacturers, right, sir?

A. Correct.

Q. And they responded to this material, including to this specific claim, right, sir?

A. Correct. They respond to draft materials, yes.

Q. Yes.

MR. MARKETOS: We'll take a look at RX-190 just for the witness. Thank you.

BY MR. MARKETOS:

Q. Can you see that that's a clean copy, sir, of the response that came to you, specifically to you, from the Department of

Health and Human Services at the Food & Drug Administration? Do you see that?

A. Yes, uh-huh.

MR. MARKETOS: All right. We'd offer RX-190, Your Honor.

MS. BROWN: Same objection, Your Honor.

THE COURT: All right. So admitted.

(Exhibit R-190 admitted into evidence.)

BY MR. MARKETOS:

Q. All right. Let's turn, if we could, sir, just to the front page, and I'd like to display this to the jury if we could.

Do you see that this is a letter that came to you, sir, on April -- actually -- thank you. Let's go to page 5.

You can see there's a date at the bottom from Aline Moukhtara.

Do you see that, sir?

A. Yes.

Q. That's dated 4/29/2009, right, sir?

A. Correct.

Q. And that individual was a member of the government, specifically DDMAC, at the Food & Drug Administration, correct?

A. Correct.

Q. All right. And if we take a look at the first page of the letter, this is a letter: Dear Dr. Patel, This letter advises

Johnson & Johnson Pharmaceutical Services, LLC, of comments for proposed promotional material submitted on January 27, 2009, to DDMAC, right? The Division of Drug Marketing, Advertising, and Communications, right, sir?

A. Yes.

Q. If we turn to page 3, now, this is an official communication from the Food & Drug Administration, right, sir?

A. Correct.

Q. It's in writing, right, sir?

A. It is in writing, yes.

Q. What was told to you while you were with Janssen was that there were items of concern to the Food & Drug Administration relating to the minimization of risk in those promotional materials, right, sir?

A. Yes.

Q. Specifically, the claim that Prezista had low impact on cholesterol is misleading because it minimizes the risks associated with the use of Prezista.

Do you see that?

A. Yes.

Q. Specifically, it suggests that patients will not experience an increase in cholesterol, low-density lipoproteins, and/or triglycerides, when this is not the case, right, sir?

A. Yes.

Q. In fact, the Food & Drug Administration goes on to state, according to the serious adverse drug reactions, the adverse drug reactions section of the package insert -- that's the label, right, sir?
A. Yes.
Q. The following serious adverse drug reactions of at least moderate intensity occurred in the Phase 2b studies.
Do you see that?
A. Yes, I do see.
Q. And DDMAC specifically pointed out hypercholesterolemia, low-density lipoprotein increases, and hypertriglyceridemia as side effects of Prezista, correct?
A. Correct.
Q. So what the Food & Drug Administration communicated to you at Janssen was that low impact on cholesterol is misleading, right, sir?
A. Based on this letter, they communicated if you don't present other contextual information about the adverse events that were reported in clinical trial, this claim is misleading.
Q. Let's unpackage that a little bit.
What they said was the claim that Prezista had low impact on cholesterol is misleading because it minimizes the risks associated with the use of Prezista.
That's what the words say, right, Mr. Patel?
A. Those words are in conjunction with the draft ad, so you

have to look at the draft ad, how it was submitted and how the comments relate to it. So you have to look at both together.

Q. The claim that Prezista, quote, had low impact on cholesterol is misleading because it minimizes the risks associated with the use of Prezista.

That's what the government told you, true?

A. Your summarization of the FDA letter is incorrect. I think what FDA pointed out is the claim that was submitted did include to inform consumer that there are adverse reactions serious that have been reported in clinical trial.

In absence of that data, the claim that was proposed is misleading. It could minimize the risk. The consumer may read it and believe that there are no side effects associated with the cholesterol, which, in fact, it was in the package insert, as they pointed out here. So the presentation was not complete.

Q. Sorry. Mr. Patel, do you remember what my question was?

A. Can you repeat again, please? Sorry.

Q. Mr. Patel, you just gave us a lengthy explanation, but those words that you just provided are not, in fairness, in the Food & Drug Administration's letter that we're all looking at, fair?

A. I think the way I read it, that's how I interpret it based on my experience working at FDA, working with the reviewer, ongoing conversation, is how they write it. This is how you

interpret.
Q. Okay. Let me see if we can interpret the second sentence.
Specifically, low impact on cholesterol suggests that patients will not experience an increase in cholesterol, low-density lipoprotein, and/or triglycerides, when this is not the case.
That's what the FDA was saying, fair?
A. That's their statement, yes.
Q. What the FDA also said, sir, was that this ruling, that this information, this authorized letter, this guidance applied to the advertising in question and to all future promotional materials containing the same or similar claims or presentations, true?
A. True.
Q. Let's go ahead and take a look at that for the members of the jury.
MR. MARKETOS: That's on page 1, Ms. Johnson. Second paragraph. There you go.
BY MR. MARKETOS:
Q. DDMAC has reviewed the proposed launch direct-to-consumer journal advertisements and offers the following comments, which apply to this as well as future promotional materials containing the same or similar claims or presentations, right, sir?
A. Correct.

Q. That means until and unless there is a letter from the Food & Drug Administration that says this message, low impact on cholesterol, is okay, this guidance is that claim would be misleading, right, sir?

A. Can you rephrase the question? Hard to understand your question.

Q. Any future claims relating to low impact on cholesterol would also fall under this guidance from the FDA.

That's what they're telling you in that sentence we're looking at, right?

A. This applies means if you make the same claim as in a draft ad, which, you look at it, it didn't have all the contextual information. If you present same claim as proposed, it would be misleading. So exact same wording, exact same presentation, it would be misleading.

Q. Exact same wording.

Exact same, is that what you said?

A. Exact same wording, exact same presentation that we had proposed that FDA took issue.

Q. What they actually said, sir, was any future promotional materials that contain the same or similar claims or presentations. That's what they were referring to, right? Same or similar, right, Mr. Patel?

A. I think you have to look at the -- what you mean by similar, like so we have to look at the context of the claim

and to say does the guidance apply. So that's the review. We have to review that claims.

Q. Yes, sir. Low impact on cholesterol is the same or similar as low impact on lipids, isn't it?

A. With proper context, it could be explained.

Q. It's your testimony to the members of this jury that low impact on cholesterol and low impact on lipids are not the same or similar claims?

A. I think my testimony is you have to look at the -- how the claims and additional context is presented to see if the FDA comments on consumer materials applied to other materials if they have the same claim or same presentation.

Q. But my question was different, Mr. Patel.

Is it your testimony to the members of the jury that low impact on cholesterol and low impact on lipids are not the same or similar?

A. I think I would use word "similar" because cholesterol is a very specific number, and lipid could include triglycerides, cholesterol, LDL, HDL. There's more information on that. So it depends on how you describe in the promotional material.

Q. Is low impact on lipids similar to low impact on cholesterol, Mr. Patel?

A. As face value, yes, it's similar.

Q. Sir, with respect to Prezista's promotional marketing materials, this letter from the FDA in April of 2009 was the

only written communication that Janssen ever received with respect to low impact on cholesterol, correct?

A. This is the only advisory feedback we received, yes.

Q. This letter that the members of the jury can see right here, Relators' Exhibit 190, is the only written guidance, advisory opinion, or otherwise, that Janssen ever received about Prezista and lipids, correct?

A. Written, yes.

Q. As we sit here today, Mr. Patel, you can tell us, sir, Janssen never received written approval from the FDA about any message pertaining to low impact on lipids, correct?

A. Sorry. Can you restate the question?

Q. Yes, sir. The FDA never provided written approval to Janssen with respect to the marketing message low impact on lipids, true?

A. That is not true.

Q. I'm sorry, sir. A moment ago I asked you whether or not this letter was the only written authorization that Janssen ever received with respect to same or similar claims to low impact on cholesterol. Perhaps I misunderstood you, so let me ask my question again.

A. Sure.

Q. This letter that we're looking at dated April of 2009, Relators' Exhibit 190, this is the only written communication, the only authorized written communication from the FDA to

Janssen pertaining to cholesterol, lipids, and Prezista, true?
A. My testimony is this is advisory feedback. That's a written advisory feedback we received. Your question is approval. That's two different things.
Q. Okay. Let me phrase it differently.
A. Thank you.
Q. Whether it was approval, advisory, or otherwise, Janssen never received anything in writing pertaining to Prezista, cholesterol, lipids, or otherwise other than this letter that we're looking at, true?
A. Correct.
Q. Janssen never received FDA's written approval with respect to any message that Prezista had a low impact on lipids, true?
A. I cannot answer that question because it's not consistent with FDA process of providing approval letters.
Q. Janssen never received any advisory information approving of the message low impact on lipids, correct?
A. This is the only advisory feedback we received.
Q. One more time, Mr. Patel.
Janssen never received any advisory opinion from the Food & Drug Administration in writing approving of the use of the message low impact on lipids for Prezista, true?
A. We never submitted to FDA that --
THE COURT: Dr. Patel, listen to the question and answer the question that is posed to you, not some other

question that's not being asked. I'm directing you to do that.

Understood?

BY MR. MARKETOS:

Q. Janssen never received written advisory opinion from the Food & Drug Administration approving of the use of the message low impact on lipids for Prezista, true?

A. Correct.

Q. Janssen never received written advisory opinion or written approval of the promotional message minimal impact on lipids for Prezista, true?

A. True.

Q. Janssen never received written advisory opinion approving of the message proven lipid profile for Prezista, true?

A. True.

Q. Janssen never received written approval or an advisory opinion from the Food & Drug Administration with respect to the message lipid-friendly for Prezista, true?

A. True.

MR. MARKETOS: Can we switch to the ELMO, please, Ms. Johnson?

BY MR. MARKETOS:

Q. So that we can help the members of the jury understand your testimony, Mr. Patel, is it accurate to say that the FDA never approved in writing of the promotional message low impact on lipids for Prezista?

A. Can you rephrase the question?
Q. Yes, sir. The FDA never provided written approval of the message low impact on lipids for Prezista, correct?
A. I can only answer never received advisory feedback. I think you're switching the question.
Q. Well, let's do both. You certainly never received any written approval from the FDA with respect to low impact on lipids message, right, sir?
A. Sure.
Q. And you never received any advisory opinion in writing stating it was okay either, right, sir?
A. Correct.
Q. You never received -- Janssen never received any written advisory opinion from the FDA pertaining to minimal impact on lipids, right, sir?
A. We never received advisory feedback on that claim.
Q. Well, if you never sought it, you never got it; is that fair?
A. That's fair.
Q. So you can tell the members of the jury that Janssen never received written advisory opinion or written approval for the promotional message minimal impact on lipids, true?
A. True.
Q. You can also tell the members of the jury, sir, that Janssen never received an FDA written advisory opinion or

approval for the promotional message proven lipid profile, true?

A. True.

Q. And you can also tell the members of the jury that Janssen never received written FDA approval or an advisory opinion pertaining to the promotional message lipid-friendly, true?

A. True.

Q. And, sir, that also pertains to a message like similar to Reyataz.

Janssen never received a written advisory opinion or written approval from the FDA to market its drug Prezista as similar to Reyataz, true?

A. True.

Q. Any suggestion at any time that Janssen had received FDA approval for these messages that we're looking at here, sir, any suggestion, during the course of this trial, that Janssen had received FDA approval for these messages, that would be a false statement.

Do you agree?

A. Can you repeat the question?

Q. Yes, sir. You can tell us that any suggestion from anybody, during the course of this trial, that Janssen actually obtained approval for low impact on lipids, minimal impact on lipids, proven lipid profile, or lipid-friendly, that's not true, is it?

A. I have to look at the -- how they are summarizing to provide the answer.
Q. You need more context?
A. Context, yes.
Q. Okay. Here's more context, sir. Let me see if I can provide it.
MR. MARKETOS: I might need the help from my resident genius to bring this into focus. Resident genius?
THE COURT: Ms. Wendel. Yeah, we all know who the resident genius is over there.
Mr. Marketos, let me just ask you this. Is this particular topic, are we going to go past in just a few minutes?
MR. MARKETOS: I think I can do this part.
THE COURT: You want to do this part, then we can close for lunch recess?
MR. MARKETOS: Yes.
THE COURT: Okay.
MR. MARKETOS: All right. Maybe not. Maybe now is a good time so I can get it focused.
THE COURT: Why don't we do that. You can work that out over the lunch break.
Folks, we're going to break for lunch. 1:00 p.m. Let's get the jurors out of here.
All right. Folks, I'll see you guys in about 35

minutes.

(The jury exits the courtroom at 12:27 p.m.)

THE COURT: Folks, be seated.

Dr. Patel, you can step outside and take your break as well.

THE WITNESS: What should I do with the document?

THE COURT: You can leave that there for now, but you're on break. We're off the record.

(Discussion held off the record.)

(Recess taken from 12:28 p.m. to 1:06 p.m.)

THE DEPUTY CLERK: Please remain seated.

THE COURT: Are we ready, Mr. Marketos?

MR. MARKETOS: Yes, Your Honor, thank you.

THE COURT: Should we get Dr. Patel back in the witness box? Come on up, Doc.

Kim, you'll see if these guys are done eating over there?

THE DEPUTY CLERK: Yeah.

(The jury enters the courtroom at 1:07 p.m.)

THE COURT: Have a seat, folks. Welcome back from lunch.

Mr. Marketos, you can continue when you're ready.

And, Dr. Patel, just to remind you, you're still under oath from earlier, prior to lunch, okay?

THE WITNESS: Yes.

MR. MARKETOS: Thank you, Your Honor.

BY MR. MARKETOS:

Q. Good afternoon, Dr. Patel.

A. Good afternoon.

Q. Sir, I may have solved my technological difficulties. We'll see if that actually happens.

MR. MARKETOS: Ms. Johnson, can we switch to over on the ELMO? There we go. Look at that.

BY MR. MARKETOS:

Q. Sir, I just want to ask you, it would assist the jury in understanding your testimony to review the discussions we had about these messages.

Do you agree?

A. Yes.

MR. MARKETOS: Your Honor, I'm going to mark this as a demonstrative, Plaintiffs' Exhibit 1733 for demonstrative purposes only.

THE COURT: Okay.

(Exhibit R-1733 marked for identification.)

MR. MARKETOS: Thank you.

We can switch back, Ms. Johnson.

BY MR. MARKETOS:

Q. Sir, I wanted to turn briefly back to the letter from DDMAC that we were just discussing before we took the break.

MR. MARKETOS: And go back to RX-190, please,

Ms. Johnson. And we'll take a look at the first page.

BY MR. MARKETOS:

Q. A couple of things, Dr. Patel, before I move on from this letter. Let's take a look at that second paragraph again, please. What DDMAC, with the federal government, said in this letter is that the advisory opinion it was rendering about the claim low impact on cholesterol, that opinion from the federal Food & Drug Administration would apply to this as well as future promotional materials containing the same or similar claims or presentations.

Do you see that, sir?

A. Yes.

Q. All right. And let's just explain what that means. That means that the claim that they were focusing on was low impact on cholesterol, right, sir?

A. Yes.

Q. And a presentation, that's something different. That's how information is actually displayed. For instance, it might be some type of scientific information that is presented as part of the promotional materials, right?

A. Presentation could include layouts, format. So it's many things in the regulation.

Q. Okay. Sir, so what the -- just so that we're clear, what the Food & Drug Administration was saying is that its advisory opinion that low impact on cholesterol was misleading would

apply to the same or similar claims or presentations, right?
A. As written, yes.
Q. And that would be for all future promotional materials as well, correct?
A. Correct. And we clarified with the FDA.
Q. That would apply to all future promotional materials also, correct?
A. As written, yes.
Q. As written. As written in the written letter from the FDA?
A. Correct.
Q. And if we take a look at the bottom, the last paragraph, of course what matters is what's in writing, right, Mr. Patel? They actually remind you of that in the last part of the letter, of page 4.
MR. MARKETOS: Right above the signature block if you would, please. There we go.
BY MR. MARKETOS:
Q. DDMAC reminds you that only written communications are considered official, right, sir?
A. Correct.
Q. And, of course, you know that that's part of the regulations, right?
A. Correct.
Q. Now, after this letter was received, Janssen continued to

put promotional materials into the field containing the promotional message low impact on lipids, true?

A. Incorrect.

Q. One more time, sir. Let me make sure I've accurately framed my question, okay?

After this letter, after the date of this letter, after April of 2009, Janssen continued to have the promotional message low impact on lipids provided to its sales force; is that true?

A. We didn't pursue or we did not promote this claim in any direct-to-consumer materials. That's -- the feedback was on direct-to-consumer material.

Q. My question was maybe a little inarticulate, Dr. Patel.

All I'm asking about right now is the promotional materials that went to health care providers after this letter was received, okay? Do you understand what I'm asking about?

A. Thanks for clarification. Okay.

Q. After this letter was received by Janssen, Janssen continued to put the message low impact on lipids on its promotional materials that the sales force used across the country with doctors?

A. Yes, that's correct.

MR. MARKETOS: If we take a look at Relators' Exhibit 1724. You can show that just for the witness, please, Ms. Johnson, and counsel.

BY MR. MARKETOS:

Q. As part of being in regulatory, sir, were you also responsible for reviewing business plans or communications to ensure that they didn't contain false statements in them?

A. Business plans are not promotional, so compliance will review, and if they have any question, they will refer to me if there is any conversation about promotional tactics.

Q. Understood, sir.

In 2009, you can tell the members of the jury that Janssen continued to promote Prezista as having a low impact on lipids to doctors, correct?

A. Correct.

Q. If we look at -- and the same with 2010, correct?

A. Correct.

Q. And the same with 2011, '12, '13, and '14?

A. Correct.

Q. But in 2010, something else happened, Dr. Patel, that I'd like to ask you about.

A. Okay.

MR. MARKETOS: Let's take a look at Relators' Exhibit 1727.

BY MR. MARKETOS:

Q. While we're bringing that up, sir, Janssen also continued, after having received that DDMAC letter in April 2009, it also put the message out, "proven lipid profile" for Prezista, to

doctors, right, sir?
A. Sorry, I was reading the letter. Can you repeat the question? Sorry.
Q. Yes, sure. I'm going to get to what's in front of you in just a second.
After that letter April 2009 from the federal government, Janssen continued to put the message out, "proven lipid profile," to doctors, correct?
A. I remember reviewing low impact on lipids. If the claims had changed later, I don't recall that. But, yes, we did continue.
Q. You don't recall whether or not Janssen was also promoting Prezista as having a proven lipid profile?
A. While I was in regulatory I remember low impact on lipid.
Q. That's a different question. I'm sorry. I'm just asking whether you remember proven lipid profile as a message pushed to the sales force to sell to doctors the drug Prezista?
A. I don't recall.
Q. How about "minimal impact on lipids," do you recall that message being promoted by Janssen sales force to doctors?
A. No.
Q. You don't recall that at all?
A. No, I don't -- I don't remember approving that claim, so I have no -- that claim was never approved by me.
Q. All right. If that happened, that was before your time in

2010; is that right?
A. I was there from '06 to '10, so never remember approving that claim.
Q. I'm sorry. Thank you, sir.
You were overseeing regulatory promotional advertising from 2006 to 2010. You don't recall approving the message, "minimal impact on lipids" for Prezista; is that right?
A. Correct.
Q. If that message was being used out in the field by the sales force and there were promotional materials shown to doctors with the message "minimal impact on lipids," you're here to tell the jury you did not approve of that message?
A. I didn't approve that specific claim. I have to look at the context of what they were presenting.
Q. I'm not asking about context, sir, I'm asking about words, "minimal impact on lipids," four words.
A. No, I did not approve it.
Q. I'm sorry, I stepped on you.
You did not approve of any claim "minimal impact on lipids" at any time that you were at Janssen?
A. Correct.
Q. Now, after the letter --
MR. MARKETOS: Let's go back just briefly to Exhibit 190, please, Ms. Johnson. RX-190, and we'll turn to page 3.

BY MR. MARKETOS:

Q. Page 3 of RX-190 --

MR. MARKETOS: You can show it, this is in evidence. Thank you.

BY MR. MARKETOS:

Q. Page 3 is the page of the letter that came from the government that referred to minimization of risk with respect to the lipids and Prezista. Do you recall that? We discussed this for a little bit.

A. Yes.

Q. And to be clear, they're talking about a claim, not a presentation. It says: The claim that Prezista had -- and it's in quotation marks -- had low impact on cholesterol is misleading, right, sir?

A. Yes.

Q. And they gave the reason because it minimizes the risks associated with the use of Prezista, correct?

A. Correct.

Q. Okay. And in 2010, sir, you were concerned about an enforcement action that occurred against another manufacturer because you were concerned that the same outcome might happen to Janssen with its promotional messages, true?

A. I have to look at the context of the letter to answer your question.

MR. MARKETOS: All right. Let's take a look at

RX-1727. Just for the witness, please, Ms. Johnson, 1727. Thank you. There we go.

BY MR. MARKETOS: --

Q. Dr. Patel, there's an email from you to Jason Kenig, Guy De La Rosa, and Bryan Baugh, those are all Janssen/Tibotec employees. And it's dated May 10, 2010. Do you see that?

A. Yes.

MR. MARKETOS: We'd offer RX-1727.

MS. BROWN: No objection.

THE COURT: So admitted.

(Exhibit R-1727 admitted into evidence.)

MR. MARKETOS: Thank you. We can publish that.

BY MR. MARKETOS:

Q. Dr. Patel, the subject here was Prezista lipid data and patient case studies, do you see that?

A. Yes.

Q. You attached materials related to Invirase, do you see that?

A. Yes.

Q. That was actually a competitor's drug, a drug that was promoted by Roche, right, sir?

A. I don't recall, but...

Q. Okay. You say here: Jason, Guy, and Bryan, tomorrow we should plan to review the recent DDMAC letter to Roche. See attached. And our current promotional materials.

Right, sir?

A. Yes.

Q. So we'll look at the letter that's attached. But what you wanted to do with the other members of Janssen, Mr. Kenig, Mr. De La Rosa and Mr. Baugh, was you wanted to review a letter that had gone from the government to a competitor about its drug, and Janssen's current promotional materials, right?

A. To review it, yes.

Q. Yes, to review it.

All right. Sir. And if we see what's attached, what was attached was a letter from the FDA from DDMAC to Roche stating specifically concerns that it had with the presentation of the lipid profile for Invirase. Do you recall that?

A. I don't recall the substance of the letter.

MR. MARKETOS: All right. Let's turn to the second paragraph. There's a background section. And we can keep going, Ms. Johnson, you'll see minimization of risks. Page 2 of the letter. Thank you. There we go.

BY MR. MARKETOS:

Q. You can take a look at that, sir, and you can see --

MR. MARKETOS: And if you want to blow up just the top half of it, Ms. Johnson, for the witness so we can see what the letter is about. Thank you.

BY MR. MARKETOS:

Q. Take a moment to review it, sir, see if this comes back to

memory. I'll represent to you that the discussion with the FDA was its concerns with that drug and how it was being promoted with respect to lipids.

Would it help if we turned to the next page, Dr. Patel?

A. Sorry, I'm a little slow, but let me finish reading. Sorry.

MS. BROWN: Your Honor, could I request, if the witness wants it, can he have a copy, since it's multipages?

THE COURT: How many pages is it?

MR. MARKETOS: I'm just going to the next page, Your Honor.

THE COURT: It's fine. He can just see it off the screen.

Dr. Patel, can you read off of that screen?

THE WITNESS: I can, I just need time.

BY MR. MARKETOS:

Q. All right, sir. Can you see that the discussion from DDMAC with respect to this competitor's drug refers to precautions relating to hyperlipidemia and elevated cholesterol?

A. Yeah, I do see that.

Q. All right. And if you turn to page 7, the fourth paragraph refers to minimization of risk, right, sir?

A. Yes.

Q. And that competitor's drug was making the claim minimal

impact. You can see that in the bottom right, right, sir?
A. Yes. Can I -- do you mind if I read the entire two paragraphs to get a context?
Q. Sure.
A. (Reading.)
Okay.
Q. Dr. Patel, the Food & Drug Administration and DDMAC, that agency was concerned with representations by pharmaceutical manufacturers about side effects relating to lipid profiles after a patient would take a drug.
Do you agree?
A. Yes.
Q. And the reason that the Food & Drug Administration and DDMAC is concerned about messages from drug manufacturers like Janssen or Roche in this case is because if you minimize the impact, if you minimize the risk associated with lipids and cholesterol and triglycerides, patients might not know that that could lead to congestive heart failure, right, sir?
A. Can you rephrase your question?
Q. Sure. What we're talking about here is a side effect that can lead to bad things happening to somebody's heart, you understand that, right?
A. That's really a medical question. I would defer to medical to answer that.
Q. Okay. You do understand at least that this subject,

lipids, cholesterol, triglycerides, that's something that you are aware DDMAC was concerned with as it relates to representations from drug companies, right?

A. The letter you shared with me, the drug has specific warnings or precautions in their label, and how they present it in light of efficacy claim, FDA found that overall presentation of risk was minimizing.

Q. Yes, sir.

A. So this drug had warning and precautions related to hyperlipidemia.

Q. Yes, sir. And of course, as we all know, Prezista itself had adverse effects and serious ADRs associated with hyperlipidemia and hypercholesterolemia and triglycerides, right, sir?

A. Correct.

Q. That was on Prezista's label, right, sir?

A. Yes.

Q. And you know that that subject matter, lipids, is of concern to the Food & Drug Administration, correct?

A. I can't answer that question.

Q. Okay. Minimizing risks you do know is a subject matter that the FDA is very serious about?

A. Correct.

MR. MARKETOS: We turn to RX-1728 and this is just for the witness, please, Ms. Johnson.

BY MR. MARKETOS:

Q. This is, sir, a meeting that was actually scheduled so that you and your colleagues at Janssen could talk about the letter that had come from DDMAC to a competitor about its cholesterol information in Janssen's promotional materials, right?

A. I'm looking at the subject. Yes.

Q. And you can see it's dated May 11, 2010?

A. Yes.

Q. It was the next day.

MR. MARKETOS: All right. We'll offer Relators' 1728, Your Honor.

MS. BROWN: No objection.

THE COURT: So admitted.

(Exhibit R-1728 admitted into evidence.)

BY MR. MARKETOS:

Q. And the subject is: Discuss Invirase FDA feedback letter and Prezista material review, right, sir?

A. Yes.

Q. So you're going to discuss with your colleagues -- let me back up for a second. Mr. Jason Kenig, he was the product manager at Janssen for Prezista, correct?

A. Correct.

Q. Mr. Guy De La Rosa, Mr. Bryan Baugh, they were also involved with the promotion of Prezista to physicians, correct?

A. No. They were medical affairs colleagues.
Q. I see. But their input is what was being asked for with respect to the promotional materials for Prezista, right, sir?
A. Correct. As I said, it was part of multidisciplinary review. Medical is part of the reviews, so that was -- their role is to provide medical feedback.
Q. Yes, for Prezista material review, that's promotional material?
A. Correct.
Q. So you had that meeting, you attended that meeting, and you had that discussion, right, sir?
A. Based on this email, it looks like I had a meeting, yes.
Q. You were a required attendee at that meeting, right?
A. Yes, yes.
MR. MARKETOS: All right. And if we take a look at Relators' Exhibit 1729 just for the witness, please, Ms. Johnson.
BY MR. MARKETOS:
Q. Dr. Patel, Relators' Exhibit 1729, this is an email from you to Jason Kenig, the product manager for Prezista, and for Benjamin Kozub, he was the head of the marketing department overseeing Prezista's marketing, right, sir?
A. Yes.
Q. This was two days after the meeting we just saw, right?
A. It sounds right.

Q. May 14?
A. Yeah. Sorry, I'm not keeping track of all the dates.
Q. No problem.
MR. MARKETOS: We'll offer Relators' 1729.
MS. BROWN: No objection.
THE COURT: All right. So admitted.
(Exhibit R-1729 admitted into evidence.)
MR. MARKETOS: Let's publish that to the jury.
BY MR. MARKETOS:
Q. What you sent to Mr. Kozub and Mr. Kenig, sir -- and you can actually show the entire email if you would, please, Ms. Johnson.
The entire email is just one line from you, right, sir?
A. Yes.
Q. And you attach -- in May of 2010, you attach that DDMAC letter from April 2009 where DDMAC had given you advice that low impact on cholesterol was misleading, correct?
A. Correct.
Q. And what you said in one line was "See page 3 of the letter," right?
A. That's what I see on the email, yes.
Q. Yes, sir. You received information about a competitor drug and an enforcement action relating to its representations about lipids and cholesterol, Invirase, correct?
A. Yes.

Q. You set up a meeting with your colleagues to discuss that enforcement action against a competitor and Janssen's own promotional materials, right?
A. Correct.
Q. And then two days later, you sent a letter from April of 2009 where DDMAC had given you the guidance that that claim, low impact on cholesterol, was false and misleading, correct?
A. Correct. I share what we received on direct-to-consumer material.
Q. Yes, you shared what you received on direct-to-consumer material, and to be clear, as you have testified, messages that go to consumers and messages that go to physicians are governed by the same regulations by the FDA, correct?
A. They are governed by the same regulation, correct.
Q. They all have to be true and they can't be misleading, right, sir?
A. Correct.
Q. Same standards apply to doctors; same standards apply to consumers, right, sir?
A. I can't answer the question. It's a very complex process to understand. Consumer audience is different than health group professionals, so expectations from FDA are different for each audience. I can explain more, but I can't simply answer yes or no.
Q. Well, we'll see if you can answer yes or no to this

question.

The same rules and regulations, as you've already told us, the same rules and regulations from the FDA govern communications and marketing messages to patients, consumers, and to doctors. That's 21CFR -- 24CFR201, right, sir?

A. 21CFR202.1, same regulation.

Q. You got it. 21CFR202.1, right?

A. That's the regulation that governs the prescription drug advertising and promotion.

Q. And it governs it with respect to consumers and to doctors?

A. Correct.

Q. Any audience, right, sir?

A. Correct.

Q. And so you sent this letter to Mr. Kozub and Mr. Kenig, and you said "see page 3" and that's all you said, right, sir?

A. That's all I said, yes.

Q. If you go to page 3 of the letter, of course, if we go back to page 3 of the letter, which is attached to your email, that's, of course, the part of the letter that was talking about minimization of risk, the claim that Prezista had low impact on cholesterol is misleading, because it minimizes the risks associated with the use of Prezista, right, sir?

A. Yes, I see it on the screen. Yep.

Q. And that's what you were bringing to the attention of the

head of the marketing department and the product manager for Prezista, right, sir?

A. I was informing them what we had received so we can have a discussion with the team.

Q. Over a year after you received the letter, right?

A. I'm sorry. I missed the time. This was in 2009.

Q. Yeah.

MR. MARKETOS: Let's go ahead and take a look at the email cover if we could, please, Ms. Johnson.

BY MR. MARKETOS:

Q. This is now May of 2010, Dr. Patel.

A. I see. Yeah.

Q. Just to be clear, it's more than a year after this letter has been sent to you and Janssen by the Food & Drug Administration?

A. Correct.

Q. And you're now sharing it with the head of -- the product manager for Prezista and the head of marketing for Prezista, correct? Mr. Kenig and Mr. Kozub, you're sharing it with them, right?

A. Correct, to prepare for the conversation you showed me, the Invirase letter the FDA had issued. So all these topics align.

Q. Thank you. That's so you could discuss with the people that needed to know the fact that this message might become a

problem, right?
A. That's speculating. I simply shared we should look at the comments and discuss as a team.
Q. What you said was "see page 3 of the letter," right, sir?
A. Yes.
Q. It was a careful communication, would you agree?
A. I think the people knew, when I set up the meeting to discuss FDA enforcement, so the topic was already that we're going to discuss the lipid message. So this is in context of that.
Q. All right. So what we know then is that you had those discussions with the other members of your team after having received an enforcement action against a competitor, right?
A. Yes.
Q. And you discussed specifically the letter you got from DDMAC about low impact on cholesterol being misleading, correct?
A. Correct, for the direct-to-consumer materials, yes.
Q. Direct-to-consumer materials, sure.
Are you telling the members of the jury, sir, that you weren't concerned that messages being relayed to doctors about low impact on cholesterol was misleading?
A. That is correct.
Q. Okay. Sir, if we take a look at what happened after this meeting, safe to say Janssen did not make any changes to its

marketing materials after you had this meeting, correct?
A. If that was a team decision, yes.
Q. That wasn't part of my question, Dr. Patel. My question was only about whether Janssen made any changes to its messages that it delivered to doctors about the lipid profile of Prezista after the meeting that we just saw.
A. I have to look at the material that you are referring to to answer your question. If we made any changes or not, I have to look at the final material.
Q. Proven lipid profile, low impact on lipids continued to be the marketing message to doctors throughout your tenure at Janssen, true?
A. Correct. That is correct.
MR. MARKETOS: May I have the ELMO, please, Ms. Johnson?
BY MR. MARKETOS:
Q. We've seen a slide that's been featured during this trial, sir -- I know you've not been here -- with some sales representatives and prescribers and a pharmacy, a Part D sponsor, and I'll see if I can zoom out a little bit. There we go.
Do you see this slide, sir?
A. Yes.
Q. Okay. Sir, I'm going to put Janssen right up top here. So the way it worked in real life is that Janssen was

delivering messages to prescribers through its sales force, right?

A. From the schematic, yes.

Q. The prescribers would write prescriptions that were filled at pharmacies, right, sir?

A. Correct, according to the schematic.

Q. The pharmacies would submit their prescriptions to the Part D sponsors for Medicare and Medicaid, correct?

A. I'm not a reimbursement specialist, so I cannot answer questions on that.

Q. You're aware of the fact that these drugs were reimbursed by the federal government?

A. Yes.

Q. Medicare and Medicaid, right, sir?

A. Yes.

Q. And so that money would then go back to Janssen, right, sir?

A. Again, I'm not a specialist on reimbursement to say it's money or it's a cost of a drug. I don't know what's being sent to Janssen, so I can't answer that question.

Q. Cash money went from the federal government to taxpayers to Janssen.

You're aware of that fact, are you not?

A. Janssen was reimbursed for the drug.

Q. Yes. In money, in US dollars?

A. I assume so.
Q. All right, sir. Are you aware of any time, Dr. Patel, that Janssen ever retracted any message that its sales force had been delivering to doctors low impact on lipids, minimal impact on lipids, lipid-friendly, proven lipid profile, similar to Reyataz? Are you aware of any time that Janssen ever retracted that message out in the field that was going to doctors?
A. To answer your question, only two claims that were approved was low impact on lipid, and I understand proven lipid profile may have been approved. Other claims were not approved. So there is no -- to my knowledge, I don't know if other claims were retracted, but low impact on lipid and proven lipid profile we continued to include in the promotional materials.
Q. Are you aware of any message that was delivered to doctors in the United States by Janssen's national sales force that was ever retracted by Janssen with respect to lipids?
A. I don't recall.
Q. You don't recall that happening, or you know it did not?
A. I don't recall if -- because your question is pretty broad.
Q. It is broad, sir, yes.
A. So I can't answer the question without knowing all the context, like did we have a label change or did we have

enforcement by FDA that we had to retract. But to my knowledge, we continued to present two claims that we included in the promotional materials for health care professional.

Q. I just want to tighten this up so we can move on, sir.

As we sit here today, are you, Dr. Patel, aware of any time that Janssen retracted a message about Prezista's lipid profile in any form or fashion that had been delivered to doctors?

A. Not to my knowledge.

Q. Are you aware, Dr. Patel, as we sit here today of any time Janssen reimbursed the federal government for monies it had received from Prezista prescriptions as a result of a false or misleading message?

A. I'm not expert to answer that question.

Q. You can tell me if you're aware of it or not, sir. That was my question.

A. No, I'm not aware of.

Q. Sorry. Let me reframe it, okay?

A. Sure.

Q. From the whole time that you were at Janssen, from 2006 to 2014 until you left in 2015 -- from that time period, that's what I'm asking about, okay?

A. Okay.

Q. Are you aware of any time that Janssen reimbursed the federal government for any monies it had received for Prezista

prescriptions that were based upon a false or misleading message about its lipid profile?

A. I'm not aware of that.

Q. As I understood your testimony, sir, you said there were only two approved messages, as I understood, relating to Prezista's lipid profile -- relating to Prezista's lipid profile.

Did I understand you correctly?

A. Yes. The documents you shared definitely showed that low impact on lipid with all the data underneath was approved for health care professional materials, and you referenced that proven lipid profile was approved in 2010. So those are only two that I remember reviewing and approving, but I don't remember other claims that you referenced that were ever approved by company.

Q. Thank you, sir, but let's make sure that we're clear with our language here.

You're talking about two messages, low impact on lipids and proven lipid profile, that were approved by you, right?

A. Approved by me, yes.

Q. Not approved by the Food & Drug Administration, right?

A. I disagree with that. It's a complex answer. It takes -- it requires some explanation to answer your question.

Q. One more time, sir. Let me just make sure I get it.

When you were telling the members of the jury that there

were only two approved messages, you were talking about only two approved messages that you had approved by use of the sales force, correct?

A. We approved those messages we shared with FDA. We never received enforcement.

Q. I think it was a yes-or-no question.

Should I ask it again, Dr. Patel?

A. Yes, I approved those claims.

Q. One more time, sir. There are two approved messages, proven lipid profile and low impact on lipids, and you approved them, right, sir?

A. Yes.

MR. MARKETOS: Can we switch to the ELMO, please? Thank you.

BY MR. MARKETOS:

Q. All right. I'm going to do my best with this, sir.

Is it true that proven lipid profile, lipid-friendly, low impact on lipids was approved by the FDA?

A. As I say, it's a complex answer. I cannot simply answer yes or no.

Q. Is it your testimony, sir, that the term "proven lipid profile" was actually approved by the FDA?

A. Yes. Consistent with the current process, that's my understanding.

Q. I'm sorry?

A. Based on current FDA process, those claims are deemed as approved for sales force to promote.
Q. I'm sorry. What do you mean by current FDA process?
A. The way the review process works, company approves those materials. We submit to FDA on Form 2253. Once you submit to FDA, if they have any objection, they will inform you in a writing enforcement that those claims are misleading. We never received any feedback from FDA once we submitted those materials with those claims. So we continued to promote those because we believe that the claim had adequate information to support the claim.
Q. I'm sorry, sir. You said "current FDA process."
Those were the words you used, right?
A. Correct.
Q. Are you talking about current 2024 FDA process?
A. The process at that time too. For any traditional --
Q. Mr. Patel, I'm just asking what you meant by the term "current," sir, and then you're going to get an opportunity to give us all the context when Janssen's lawyers start asking you questions, okay?
A. I misspoke the word "current." What the process existed at that time, based on the understanding of the process, we believe those are approved claims that reps should be able to disseminate to health care professional.
Q. All right. Sir, let me see if I can unpack that.

A. Okay.
Q. You have testified to the members of the jury that the only form of approval that the FDA can provide is in writing, true?
A. That's not true.
Q. The only authorized communications that come from DDMAC or the FDA must be in writing per the regulations, true?
A. Per regulation, FDA provides advisory feedback and enforcement. You're referring to approval. That does not exist.
Q. Dr. Patel, you've never received anything in writing with respect to any lipid profile message from the FDA, advisory or otherwise, that approves of any lipid profile message for Prezista; isn't that true, sir?
A. My testimony --
Q. No, sir. I'm sorry. Not your testimony. I asked you a yes-or-no question.
Shall I reframe it?
A. Yes.
Q. Never did Janssen receive in writing from the FDA, whether it was advisory or approval or otherwise, anything that approved of the message relating to Prezista's lipid profile, true?
A. It's false because we did receive for direct-to-consumer materials. So, again, this is -- your question is misleading.

I'm not understanding what materials you're referring to.

Q. I'm sorry. Are you saying that there was something approving direct-to-consumers that came from the FDA? Are you saying, Dr. Patel, that there was something that came from the FDA that approved -- I don't care what form it took. I don't care if it came by carrier pigeon. I don't care if it came by letter, FedEx, fax, or otherwise.

Are you saying -- are you telling the members of the jury that something came in writing from the FDA approving of any lipid profile message for Prezista?

A. I think my --

THE COURT: Dr. Patel, he's not asking you to characterize your testimony. He's asking you to answer the question he's posing to you right in this moment. Listen to the question. Answer it.

THE WITNESS: Okay. Sorry. Repeat again.

BY MR. MARKETOS:

Q. The FDA never put anything in writing to you or to Janssen approving or giving advice in approval of a lipid profile message for Prezista, true?

A. It's false.

Q. It's false?

A. Because we just reviewed direct-to-consumer material that was advisory feedback we got on low impact on cholesterol. So I think your question is we never received anything. That's

not true. We did receive on consumer materials the feedback on the claim that was presented.

MR. MARKETOS: Your Honor, may I ask for my question to be read back?

MS. BROWN: Your Honor, may we approach on this?

THE COURT: No, I'm just going to ask the question again.

Dr. Patel, listen to me. Maybe it's my voice. He's not asking whether you got anything in writing, so this is the question.

The FDA never put anything in writing to you or to Janssen approving or giving advice in approval of a lipid profile message for Prezista, true?

THE WITNESS: The first part is true, Judge. The second part, they did advise us.

THE COURT: Not approving the lipid profile, right?

THE WITNESS: They did approve -- there is no approval document, yes.

THE COURT: So that was the question.

THE WITNESS: Sorry. I misunderstood, because first question was yes, second question is no. Second part of the question -- because we did have advisory.

THE COURT: But the advisory piece you received before didn't approve of the message. Didn't it actually say they had concerns about the message?

THE WITNESS: They had concerns, correct.

THE COURT: So then the answer would have been -- I got to be honest, Dr. Patel. I want you to listen to the question that's being asked, because I just asked the same question that Mr. Marketos did, and your response came fairly clear to me.

Now you want a sidebar? We can sidebar. Let me see counsel.

(Sidebar discussion as follows:)

THE COURT: He answered my question fine, and I read it verbatim.

MS. BROWN: I just wanted to say to the Court I think he is truly trying to answer that he believes that consumer piece was providing advice. And the question had two pieces to it --

THE COURT: Right. And --

MS. BROWN: -- approval and advice.

THE COURT: -- the advice piece was about approving the message. It wasn't just advice. So you have to listen to the question. It said you never received anything in writing from the FDA approving of this message or advice approving of the message. And he says, oh, well we got advice before. We just went through that document for 35 minutes where they weren't approving of anything. That document says they had concerns about the lipid message and said that it minimized the

impact that's on the PI. So it's not a difficult question. He's highly educated, and he answered my question fairly quickly.

MS. BROWN: I think it's a little more nuanced, Your Honor, and I'll have him explain when I question him. I think he was truly trying to answer the advice piece, and I think he believes that DTC feedback gave advice of how they should interpret the --

THE COURT: It did give advice, but I think it's clear to everyone, including the jury, that was not advice saying we approve of your message.

MS. BROWN: I understand, Your Honor.

THE COURT: It was advice that was criticizing the message.

MS. BROWN: I just think there was a disconnect, but I understand.

THE COURT: He needs to focus on the questions.

MS. BROWN: I understand.

THE COURT: I understand your position but -- I get it.

MS. BROWN: I just think we're losing a little in translation. I really do think he's trying to answer.

THE COURT: Well, I read it verbatim.

MS. BROWN: I understand.

(End of sidebar discussion.)

BY MR. MARKETOS:

Q. Dr. Patel, I'm going to give you one last opportunity to answer this question for the members of the jury, okay, sir?

A. Okay. Sorry about that.

Q. That's all right, sir. I'm going to try to frame it fairly so that you can give an honest answer, okay?

A. Yes.

Q. At no time are you aware of the Food & Drug Administration putting in writing any approval of a lipid profile message for Prezista, true?

A. Correct, true.

Q. At no time are you aware of the FDA putting in writing any advisory opinion wherein it approved of a lipid profile message for Prezista, correct?

A. Again, this answer, advisory feedback does not give approval. They provide feedback on draft claims that were submitted. So they never approved those claims because they're a draft.

Q. At no time did you ever receive an advisory opinion from the FDA about Prezista's lipid profile that contained any advice other than low impact on cholesterol is misleading?

A. Correct. That's a correct statement.

Q. Very quickly, sir, as I understand it, you were in compliance also a portion of your time at Janssen over the promotional speaker bureau for Prezista and Intelence, correct?

A. Sure.
Q. And during that time, sir, that you were at Janssen providing compliance oversight to that program, are you aware of the fact that Janssen was tracking speaker prescriptions for the speakers who were paid to speak on that bureau?
A. To my knowledge, when I was a compliance officer, that was against policy.
Q. That wasn't my question to you, sir.
A. No.
Q. Let me make clear. Need to be clear. You just said something was against policy.
It's your testimony that tracking the prescriptions of speakers on a promotional speaker bureau is against or was against Janssen's policy while you were there?
A. Yes.
Q. I'm asking a different question. I'm not asking about what's written on a piece of paper as a policy. I'm asking about what was actually happening in real life, okay? Do you understand the distinction?
A. Okay.
Q. Are you aware of the fact that in real life, Janssen was tracking the prescriptions that the speakers who were being paid to speak on that bureau were writing for Prezista?
A. No.
Q. Are you aware of the fact that Janssen was tracking the

prescriptions of Intelence for the speakers on the Intelence promotional speaker bureau?

A. No.

Q. Are you aware of the fact that doctors were removed from the speaker bureau for Prezista for not writing enough Prezista prescriptions?

A. No.

Q. Are you aware of the fact that doctors were removed from the Intelence promotional speaker bureau for not writing enough Intelence prescriptions?

A. No.

Q. If those facts had been made known to you, sir, you would have said that's against company policy?

A. Correct.

Q. And that's because, sir, that makes the program look like it's providing kickbacks to doctors?

A. I had to consult with the --

(Technical interruption.)

THE COURT: I don't think that was for you, Doc. I don't know what's going on there.

THE WITNESS: So I would have to consult with my legal counsel to understand if that activity occurred would be a violation of the law.

(Technical interruption.)

THE COURT: I feel like my courtroom just got hacked.

I honestly don't know what that was.

MR. MARKETOS: Just turn off all the TVs, Judge.

THE COURT: Is this for the next witness potentially?

MR. MARKETOS: Not ours.

THE COURT: Let's get back on track. I don't know what that was, but we'll continue.

MR. MARKETOS: Thank you.

BY MR. MARKETOS:

Q. Pardon the interruption, Dr. Patel.

The reason that there's a policy in place at companies like Janssen and other pharmaceutical companies that you can't track speaker prescriptions for the drugs that you're selling is because you're paying those speakers to speak to an audience, right, sir?

A. That was a company policy, correct.

Q. That was the company policy. I heard that.

The reason those policies exist is because you don't want to run afoul of the Anti-Kickback Statute, right?

A. Again, I would have to consult with my legal counsel to see if that's the right interpretation of the statute.

Q. You were the head of compliance for the company.

Are you telling us you don't know why that policy was in place?

A. I was not a head of compliance. I was a compliance officer for CNS franchise.

Q. From 2010 until 2015 when you left, you were in compliance overseeing this unit of Janssen, correct?
A. I had management responsibility for Tibotec Therapeutics and CNS, yes.
Q. So that's a yes, right?
A. Yes.
Q. Thank you. And during that time period, are you telling us that you don't know why that policy existed?
A. I understand why the policy existed.
Q. The policy exists so that Janssen doesn't track the speakers that it's paying cash money to to speak on a speaker bureau, right, sir? That's why the policy exists.
A. I don't understand your question. Sorry.
Q. The reason why you don't want to remove speakers who are being paid cash money to speak on a speaker bureau if they're not writing enough prescriptions is because then it seems like the program is a vehicle to funnel cash to doctors for prescriptions; isn't that true?
A. No, I disagree with your assessment.
Q. I see. Okay. You think those policies existed at Janssen for some reason other than the Anti-Kickback Statute; is that right?
A. Those policies are based on laws and regulations, so I have to look at which one we are referring to. So I think anti-kickback is one of them.

Q. Okay, sir. Anti-Kickback Statute is one of the reasons those policies exist; is that right?
A. Correct.
Q. And you can tell the members of the jury that the Anti-Kickback Statute relates to the payment to induce a doctor for prescriptions that turn into money that come back to Janssen, right, sir?
A. Correct.
Q. And the law is in place -- and you know this given your training -- the law is in place to prevent pharmaceutical companies from corrupting doctors' medical judgment, right, sir?
A. Correct.
Q. And you don't want to use a vehicle, a cash vehicle, to pay doctors who will then prescribe your drugs. You don't want that to be an inducement to those doctors, right, sir?
A. Providing inducement to prescribe was against company policy, correct.
Q. Okay, sir. And if, in fact, the president of the company that goes by the name of Glenn Mattes has testified that, in fact, speaker prescriptions were being tracked by Janssen, you would have told him that's a violation of company policy?
A. Yes.
Q. If, in fact, speakers were being removed from the Prezista and Intelence speaker bureau because the doctors weren't

writing enough prescriptions of those drugs, you would tell Mr. Mattes that was against company policy, right?

A. Yes.

MR. MARKETOS: No further questions. Thank you, Your Honor.

THE COURT: All right. Thank you, Mr. Marketos.

Ms. Brown.

MS. BROWN: May I proceed, Your Honor?

THE COURT: You may.

MS. BROWN: Thank you.

CROSS-EXAMINATION

BY MS. BROWN:

Q. Good afternoon, everyone. Good afternoon, Dr. Patel. How are you?

A. Good afternoon.

Q. Good. Let's just pick up where we left off quickly on the speaker bureau program.

A. Sure.

Q. Do you understand that Janssen has a policy that governs the selection of speakers for its speaker bureau?

A. Yes.

Q. And do you understand that that policy includes objective criteria by which speakers are selected for service on the bureau?

A. Correct.

Q. Do you understand that that policy includes compensation at fair market value for the services speakers provide?
A. Yes.
Q. Do you understand that one of the criteria that is used to select speakers is, in fact, their experience with our products?
MR. MARKETOS: Objection, Your Honor, leading the witness.
THE COURT: I'd ask you to rephrase it. I'll sustain it.
BY MS. BROWN:
Q. To your knowledge, Dr. Patel, is experience with our products one of the criteria that is used to objectively evaluate speakers?
A. Yes.
Q. Does that make sense to you from a compliance standpoint?
A. Yes.
Q. And why is that, sir?
A. Because we want them to share their experience with the product, so appropriate patients can get our product that are consistent with their indication. So we would want them to share their experience as part of speaker program.
Q. Would you have a concern, Dr. Patel, from a compliance standpoint if Janssen was engaging doctors to speak on the bureau who had very little or no experience prescribing our

medicines?
A. Yes.
Q. Why is that?
A. If somebody didn't have any experience or knowledge of our medicine, that would not meet the criteria. How would they communicate about the product information. So I think having experience is not the only requirement. It's one of the requirement.
Q. Was it the case, Dr. Patel, during the time period you were at Janssen, that you never saw a return on investment done on whether, once we compensated a speaker for a speaking engagement, they increased their prescriptions?
A. Correct, that was against our policy too.
Q. Okay. Do you understand, however, Dr. Patel, did you learn at your time at Janssen that the sales force has data of prescribing of all doctors they're visiting?
A. Correct.
Q. And from a compliance standpoint, analyzing that data can be appropriate?
A. Yes.
Q. All right. Let's talk, Dr. Patel, a little bit about some of the questions you were asked today.
First of all, would you tell us just generally, when it comes -- we've heard a lot in this trial about approved messages that were given to sales reps to share with doctors.

Are you familiar with those?

A. Yes.

Q. Can you tell us -- I want to walk through the steps of how something gets approved to be given to the sales force.

Can you tell us first what the internal process is?

A. Sure. Marketing team will create materials, will submit to a committee called promotional review committee that is made up of medical experts. We have a medical doctor on our committee, legal, regulatory, and compliance, depending on the topic.

We cross-functionally review the material, the data, to make sure the data supports the claim that we want to make. We interpret the FDA regulation and try to comply with the FDA regulation to our best knowledge. And those materials are then submitted to FDA on Form 2253 before the reps are allowed to use.

Q. Okay. There was a lot of discussion today about advisory opinions or another type of process.

Are there generally two types of processes that you used to give information to the FDA about potential promotional materials?

A. Yes.

Q. And is one of those processes something called a Subpart H process?

A. Subpart H is a regulation, so if your product delivers an

unmet medical need with limited data, FDA will allow the drug to come on the market earlier before completing large clinical trials.

Q. Let me stop you right there, Dr. Patel. The drugs we're here speaking about are Prezista and Intelence.

Did FDA give Subpart H early approval to both of those medicines?

A. Yes.

Q. And how does that impact the review process of promotional materials?

A. So under Subpart H regulation, it's FDA mandate that any communication we want to do with health care professional or consumer has to be submitted to FDA. They will look at our proposed claims, the supporting documents, and they provide feedback.

And once they provide feedback, company incorporates feedback. Or sometimes we disagree with them, and we will go back to FDA and say we have different interpretation of the statement or your feedback.

But if we implement FDA feedback, then we submit final material addressing all the comments from FDA -- again, to FDA on a Form 2253, which is a final submission, say this is the final material we're using. And then FDA have opportunity at that point to issue an enforcement.

An enforcement is the second process. Advisory opinion

and enforcement. So those are only two processes. FDA never writes a letter to say we approve your claim. They give you advice, and if they have issue with the promotional material they've been submitted, they will issue enforcement. We looked at today that some company had received if they didn't like the presentation that's in the final piece.

Q. Let me see if I can break that down a little bit to help me understand.

So you were asked a lot of questions about nothing in writing, nothing in writing.

Do you recall those questions, sir?

A. Yes.

Q. Okay. I want to show you this -- something I just wrote up. So let's just start with some questions I have about this "nothing in writing" as it relates to Subpart H.

So Subpart H is before the medicine gets the formal approval; is that right?

A. Correct.

Q. Okay. Did you say, Dr. Patel, that under that time period, Janssen was submitting draft promotional pieces?

A. Correct.

Q. Did Janssen, when we were under the Subpart H time period, ever use a promotional piece that did not first go to the FDA?

A. No.

Q. Did we ever use a promotional piece that we did not hear

back from the FDA on?
A. We did.
Q. Okay. So tell us how that would work?
If you're under Subpart H and you get nothing in writing, do you use the piece, do you not use the piece?
A. So Subpart H regulation requires FDA 30 days to review and provide feedback. So once you submit the material for its approval, they have 30 days to review. After 30 days, it's up to sponsor to wait for the comments, or if we have already received the comments on the same -- similar claim, similar presentation, we incorporate those comments and we inform FDA that we're not waiting for your feedback on these materials. And we move forward and we submit on 2253.
Q. Under Subpart H, you get nothing in writing, you wait 30 days. Would you, Dr. Patel, use the piece or not use the piece?
A. We will submit the piece on Form 2253 before we use it.
Q. So really here the answer is send final piece to FDA?
A. Correct.
Q. Okay. Then tell us about the 2253 process.
A. Sure. That's the requirement for all company -- all products that are approved by FDA, that sponsor must submit -- our company must submit the final material that they intend to use, either health care professional or consumer, and we have to submit before the day of first use.

And once you submit that material, FDA reviewers -- and my experience at DDMAC, when I did fellowship, we review all those materials, and if there are claims that are problematic, if they believe the claims are off label or false and misleading, at that point, FDA will issue an enforcement. Because the piece is already out, so that's the enforcement. They will issue enforcement to let the manufacturer know the claims are false and misleading, and you should remove it from the promotional materials.

Q. So under the 2253 process, if you get nothing in writing back from the FDA saying there's a problem with what you sent, do you use the piece, or do you not use the piece?

A. We continue to use the piece because we believe that we have done our best as a company to meet the regulation, meet the requirement, and FDA has an opportunity to let us know if they have issues with our materials.

Q. Is there such a thing under this 2253 process that you're describing to us of the FDA sending a letter saying we approve what you sent us?

A. No. FDA never -- sorry.

Q. Go ahead.

A. FDA never sends approval letter saying your promotional material is approved. That's not their process.

Q. Okay. And so you were asked a number of questions about whether we received approval letters from the FDA in writing.

Do you remember those, sir?
A. Correct.
Q. Does the FDA regulation 2253 that governs this review, does it provide for an approval letter process?
A. No.
Q. Does it instead provide for an enforcement process?
A. That is correct.
Q. And tell us about what that looks like.
A. So once the piece is out in the public domain, it's been used by -- with the physicians or consumers, at that point, FDA will make a determination if the claims are misleading, creates public health risk, if companies promoting off label. They will issue two types of enforcement, warning letter or a notice of violation. And that's the only regulatory mechanism they can communicate with the industry because the piece are already submitted on 2253.
Q. Okay. So if we just try to understand what our options are, Dr. Patel, under 2253, it sounds like approval letter is not an option, correct?
A. Correct.
Q. Okay. So that's no.
But an enforcement letter is an option, right?
A. Yes.
Q. And it's also an option that you get nothing back in writing, right?

A. Correct.
Q. And if you get nothing back in writing, you told us you can use the piece, correct?
A. Yes.
Q. And if you get an enforcement letter, what do you have to do?
A. So typically enforcement is FDA made a determination that what you presented is minimization of risk, false and misleading, off label. Whatever the regulation you violated, they'll ask to remove those claims from that material or any future materials.

And if it's a warning letter, then we have to do a corrective campaign, go back to health care professional and let them know that what we shared was misleading and here is the correct information.

Q. You were shown a letter that was sent to a competitor at Hoffmann-La Roche.

Do you recall that document?

A. Yes.
Q. Okay. And I want to ask you, is this -- let's take a look at that document. It was Plaintiffs' 1727.

This is a letter that got sent to another company, not us, right?

A. Yes.
Q. Okay. This is sent to a different pharmaceutical company

in Nutley, New Jersey, right?
A. Yes.
Q. And what I can see here, it says -- it's referring to professional sales aids that were sent under cover Form 2253.
Do you see that?
A. Correct.
Q. Is that the same 2253 we were just talking about where we essentially have two options that the FDA can take?
A. Yes.
Q. All right. They either do nothing and you use the piece, right?
A. Yes.
Q. Or they send an enforcement letter like the one a competitor got, right?
A. Correct.
Q. All right. So what do you understand was happening in the feedback that was coming from the FDA to another company about the materials they sent under 2253?
A. As a regulatory professional, it's always our -- we look at enforcements from FDA to learn from it to see if our presentations are similar, do we have same issue. So we discuss as a core team with legal, medical, because sometimes there are apples-to-orange comparison. But we really learn from those letters to see what the topics that FDA is concerned about and are we making the similar presentation or not, and we

make then a final determination, should we update the materials or not update the materials.

Q. Do I understand you to say, Dr. Patel, that even when Janssen doesn't get an enforcement letter, we're considering letters that are being sent to other companies in case they might inform us?

A. Yes.

Q. Okay. And this letter that got sent to another company under 2253, it had to do in part with that company's lipid messaging, correct, sir?

A. Correct.

Q. And one of the things the FDA points out on page 2 is that for this company's medicine, hyperlipidemia was listed in the precaution section of the label.

Do you see that?

A. Yes.

Q. What's the significance of that to you as you interpreted this letter?

A. So from a regulatory regulation and my experience working in FDA, typically the risk category, our box warning is the highest risk. Second is your warning and precautions, and then you talk about the adverse drug reaction.

So when somebody has a warning and precaution or precaution about a particular topic, if you present something that minimizes the precaution, then FDA will definitely have

objection to that.

Q. When you reviewed this letter that went to a different company, did you consider the fact that we did not have hyperlipidemia in the precaution section of Prezista or Intelence?

A. Correct.

Q. Okay. And would you have considered -- this was the paragraph that had to do with the particular message this company was distributing.

Do you see that?

A. Yes.

Q. Would you have considered the context of the promotional message the other company was distributing?

A. That is a very important part of regulatory analysis is not only we look at the letter, but we look at what they were promoting. So what was not shared is what is their material, what claim, and how they were presenting, what information they were omitting that was in the label.

So all those analysis goes into make a determination is what is really why FDA took enforcement. So the context and totality of the presentation is very important.

Q. Okay. This letter was sent to this other company in April of 2010.

Do you see that, Dr. Patel?

A. Yes.

Q. And during that period of time, were we sending promotional pieces about Prezista and Intelence to the FDA under 2253?
A. Correct.
Q. What does this letter tell you about whether or not the FDA, when it gets a submission under 2253, whether it actually looks at it and considers whether it's appropriate?
A. Sorry. Can you repeat that question?
Q. Sure. When you evaluate this letter, the enforcement letter that goes out from the FDA to another company, what does that tell you about whether the FDA is actually looking at the 2253 submissions and sending out letters, if needed?
A. Based on my training at FDA, reviewers do review all 2253. They're responsible for reviewing, and if they have concerns like they have concerns here, then they'll take the next step to issue enforcement.

So the materials that we were submitting prior to 2010 that included the lipid message, they were definitely reviewing, and there was a long history with FDA on Prezista. Same reviewer that issued enforcement was the same reviewer that reviewed all of Prezista materials too.
Q. What's the significance of that, Dr. Patel?
A. If she had concern with our promotion of lipid messages, we would have received a similar enforcement too.
Q. Did we ever get an enforcement letter like the one that

went to Hoffmann-La Roche following up on our FDA 2253 submissions about the lipid messages?

A. Never.

Q. How do you interpret that as the regulatory specialist at Janssen?

A. When you look at this letter and look at our presentation and not getting any FDA communication that what you are promoting is false and misleading, from a regulatory perspective, that means that we have done our best to present all the facts that supports the claim and our studies were supporting the claim, so we continued to use those claim. We believe that those claims are proven indirectly by FDA.

Q. And I want to show you some of those submissions and talk about what went to the FDA on those pieces.

You were shown -- and I believe it's now already in evidence -- D-2088, and this is -- is this the cover letter of a 2253 submission, sir?

A. Yes.

Q. Okay. And if we look down here at the bottom, we see that you are the responsible agent, Amit Patel, correct?

A. Yes.

Q. Okay. And just tell us briefly, what is everything listed here on the cover sheet going to the FDA?

A. So as I explained, these are all the final materials that we submitted to FDA supporting the launch of naïve indication

that included data that was approved by FDA in the label. So this is a final submission of all the materials for Prezista.

Q. It says up here Form 2253 is required by law.

A. Yes.

Q. Do you see that?

A. Uh-huh.

Q. Did Janssen ever provide to its sales representatives any approved promotional pieces to use with doctors that it did not submit to FDA under 2253?

A. No.

Q. Okay. Did Janssen ever receive an enforcement letter from FDA about the 2253 materials it sent on Prezista and Intelence for use with doctors?

A. No, not with the use with doctors.

Q. Okay. I want to talk to you about that consumer piece, but this case is about messages that went to doctors.

A. Okay.

Q. So let me show you what went in this submission here.

If we go to page 46, do you see this claim, low impact on lipids?

A. Yes.

Q. Okay. Low impact on lipids was a promotional claim submitted to the FDA pursuant to 2253, correct, sir?

A. Correct.

Q. Janssen did not receive any enforcement letter or

follow-up from the FDA providing comments on the low impact on lipids claim we submitted for use with doctors, correct?

A. Correct.

Q. Okay. You testified, sir, that you were -- all right. Let's come back to that.

In addition, sir, we also submitted to FDA promotional speaker materials; is that right?

A. Correct.

MS. BROWN: Your Honor, permission to admit D-2084? I don't think it's tabbed.

MR. MARKETOS: No objection, Your Honor.

THE COURT: So admitted.

(Exhibit D-2084 admitted into evidence.)

BY MS. BROWN:

Q. In addition, sir, to the low impact on lipids being submitted in connection with promotional pieces, are you aware of lipid language being submitted to the FDA via speaker decks that were being approved by the company at the time?

A. Yes.

Q. All right. And this is another Form 2253 as required by the law, correct, sir?

A. Yes.

Q. And once again, is that your name that appears down here?

A. Yes.

Q. All right. And if we -- it looks like we sort of get a

list.

Does this work like you can package up a bunch of different promotional materials and send them all at once, Doctor?

A. Yeah. On a Form 2253, you have to designate are you submitting these materials -- and you can see under eight, please check one, it says professional or consumer. So all professional materials goes together in one form. And if you are submitting consumer materials, you have to do a separate form.

Q. Why does the FDA make a distinction between the submission of professional materials and consumer materials based or your experience?

A. While I was at FDA, there is two different groups. Professional reviewers and consumer reviewers are two separate reviewers. They look at the intended audience. Consumer level, consumer audience, they expect company to include information that is at the fifth or sixth grade level versus health care professional materials they expect company to include a lot of contextual information or scientific data that consumers may not understand. So that's more appropriate for a company to disseminate that.

It's same as if you look at prescribing information. First part of prescribing information is very technical jargons. That is for health care professional. They're

trained to understand. And then the last page of a prescribing information is medication guide or called patient labeling. It's very simple, consumer-friendly.

So that's the distinction, is the content is different in professional materials versus the consumer material.

Q. And, Doctor, did you just say that there are two different sets of reviewers at the FDA for consumer pieces versus professional pieces?

A. Yes.

Q. Okay. But I thought I heard you testify on direct that the same regulation applies to both, that they have to be fair and balanced; is that true?

A. That's a very general regulation requirement. Promotion should be on label, should include risk information. Fair balanced means is if you're talking about efficacy, you should talk about safety.

But what was not discussed is what does the context require for professional versus consumer, and you can look through all the Subpart H FDA comments that we received. Professional materials, they ask for a lot of context. Without the context, the claim can be misleading.

For consumer it has to be more face valid, because consumers cannot understand technical jargons. So their concerns are company including claims that requires a lot of context, if it's not included, it's not appropriate for

consumer audience.

Q. Based on your experience both at the FDA, the DDMAC agency that evaluates Form 2253 requests, and your experience at Janssen, is there a difference between the way the FDA implements these regulations as it relates to consumer pieces versus professional pieces?

A. I think FDA does look at the audience in mind when they are reviewing the content and providing the feedback. And they do look at the regulation requirement because there are regulation in the 21 CFR 202.1. There are different ways that things can be false and misleading.

So they look at that more from a consumer audience, what you present, is information enough for consumer to adequately understand the risk of the product. And if it's not included, they would object to that.

Q. Do you -- as part of your job when you were reviewing these pieces internally and liaising with the FDA, do you ever have conversations with the FDA about these pieces?

A. Yes.

Q. Did you do that as it related to any Prezista or Intelence pieces?

A. Yes.

Q. Counsel showed you some regulations, though, that say -- or letters that say only written guidance from the FDA is official.

Did you see that?
A. Yes.
Q. So how do the conversations with the FDA inform the job that you do evaluating and approving these pieces?
A. As part of the Subpart H, FDA is pretty open to communicate. If we get a advisory feedback on a draft claim, we can talk to a reviewer to understand better what is FDA concern, what would be -- what could company do to address the concern. And they will share their concern and feedback, but it does not change their opinion. It's written, and we have to interpret the guidance we get, but I think it provides more color, just a better understanding to -- so I can work with the organization to -- how to revise the material to incorporate FDA feedback. So it's more of a clarification, and that is important because sometimes you read the letter and it's not clearly understood what is meant by when they write multiple languages -- multiple sentence to describe their concern.
Q. Do you recall any of your discussions with the FDA regarding any Prezista pieces?
A. Yes.
Q. Did you have a conversation with the FDA about the consumer letter we looked at this morning?
A. Yes.
Q. Tell us about that.
A. So --

MR. MARKETOS: Your Honor, I'm going to object to hearsay. She's asking about a telephone conversation.

THE COURT: Let me see you folks at sidebar.

(Sidebar discussion as follows:)

MR. MARKETOS: She's trying to elicit a telephone conversation with Mr. Patel and a third party unidentified over the phone who is now going to try to explain this.

THE COURT: What's the difference between the letter you put in?

MR. MARKETOS: Well, the letter was to him directly as an official writing from the government, and there's no objection to it and it's 803(8). Now he's talking about a phone conversation --

THE COURT: Phone conversation with the FDA.

Ms. Brown?

MS. BROWN: Yes, Your Honor. He testified this is part of how he does his job. This is part of information that he considers in making these decisions. And at the very least, Your Honor, it goes to our state of mind and our knowledge and our intent. We were having conversations with the FDA and being told about what would or would not make these pieces misleading, and that informed how -- where our state of mind is at issue, that informed what we thought.

THE COURT: Ms. Brown's argument is that it goes to the impact of the listener, that they're not offered for the

truth in saying if I was told by the FDA that this was okay, then why would I take any action to change the messaging.

MR. MARKETOS: And they're going to offer it for the truth of the matter asserted that the FDA had this conversation and something that we've never seen.

THE COURT: Well, Ms. Brown, I want to be very clear. So you're making the point to me to say, look, Your Honor, we believe it's admissible because we know it's a hearsay statement. There's an exception, because really this is dealing with the impact on the listener. This is not hearsay because we're not offering it for the truth.

MS. BROWN: Yes, sir.

THE COURT: That would mean, just to be clear, that when the end of trial comes and you're in closing argument, you can't argue the truth of that saying you heard testimony, the FDA told them it was okay. What you could say is you heard testimony that the reason why -- his understanding because that's why he didn't do anything. But you have to be careful about arguing that the FDA approved something if you don't have someone from the FDA saying it.

MS. BROWN: Understood, Your Honor. I think what we would say is you heard from Dr. Patel that in interpreting this consumer piece, he spoke to the FDA. And based on feedback, he understood blah, blah, blah, blah, blah. And we continued to do this with the understanding that we were complying with 2253

and that these pieces, that we never received enforcement, and that's the way 2253 works.

MR. MARKETOS: That's going to be for the truth of the matter asserted.

THE COURT: Well, let me ask you this. How does the effect on the listener play out then, right? Because he has to be able to say...

MR. MARKETOS: If they're arguing mistake, that's one thing. But now they're trying to prove that the FDA approved it in a phone call.

THE COURT: I think what they're trying to show is that he may not have taken certain action because he understood that there was not a problem. I mean, that's --

MR. MARKETOS: Right, based on a conversation that he's going to relay about -- call the witness. We're in trial. You want to call the FDA person who had this conversation, that's an in-court statement. Now he's going to testify about an out-of-court statement from some unnamed FDA bot. And we have no way to test that, no way to confront the witness, and it is not an official statement. Everything that's official from the FDA has to be --

THE COURT: Is it in his deposition?

MS. BROWN: It is, Your Honor. He spoke about it in his deposition, and he just testified this is the way he does his job. He has frequent conversations with both the consumer

and the professional reviewer at the FDA.

THE COURT: So what are you establishing other than he's communicating with the FDA by phone at times?

MS. BROWN: That he spoke specifically about this piece and his understanding, based on that conversation, was the critique articulated in the consumer document was that we had just listed that statement standalone and we didn't include any of the backup data, and that's what made it difficult for a consumer audience to understand before context of that. And his belief is the health care pieces, why we received 2253 is they do include --

THE COURT: Do you have anybody from the FDA coming to back that up?

MS. BROWN: No.

THE COURT: Did he ever identify the FDA in a deposition?

MS. BROWN: He may have identified the name of the reviewer, Your Honor. I think he knows --

THE COURT: Well, I'm trying to figure this out, too, because it does sound very close to offering it for the FDA approved of this.

MS. BROWN: Well, I think, Your Honor, it's different. We get this letter, and his job is to interpret the words on the page. And part of the way he does that, part of the effect on the actions that he takes or doesn't take is

informed by what he does in the ordinary course.

THE COURT: I'm sorry. Didn't he already testify that -- and you correct me if I'm wrong, but he testified on your examination that there is no approval letter. I submitted all these documents. And if there's silence, it's like silence, it's acquiescence by silence.

MS. BROWN: Correct.

THE COURT: So he established that process. What you're trying to do is get an unnamed third party from the FDA's statements in to the jury? Why don't you call the FDA guy?

MS. BROWN: But, Your Honor, here's why I believe, you know, this is the consumer piece, right. I could have just left it there --

THE COURT: He established that also. On your examination, you elicited some testimony that there's a difference between a layman and a standard for a physician, and that something that may be insufficient marketing for a layman because they don't have any kind of medical expertise may not be the same standard for a doctor. So you've elicited that testimony.

MS. BROWN: But what Mr. Marketos has tried to establish is that, hey, the only written message you got under Subpart H or the advisory method, the only information you got was that minimal impact on cholesterol is misleading. So he

needs to understand and give the basis --

THE COURT: I agree. Then why didn't you call the FDA?

MS. BROWN: -- for his understanding.

THE COURT: Why not call the person that he spoke with?

MS. BROWN: Well, I don't think we need to, though, Your Honor. He made this --

THE COURT: You do. You do. Just because they have some evidence that you're looking to refute doesn't mean you get to get some hearsay statement in from the FDA to refute it. There is direct evidence that you can refute by having a witness in court make the statement, but what you're saying is, well, we need to refute this evidence, and the only way for us to refute it is through a hearsay statement.

Well, that's not my fault. Why didn't you call the person that Dr. Patel told you I spoke to this person at the FDA? Why not depose that FDA person?

MS. BROWN: I think what's at issue, Your Honor, is the decisions Dr. Patel made, and I think what's relevant is what informed those decisions. And our state of mind is at issue in this trial. What our intent was is at issue, and we have to be able to elicit that Dr. Patel, the person in charge of giving these statements, to proving these statements for the sales force to take out, had a good faith basis to think that

this was an appropriate message.

THE COURT: At the end of the day, you're going to put before this jury that the FDA signed off on this.

MS. BROWN: That's actually not what I'm going to suggest, Your Honor. I'm going to have him explain what his interpretation of this guidance, this is an advisory opinion that came from the FDA, and what I need him to explain is how he interpreted that as it relates to the consumer pieces for which we didn't receive --

THE COURT: Here's what I'll allow you to do. I'll allow you to elicit testimony that he communicated with the FDA verbally, maybe not in writing. And that from those communications, this is it, from those communications it was his understanding that -- whatever, I'll paraphrase, there was no problem. What he's not going to be able to elicit is this is what the person said to me.

MS. BROWN: I will make that clear that he's not to say that.

THE COURT: And then also, to be clear, once you've elicited that testimony, if that's the only testimony you have or only evidence you have, because I don't know your defense case yet, if that's all that remains, you will not be able to argue that the FDA signed off on any of this. You would only be able to argue that you heard Dr. Patel testify that based on his communications, his understanding is that this was okay.

But that's all you've got.

MS. BROWN: That's separate, Your Honor, from the 2253 process, which he just explained, and that is they don't take enforcement action, that's how the process works.

THE COURT: You have that testimony. That's why I'm not going to allow him to testify as to what the FDA told him by phone. I sustained your objection, but I'm limiting -- but I'm not completely prohibiting that examination, but it's very limited now.

MS. BROWN: It's his knowledge based on that conversation.

THE COURT: Without getting into the conversation.

MS. BROWN: Without getting into the details of who, you know -- right?

MR. MARKETOS: Yes, Your Honor.

We are going to ask for an instruction on the case law. DDMAC's silence must be in writing. There's no acquiescence. It's the law. But I just want to bring that to the Court's attention now, that as part of final instructions we will be asking for that law to be included.

THE COURT: We'll get to that. If I end up giving an instruction that hurts one of your presentations because the law is inconsistent with something you've been trying to put before the jury, that's on you all. So I'm not going to get into that today. I'm going to allow Janssen to --

MR. MARKETOS: Yes, Your Honor.

(End of sidebar discussion.)

THE COURT: All right, folks. We're back.

MS. BROWN: May I proceed, Your Honor?

THE COURT: You may.

BY MS. BROWN:

Q. Dr. Patel, I understand that part of your work at Janssen involved communicating with the FDA; is that fair?

A. Correct.

Q. Okay. I don't want you to go into the details of what anybody at the FDA told you. I want to ask you some questions about how your opinion was formed. Do you understand that?

A. Can you explain that again? It's tricky.

Q. Sure. It is tricky.

Was part of your interpretation of the FDA's comments about the consumer piece informed by discussions with the FDA?

A. Correct.

Q. Without going into the details of who at the FDA said what, can you share with us what your interpretation of the feedback from the FDA was regarding this consumer piece?

A. My interpretation was these comments were applicable to the consumer materials. The claims was presented without disclosing all the side effects that were in the package insert. The laboratory abnormalities were included in a table. Based on the conversation, FDA founded minimization of risk

because company did not disclose all that in the draft material. If we would have included all those material, FDA opinion would be different.

Q. I just want to show you quickly that. I think counsel put it up or it was attached to the exhibit counsel showed you. But do you recognize this as the consumer piece that was at issue in the letter counsel went over this morning?

A. Yes. And -- yes.

Q. Let me just highlight. This is -- when we say a consumer piece, where does something like this appear?

A. This is a journal ad that -- it would appear in a magazine.

Q. Okay.

A. So consumers will read it in a consumer magazine, pick it up at the grocery stores, that provides them the basic information and suggests them to go to the website to get more information. But it's a journal ad.

Q. Okay. And if we go back to the letter from the FDA, the statement that they were concerned about in this consumer piece was Prezista had a low impact on cholesterol, right?

A. Yes.

Q. And if we go to the actual journal ad that was being proposed, it said, "had low impact on cholesterol," right?

A. Yes.

Q. And below it, it says, "Prezista does not lower

cholesterol levels and has not been shown to provide any heart-related benefits," correct?

A. Correct.

Q. What was your understanding doing your job at Janssen about what about this draft statement gave the FDA concern?

A. Sure. So if you look at the statement above, it says had low rates of diarrhea. So both diarrhea and lipid information are in the same section of the label, which is the adverse drug reaction. And FDA was okay with company making low rates of GI side effects claim as long as you provide proper context, which is what is the frequency of diarrhea reported, which you disclose clearly so people understand it's not 90 percent, it's 6 percent, that supports the word low.

Q. I'm sorry, can I just interrupt you, Dr. Patel?

A. Sure.

Q. Are you saying -- when you said you have to give kind of context or the rates, is that what you're referring to where there's this double asterisk and then down here it says reported as moderate to severe, and it gives the percentages?

A. Correct.

Q. We don't have any asterisk -- first of all, this was a draft piece; is that right?

A. Correct.

Q. This was never used in this format, correct?

A. No.

Q. Because this letter that came from the FDA on the consumer piece was advisory under Subpart H?
A. Correct.
Q. It was not --
A. Sorry, it was not Subpart H. It was advisory because we, during the full approval, we proactively seeked FDA feedback. And that's advisory. You could do under Subpart H or not Subpart. You could get advisory feedback if you want.
Q. Okay. And then as it relates to what we had proposed, this had low impact on cholesterol, it didn't have a little asterisk and additional information?
A. Correct. And that's the big distinction between this, what was submitted to -- what was submitted on 2253 for health care professional. It's a very different -- if you look at side by side, the health care professional materials included all the information that we similarly include here for low rates of GI side effects, like diarrhea, nausea, vomiting.

So that's really the reason why FDA took issue with this, because we didn't disclose here. And it was pretty -- when we looked at the comments, a patient would not understand what's lipid grade two, grade three abnormalities.

I think that was over -- so our attempt was to say, based on the data, so in order to be claimed to be false and misleading, FDA have to look at does the data is a good science. The data is based on good science. It's a randomized

controlled trial, which is the gold standard trial that FDA would want.

And then you look at, Are you disclosing all the facts that somebody should understand if they read this statement? Just like low rates of diarrhea, what is the percentage patients did experience? So that was missing and that's why, based on a conversation, the concern was we failed to disclose material facts.

Q. Okay. And you said compared to the health care provider piece, there was some different information provided; is that right?

A. Correct.

Q. And this was one of the health care provided pieces that had low impact on lipids. Do you see that, sir?

A. Yes.

Q. And there are a number of additional datapoints down here, including some of the percentages that we just saw in the consumer piece about GI effects, right, sir?

A. So, yeah. So this actually shows that patients did have elevation in triglyceride levels. And this data is comparing to lopinavir, which was studied in a head-to-head trial. And it provides all the information for physician to know how do you look at this information based on the cutoffs that are used to inform clinician decision what to do if patients do have elevated triglycerides, or HDL, and said there's national

guidelines that suggest what patients should be treated with.

We also disclosed next to this presentation is all the laboratory abnormalities that were -- patient had experienced. If you -- and in that, as you can see, we were very transparent that in naïve population, if you scroll down a little bit, the triglycerides, cholesterol, LDL, all the data was shared. And this is pretty hard to consumerize. And that was a challenge. And once we got the FDA feedback, company made a decision that this is not a claim that we can pursue in the consumer material. I think the health care professional materials provides room to provide all this context. Because the concern by FDA was just as a statement, low impact on cholesterol, may consumer take it as there's no side effects of cholesterol. Versus over here is you have a health care professional who can understand that, and if you look at the rates, are not like 90 percent or it's comparable and it's lower than lopinavir. And I think that was a very important context the physicians were asking for this product because protease inhibitors are known to cause lipid issue. They wanted to know what is the Prezista effect on lipids. And this is our way to provide all the facts to avoid any misleading impression.

Q. Okay.

You testified on direct examination, Dr. Patel, that you were not concerned that the low impact on lipids message that we approved for use by the sales reps and we provided to the

FDA, you were not concerned that that was false or misleading. Did I hear you correctly?

A. Yes.

Q. Tell us why?

A. Because based on review of -- first of all, lipid information is in the label. Side effects are in the label. So it's not off-label. This is a characterization of what was observed in clinical trial. We're not presenting clinical trial that is not robust in design, it's different when you're making a claim based on a study that is inadequate in design. This is the trial that got FDA approval for the product. So we are factually presenting what was the data between our product, and we were not making any superiority claim to suggest we're better than lopinavir, we're just suggesting factual data and what the ADR table was also disclosing.

So, to me, based on the totality of the presentation, FDA was okay with us using low rates of GI side effects because in the same brochure, the first page before that, had the similar low rates of GI side effects, and FDA had asked us to include all the data if you're going to use the words low rate of GI side effects. So I think it's a similar presentation of side effects. They both are ADRs and they could be equally presented.

So as you can see, we had learned through all the Subpart H conversation that low rates of GI side effect was okay by

FDA. It's a side effect and we are saying the word "low." Lipid is a side effect too. I think we're characterizing what does the low impact mean. And we put all the data out for health care professional to understand and make their decision.

Q. Did you form the opinion, Dr. Patel, based on your time working at the FDA, based on your correspondence with the FDA, based on your understanding of the regulations and feedback from the FDA, that low impact on lipids was not a false and misleading message to provide to doctors?

A. Yes. I would say low impact on lipid was not a false, misleading message if it was presented with full context. That's very important in the distinction between -- because by itself, it could be false and misleading because you're not giving by regulation all the context to support the word what does low mean. Just like diarrhea example.

Q. And when you, Dr. Patel, and your colleagues at Janssen approved these pieces for the sales reps to use with doctors, did they provide that context that you were prescribing?

A. They were required by our company policy.

Q. And I had just started to show you before we started talking about the consumer piece the fact that you also provided the FDA with speaker decks; is that right, sir?

A. Yes.

Q. Okay. And this is an example, what's in evidence, 2084, as one of the speaker presentations that contains data on

lipids; is that right, sir?
A. Correct.
Q. Does it similarly contain in the notes statements like the one we just looked at, that Prezista had a low impact on lipids based on the 48-week data?
A. Correct. And if you could see below, it's a balancing of information that provides context.
Q. It provides the actual data to support that claim; is that right?
A. Yeah. And disclosing what the toxicity were observed. So we were very truthful in sharing everything we knew about the product.
Q. And based on your knowledge and your time at Janssen, did Janssen ever receive any feedback on these speaker decks about Prezista and Intelence like the one we're looking at in 2084?
A. No.
Q. Okay.

MS. BROWN: Your Honor, permission to admit D-2163?

THE COURT: Mr. Marketos.

MR. MARKETOS: Sorry, Your Honor.

No objection. Excuse me.

THE COURT: All right. No problem. So admitted.

(Exhibit D-2163 admitted into evidence.)

BY MS. BROWN:
Q. I want to show you -- we heard a little bit about another

term that was used in some of the materials, "proven lipid profile". Do you recall that, Dr. Patel?

A. I remember during the discussion today.

Q. Okay. And here it looks like this is 2010, and we're submitting ARTEMIS 96-week lipids piece, do you see that, sir?

A. Yes.

Q. And, again, this is a professional piece like the ones at issue in this lawsuit, correct?

A. Yes.

Q. All right. And, again, this is being submitted to the government under Form 2253?

A. Yes.

Q. All right. And your name, again, is down here as the responsible official or agent?

A. Yes.

Q. Okay. And does this refresh you, Dr. Patel, about information that was provided to the FDA pursuant to this process with the claim "proven lipid profile"?

A. Yes.

Q. Okay. Based on your review of this submission, does it contain the contextual information that you were just discussing?

A. Yes.

Q. How is that, sir?

A. Because we -- when somebody use the word "proven" the

regulation requires what is the supporting data to say you have proven. So, one, we had studied this drug for 96 weeks in a randomized controlled trial. So that's substantial evidence, first. And second is, we are clarifying what we mean by the findings that were observed on lipid parameters, which are disclosed in the chart in comparison to the compared drug. We also disclosed how they, based on NCEP cutoff, what does that mean? Because that is what the medical input was to -- this is how clinician will look at it, lipid, is how's average patient in the trial perform. Of course there's always an outlier and the outliers are explained on the right side, which is the table that shows how many patients at 96 weeks had incidents which are -- could be concern for a physician, and they should appropriately manage those patients.

Q. Okay. I want to show you one more on proven lipid profile.

MS. BROWN: Permission to admit D-2215?

MR. MARKETOS: No objection.

THE COURT: All right. So admitted.

(Exhibit D-2215 admitted into evidence.)

BY MS. BROWN:

Q. One more, Dr. Patel, on the proven lipid profile. Does this appear to be another submission to the FDA that, again, used the term "proven lipid profile" and provided the supporting data?

A. I don't recall this material. Can you share with me?
Q. Yes, sure. This may have been, Dr. Patel -- were you still in role in July 2011?
A. No.
Q. Are you generally familiar with the process that continued after you moved into the compliance role?
A. I know there was somebody else transitioning in my role. But the same process is that we submit on 2253. So I think this is a final form of the material.
Q. Okay. And in terms of the one we were looking at that you do remember, do you remember any feedback from the FDA enforcing or criticizing the term "proven lipid profile" as it was used in pieces with health care providers?
A. Since I was there 2015, never received any communication informing that this presentation is false and misleading or it minimizes the risk. And even today, before appearing in Court, I looked at their website, it's the same claim is still there.
Q. And we heard some other variations of these lipid terms. And what I wanted to ask you is based on your experience, do sales reps need to go into a physician's office and read word for word the package insert or every word that's on an approved promotional piece?
A. When I was in compliance role and when I did field rides, what I generally observed is the reps used this piece as educational tool. They do cover important context and safety

information during the call. I think there's -- they don't read word to word. They generalize, but their presentation is consistent with the message that were approved here. So they cannot change the claim and make the new claim on their own. So that was -- homemade materials or claims not approved by company cannot be used in promotional setting.

Q. Are sales reps, in your opinion, required to deliver messages that are consistent with company-approved messages and with the package insert?

A. That is our company policy, yes.

Q. And sales reps, though, are allowed to use their own words that are consistent with the data and with the approved message; is that fair?

A. Correct.

Q. Okay.

Dr. Patel, do you recall a time when we did actually get feedback from the FDA about a promotional piece that was used by mistake?

A. Yes.

Q. Tell us about that.

A. So during Subpart H review, if you guys are familiar with the Google search ads, if you type in a word, a product name, you get a display which allows you to click on a link to go to the website to get more information. So there is called a sponsor ad and then there is called organic. The sponsor ad is

what company sponsors. Organic is something Google searches on your website and just pulls it.

So during a review, we had reviewed two tabs. One tab, an Excel file, was related to reminder-type ads, which basically just say Prezista, doesn't say this is HIV product, it just say go to this website to learn more. That's it. There is no representation of a product.

A second tab was proposed by marketing team to doing claims such as Prezista is an HIV treatment, click here to learn more. And during our review, we did not approve that tab. So when we got FDA enforcement we did an investigation to look at the root cause, and we determined that the person who was responsible for that actually told agency to upload both tabs. So one tab was clearly approved by company, one was not approved through the promotional review committee.

So we submitted our findings to FDA. We definitely complied with FDA, we pulled those ads immediately because, A, they were not company-approved and they were violative so we took action immediately. And we put a process in place to make sure this never happens, that only company-approved materials are used.

Q. If I could just understand that then, Dr. Patel, it sounds like somebody at the company made a mistake and submitted an ad that hadn't been approved; is that right?

A. Correct.

Q. It was a consumer Google ad?
A. Yes.
Q. And within just a couple of months did we hear from the FDA?
A. Yes.
Q. And did the FDA catch the ad that we hadn't approved?
A. Correct.
Q. Did we take action?
A. Yes.
Q. What does that tell you about the FDA oversight when it comes to promotional materials?
A. Based on my experience, typically during Subpart H FDA is definitely looking at all the materials once they provide feedback to make sure you're incorporating the feedback. Because if you're not incorporating feedback, they will take an enforcement.

Same thing with the launch of new indication, six months to one year is typically the reviewers are very looking at all your data, documentation, because that's really what -- FDA just approved the drug. They want to make sure the drug is approved and presented in a proper balance. So FDA does review all the materials, and if they have issue, they would definitely take enforcement.

THE COURT: Ms. Brown, sorry, I don't want to switch topics, but are we at a place where we can take a short break?

MS. BROWN: Absolutely, yes.

THE COURT: If we're only going to do one break this afternoon, why don't we make it 15 minutes. Then we'll see if we can stretch until 5:00, and I'll let the jurors alert me if we need to do a second break, all right? So let's do that, let's get the jurors to stretch for 15 minutes.

THE DEPUTY CLERK: All rise.

(The jury exits the courtroom at 3:01 p.m.)

THE COURT: Dr. Patel, you can step out for 15 minutes if you want to stretch or whatever you want to do.

Everyone be seated.

Ms. Brown, how much longer?

MS. BROWN: Not that much longer. Maybe less than 15 minutes.

THE COURT: Then do you have some redirect, Mr. Marketos?

MR. MARKETOS: I will, Your Honor.

THE COURT: We will get to the next witness at least, correct?

MR. MARKETOS: I believe so.

THE COURT: All right. Real quick, any objection to me -- when we get to the next witness I just want to alert the jurors to one instruction that we have a witness who is testifying, you know, remotely, they're not to consider that any sort of way other than they should evaluate that testimony

no different than if the witness was sitting in the box. That's the only instruction I want to give just so they understand. Any objection to that instruction for the next witness?

MR. MARKETOS: No, Your Honor.

MS. BROWN: No objection.

THE COURT: Everybody's in recess.

(Recess taken from 3:02 p.m. to 3:14 p.m.)

THE COURT: Dr. Patel, do you mind coming back to the witness box since you're already in?

THE DEPUTY CLERK: Please rise.

(The jury enters the courtroom at 3:15 p.m.)

THE COURT: All right. Folks, everybody can have a seat.

Just a reminder for the jurors, tomorrow we are 12:30 to 5:00. I believe that's my understanding. So I just want to make sure counsel's aware of that too, that I may not be here at 8:30 a.m. tomorrow. So we'll talk later about what time maybe we should link up depending on whether there's any issues. But whatever they are, I want to make sure we're ready to go by 12:30. So even if we have to meet 11:00 or 11:30 just to ensure that we cover any administrative issues, I'm happy to do that. But I wanted the jurors now to be reminded because I might forget by the end of the day.

So, guys, if you're ready to go by 12:30, we're good

to go. But don't show up in the morning because I may sleep in, so that's where we are.

With that, Ms. Brown, if you want to continue your examination.

And, Dr. Patel, just remind you, you're still under oath from earlier.

MS. BROWN: Thank you very much, Your Honor.

BY MS. BROWN:

Q. Dr. Patel, I have less than ten minutes of questions left, so we'll just zip through this here.

MS. BROWN: Your Honor, without objection from counsel, I'll seek to admit D-4096, D-2078, and D-4232.

MR. MARKETOS: No objection.

THE COURT: All right. So that's admitted.

(Exhibits D-4096, D-2078, and D-4232 admitted into evidence.)

BY MS. BROWN:

Q. Dr. Patel, just for the record, sir, we have been looking at a number of 2253 submissions for Prezista messaging. Do you recall that?

A. Yes.

Q. And did we similarly submit to FDA, using the same process, promotional materials that we sought to use for Intelence messages?

A. Yes.

Q. And I'll just show an example here of an Intelence slide deck that was submitted by 2253.

And is this your name down here as well, sir?

A. Yes.

Q. And, similarly, for all of the promotional materials that were provided to sales reps during the relevant time period in this case, for Intelence, were they all reviewed internally?

A. Yes.

Q. Were they all provided to the FDA pursuant to 2253?

A. Yes.

Q. And did we ever receive an enforcement letter or action from the FDA that there was a problem with any of those promotional messages?

A. Not to my knowledge.

Q. During the entire time period that you worked on promotional pieces for Intelence and Prezista being submitted to the FDA pursuant to 2253, did the company receive an enforcement action for health care provider pieces?

A. Never.

Q. Final topic, Dr. Patel. I want to talk to you quickly about the Corporate Integrity Agreements that our jury has heard about.

Are you familiar with those, sir?

A. Yes.

Q. Did you have some involvement in the work Janssen did to

comply with its obligations under the Corporate Integrity Agreements?

A. Yes.

Q. Are you familiar with something called an IRO, or an independent review organization?

A. Yes.

Q. What is that?

A. When the companies settle, and we -- with OIG and we got a CIA, as part of the CIA settlement, OIG appointed an independent review organization which is outside of Janssen to oversee over our compliance program, how effective was the compliance program, and how effective we were doing the requirement that was stipulated, how we were implementing the requirements stipulated in the CIA. So that was the role of the IRO, to oversee the implementation of the CIA.

Q. And are you familiar with something called a RAMP?

A. Yes.

Q. What is that?

A. It's part of the Corporate Integrity Agreement, and when I was a compliance officer we had to develop a risk assessment mitigation plan, called RAMP. I can explain more.

Q. Yeah. Let me just ask you a couple questions. Then I'll give you the chance to explain.

The risk assessment mitigation plan you just discussed, was that something that was prepared for Prezista?

A. Yes.
Q. Was the risk assessment mitigation process something that was prepared for Intelence?
A. Yes.
Q. So it was a product-specific plan?
A. Yes.
Q. Was it reviewed by the IRO?
A. It was provided to IRO, yes.
Q. And tell us what it included.
A. So all the pharmaceutical products that we were responsible for, Janssen, each compliance officer had to work with the business partners to identify what are the potential activities that we might be engaging with, either promotional, health care professional through speaker program, or any activities that we think that might be a potential risk.

The word potential is we don't know there's a risk but there could be a risk, and what are the mitigation efforts that company has in place as of today, policy, training, oversight monitoring, and if there's something missing that is something we need to create new, then we work with the organization including sales and marketing and the president of the company, to implement the new requirements and capture that as part of the risk assessment mitigation plan.

So it's pretty comprehensive. Covers all the off-label, potential off-label use when we know that health care

professionals are allowed to use our product off label on their own. And if there's such a high use of it, we have to capture that because that's a potential exposure for the company and sales reps too, so how are we helping them to comply.

Q. And when you say mitigation, Dr. Patel, was part of this RAMP process that was reviewed by the independent organization, did it deal with our policies and procedures to make sure the sales force was in compliance with the regulations and the policies?

A. Yes.

Q. Did you interact with the IRO, the people from the independent company, to make sure that we were meeting our obligations under the CIA?

A. Yes, compliance officers were interviewed by IRO as part of the IRO activities.

Q. Did you ever receive feedback from the independent company, the IRO, that there was something wrong or deficient about the RAMP plans for Prezista or Intelence?

A. Not to my knowledge.

Q. Okay. Did you work with the IRO to make sure we met our obligations?

A. Yes.

Q. And based on the feedback you received from the folks at the IRO you were interacting with, was your understanding that our policies and procedures were meeting our requirements?

A. Correct.
Q. Finally, Dr. Patel, I heard you say there came a time that for personal reasons, you left Janssen; is that right?
A. Yes.
Q. Did you leave on good terms, sir?
A. Yes.
Q. Are you here today testifying?
A. Yes.
Q. And did you move out of the area for personal reasons?
A. Yes.
Q. Have you remained in the regulatory pharmaceutical industry?
A. Yes.

MS. BROWN: All right. Thank you very much for your time, Dr. Patel. I have no more questions.

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

Mr. Marketos, any redirect?

MR. MARKETOS: Yes, Your Honor. Thank you.

Make sure my mic is on. Excuse me.

REDIRECT EXAMINATION

BY MR. MARKETOS:

Q. Good afternoon, Dr. Patel.
A. Good afternoon.
Q. Sir, you told me on direct examination that you're not a medical doctor, right, sir?

A. Correct.
Q. You also said you're not a lawyer, right?
A. Correct.
Q. You -- you said you would have to seek legal advice even for an understanding of the application of the Anti-Kickback Statute.
Do you remember that testimony?
A. I have understanding -- I think your question was more about the potential topic could be violation of Anti-Kickback, so that's a different question.
Q. And you'd have to seek legal advice, legal counsel, is what you told us, right, to answer that?
A. To get their input, yes.
Q. And, in fact, with respect to whether or not cholesterol or lipids can lead to congestive heart failure, you told us you're not a medical doctor, that would be more medical advice, right, sir? Do you remember that?
A. Yes.
Q. Okay. But you just testified, as I understood it, about the differences under the laws and the regulations of the FDA as it relates to consumer and direct-to-physician advertising.
Do you recall that?
A. Yes.
Q. And you also were talking about how a doctor is more capable of interpreting information in an ad.

Do you remember that?

A. Yes.

Q. Sir, I want to make perfectly clear, I think -- I think it's your testimony that from Janssen's perspective and from your perspective, Janssen received approval from the FDA for these lipid messages because they didn't say anything about them?

A. Can you repeat that question again? Sorry.

Q. Yeah. Let's make sure I've got this right, okay?

It's my understanding that it's your testimony to the members of the jury that from your perspective and from Janssen's perspective, the FDA -- you actually said -- was it tacit approval or indirect approval? That's what it was. Indirectly approved were your words.

They indirectly approved of these ads by not sending an enforcement action; is that right?

A. That is correct.

Q. Just so we're all clear, you're saying that the Food & Drug Administration indirectly or tacitly approved of Janssen's lipid messaging for Prezista by not saying anything in writing?

A. They never took enforcement, correct.

Q. So you're saying that the FDA approved indirectly or tacitly of Janssen's messaging by not writing to Janssen and taking enforcement; is that right?

A. Correct.

Q. Okay. So they didn't do anything on specific promotional materials you sent, and Janssen took that as FDA approval; is that right?
A. That's my understanding, yes.
Q. All right. Just so we're clear, sir, you testified in response to my questions on direct that the FDA will only take official action in writing, correct?
A. Correct.
Q. And that's not just an opinion. That's not something you formed from your few months being at DDMAC 20-something years ago.
That's the regulation; that's the law, correct?
A. Correct.
Q. Okay. So it has to be in writing to be official. What the FDA can also do if you submit an ad is they can respond, and if they don't have an objection to your ad they could say no further comment, correct?
A. On a draft materials only.
Q. To be clear --
A. Yes.
Q. -- on a draft material only, just like the one we saw about low impact on cholesterol, if they don't have an objection to what is being submitted to the FDA, they can write back and say we have no objection at this time, correct?
A. I think your question is confusing me. Are you referring

to draft material or the final material?
Q. Once again, sir, the draft material. That was a draft material that was submitted to the FDA that led to a response from the FDA that you've called guidance that said low impact on cholesterol is misleading.
Recall that?
A. Yes, yes.
Q. What the FDA could do in a certain situation like that is respond and say no comment at this time?
A. That is accurate.
Q. What the FDA could also do is say that's false and misleading in writing, right, sir?
A. That is accurate.
Q. Or the FDA might not respond at all, correct?
A. It's -- no. Typically for Subpart H, FDA has to either respond to you, or we tell them we're not waiting for comments.
Q. Dr. Patel, I'm not asking about Subpart H. That's before you get label approval. I'm talking about April of 2009.
That's after Subpart H approval when this letter was received, right, sir?
A. That is incorrect. Label is approved during Subpart H also, so I'm not understanding your question. Sorry about that.
Q. Let me just make sure I frame it correctly, okay?
The FDA can take one of three courses of action in

response to a draft advertisement, okay? It can say this ad is bad or false in writing?

A. Sure. Yes, correct.

Q. It can say no comment at this time, correct?

A. Correct.

Q. The FDA can also not respond at all, correct?

A. That has not been my experience.

Q. Well, sir, in fact, with respect to DDMAC, you were there for, I think you told us, a few months right out of school, right?

A. Out of pharmacy school, yes.

Q. Yes, right before you went to work for Johnson & Johnson.

A. Correct.

Q. And that was 20-something years ago that you were there, right?

A. Yeah.

Q. For a few months, correct?

A. For nine months, yes.

Q. Okay. And you understand that the FDA receives a hundred thousand promotional materials submitted by pharmaceutical manufacturers every year?

A. Correct.

Q. And there are 40 employees, right?

A. Correct.

Q. An enforcement action is taken only if they catch you?

A. That is incorrect.
Q. Well, they have to catch you doing something. They have to have reviewed an ad, right, sir? They have to have reviewed it first in order the take an enforcement action, right?
A. When they review, they have concerns, they take enforcement.
Q. Yes, sir. One of those 40 employees has to catch a misleading or false statement in promotional materials in order to take an enforcement action.
That's the order of operations, right?
A. Yes.
Q. And it's your testimony that the FDA implicitly or tacitly or indirectly approved of ads that were sent -- marketing materials sent by Janssen because they didn't say anything; is that correct?
A. Can you repeat that again? Sorry.
Q. It's your testimony, with respect to promotional materials that Janssen did deliver to the Food & Drug Administration, that they tacitly or impliedly or indirectly approved of those ads because they didn't respond to them, correct?
A. Yes.
Q. So you have nothing in writing from the FDA with respect to these lipid profile messages that says no comment, true?
A. For health care professional materials, no, yes.
Q. For any materials.

You have nothing from the FDA in writing saying no comment at this time about lipid profile?
A. That's correct.
Q. You have nothing from the FDA other than a letter that was received in April of 2009 saying low impact on cholesterol is false and misleading, right?
A. Correct.
Q. But it's your testimony to the members of the jury nonetheless that Janssen considered its promotional materials to doctors to have been approved by the FDA because they didn't respond; is that right?
A. Can you repeat that question, because -- is it a yes-or-no question?
Q. I thought it was, sir. Let me ask it again.
It's your testimony to the members of the jury that Janssen believed the FDA had approved its promotional materials for Prezista with lipid profile messages delivered to doctors because the FDA didn't respond; is that true?
A. True.
Q. And you're aware of the fact that under the regulations and the guidance manuals, that the FDA will provide comments but only those in writing are considered official, right, sir?
A. That's correct.
Q. And that's been the rule. That's what they put in the letters to you. That's what's in the regulations, right?

A. That is correct.
Q. And if you thought -- I'm just wondering. If you thought that the FDA had approved of proven lipid profile or low impact on lipids by not responding to items that you sent to the 40 employees that were there, why were you so worried about this regulatory action against Roche?
A. That is our normal review. We ensure any enforcement FDA issues, we look at it to see how -- what the issues were identified, how is their presentation, is it similar or not, to understand that so we see if we were in the same boat, we know how to make changes.
Q. According to your testimony, sir, for four years, Janssen had been delivering messages to doctors from 2006 until 2010 that contained messages about lipid profiles, right, sir? Up until that Roche enforcement action, right? Hold on. I'm sorry. Let me make sure I frame this so we don't have to go off on a paragraph, okay?

It's your testimony, as I understand it, that between 2006 and 2010, Janssen had been delivering promotional materials to doctors about lipid profiles with Prezista; is that true?
A. Not true.
Q. It's not true that Janssen had its sales force delivering marketing messages to doctors from 2006 to 2010?
A. The claims were introduced in 2008, so not the 2006. We didn't have any claims on lipids during Subpart H review

because it was in a different study design.
Q. You're saying that there were no lipid messages delivered by the sales force between 2006 and 2008, for two years?
A. Correct.
Q. So I'm sorry, sir. I represent two sales representatives, two sales reps for Janssen that were on the ground from 2006 until 2008 and beyond.
You're telling us that those sales representatives didn't deliver messages to doctors about the lipid profile for Prezista?
A. They were never approved in promotion materials. All the materials, you can look at it, there was no discussion of lipids in those materials. Low impact on lipids was never approved until we got to the naïve indication.
Q. For two and a half years, if the sales representatives around the country were telling doctors that Prezista had a low impact on lipids or a minimal impact on lipids, that was not an approved message by Janssen?
A. To my knowledge, that was not approved until eight. We submitted on 2253 in eight, 2008, as we were looking at the materials.
Q. So the drug was launched in June of 2006, right, sir?
A. Correct.
Q. And for two and a half years, you're saying that there was no approved message that those sales representatives could

deliver to doctors?
A. Not to my knowledge. We approved any messages because the studies were different.
Q. So if any messages were being delivered by sales representatives for that two-and-a-half-year period, between 2006 when the drug launched and 2008, it's your testimony to this jury that those were all unapproved messages?
A. Those were not approved by me, and I have to look at the context of when you say lipid information, because there may be something in a PI that they might be referring to. So you have to look at the package insert to see what lipid information was included.
Q. For two and a half years, if sales representatives were saying low impact on lipids, minimal impact on the lipids, just like Reyataz, similar to Reyataz, those were all unapproved messages even by Janssen, according to you?
A. Correct.
Q. All right. What we do know is that if we wanted to look at a piece of paper that came from the FDA saying this lipid message is approved by the FDA, you don't have a piece of paper for us to look at?
A. No.
Q. You mentioned, sir -- I'm trying to follow it.
You mentioned that there was a different standard that is applied to consumers versus doctors, messages that are

delivered to all of us versus those that are delivered to doctors; is that right?

A. Correct.

Q. Except that that standard is not recognized in the law, as you testified in response to my questions.

Do you remember that?

A. I think I testified that laws are similar. It's just the way you communicate to health care professional versus consumer is different.

Q. The regulations that apply to promotional advertising for pharmaceutical companies are the same for consumers and doctors?

A. Yes.

Q. An advertisement that is misleading or false to a consumer, you're saying it is not misleading or false to a doctor?

A. Correct, depending on the context.

Q. So you testified about fair and balanced. I'm not asking about something that's fair and balanced. I'm asking about whether a message is true or false, okay?

Is it your testimony that a message that is false, when it's delivered to a consumer, like low impact on cholesterol, that message is true if it's delivered to a doctor?

A. If message is delivered with proper context, it's true.

Q. So something that is false could also be true?

A. Correct.
Q. I understood you to say, sir, that you were in Janssen's compliance department from 2010 forward doing something, but there was an IRO organization that was essentially babysitting your department; is that right?
A. I wouldn't describe it that way.
Q. Okay. I'll describe it differently. They were -- there was a compliance organization overseeing your compliance organization overseeing Janssen's sales force?
A. That was appointed by OIG so --
Q. Yes.
A. -- I cannot comment on why did they appoint it.
Q. The Corporate Integrity Agreement required oversight of Janssen for its lack of compliance, right?
A. That's not my understanding.
Q. Okay, sir. But if we were to look at -- we've seen a spreadsheet of the number of speaker events that compliance attended. If we were to show that spreadsheet to the jury and sort for the number of times that you attended a speaker event from 2010 until you left, how many speaker events do you think that would show?
A. I don't know the number, but we were assigned by our head of compliance across all Janssen pharmaceutical products how many per product. We have to do speaker or rep rides, field rides, to comply with the CIA requirements.

Q. You're talking about a number of events that Janssen, company-wide, different Janssen subsidiaries had to comply with in order to meet the requirements of a Corporate Integrity Agreement they had entered into with the federal government, right, sir?
A. Correct.
Q. That's not what I'm asking about. I'm asking about Dr. Amit Patel, okay?
You were in compliance for Janssen, as I understand it, a health care compliance officer from 2010 until 2015, correct?
A. Correct.
Q. You went to no speaker events during that time period?
A. I don't remember that because I had -- Catherine Kaucher was my -- reporting to me. She was primarily responsible for Prezista and Intelence.
Q. I'm going to ask this one more time, sir.
You, Mr. Patel, attended zero --
A. Okay.
Q. -- zero speaker events between 2010 and when you left for Prezista and Intelence; is that true?
A. I have to look at the data to confirm that's accurate.
Q. Have you looked at it before today?
A. No.
Q. Have you tried to determine how many speaker events -- you testified to the members of the jury in response to questions

from counsel for Janssen and your counsel that you attended speaker events. I thought I heard that.

A. Yes.

Q. But you don't know if you attended any for Prezista and Intelence?

A. It's been over how many years? So to know the actual number, I don't know that. I don't recall that.

Q. Yes, sir. But Janssen has the data. It's in evidence in this case. There's a spreadsheet.

A. Okay.

Q. Have you looked at it to see if you went to a single event for Prezista or Intelence to determine whether they were compliant?

A. I have not looked at that spreadsheet.

Q. Do you have any recollection of going to one?

A. I did speaker program evaluation for Janssen CNS products psychiatry or Prezista/Intelence. I don't have that information.

Q. Okay. Dr. Patel, I'm trying to be fair here. Let me just frame it this way.

Do you recall going to one single speaker event for Prezista or Intelence on the promotional speaker bureau?

A. Yes.

Q. You recall going to one now?

A. I mean, at least one, yeah.

Q. You do recall going to a speaker event?
A. Yes. You're asking me just do I recall going ever, yes.
Q. You do recall going more than zero times?
A. More than zero times, yes.
Q. Was it less than five?
A. I don't know that.
Q. Somewhere between five and zero?
A. I don't know the answer.
Q. Okay. There were almost 9,000 speaker events for Prezista an Intelence that were held during this time period, 2006 to 2014.

Do you understand that?

A. Okay. Yes.
Q. Do you know that to be true? Sir, I represent the Relators in this case. I'm counsel for the Relators.

You were the head compliance officer for Janssen from 2010 to 2014, right?

A. I think you keep referring to me as head. I was not the head of compliance there. So, I'm sorry, I cannot answer your questions.
Q. Okay. You were the compliance officer for Janssen, for this unit of Janssen, for that specific time period, correct?
A. Catherine Kaucher was the compliance officer for Janssen/Tibotec Therapeutics, and I was compliance officer for Janssen CNS, which is separate from the HIV portfolio. Now,

she reported to me. That was my relationship. I had oversight management responsibility.

Q. So you were actually the compliance officer for a different company than the one that we're here talking about?

A. I had both responsibilities. She was reporting to me so I had understanding of what the Janssen/Tibotec Therapeutics compliance issues were.

Q. So Catherine Kaucher was reporting to you?

A. Yes.

Q. You were her boss?

A. Yes.

Q. So you had oversight of the compliance for this organization, Janssen/Tibotec?

A. Yes.

Q. So it's fair for me to ask you if you ever went to an event for Prezista or Intelence; is that fair?

A. Yes, fair.

Q. But you don't recall how many you went to?

A. I don't know the actual number.

Q. Sir, you were making some -- you had some discussions about the FDA taking enforcement actions, do you recall that?

A. Yes.

Q. Actually, what Johnson & Johnson teaches all of its subsidiaries, and what Janssen teaches all of its employees is, if there's off-label promotion that the FDA doesn't catch, the

False Claims Act is a mechanism of enforcement. You understand that, right?

A. I don't understand this. Sorry. Can you repeat again or clarify?

Q. Yes, sir.

Enforcement actions taken by the government, taken by whistleblowers on behalf of the government under the False Claims Act, is the primary mechanism for enforcing off-label promotion by pharmaceutical companies. Are you aware of that?

A. That's not entirely accurate.

Q. Okay. Are you aware of the fact that a case like this brought by whistleblowers on behalf of the government is a mechanism of enforcing off-label promotion under the False Claims Act?

A. To my knowledge, that's one way, yes.

Q. Mr. Patel, last question for the day, sir. Are you able to testify on behalf of Janssen as to the safety of Prezista and Intelence as they were marketed and promoted by the sales representatives to doctors around the country?

A. I don't understand your question. What do I testify for?

Q. Yes, sir. Are you familiar yourself, sir, can you testify that the products that Janssen delivered to doctors to prescribe to their patients were safe for their hearts?

A. I don't think I'm qualified to answer that question about unapproved use because Prezista was never approved to treat

heart conditions.
Q. I understand it wasn't approved to treat heart conditions, Dr. Patel. It had side effects that could affect those heart conditions. You understand that, right?
A. Okay.
Q. Do you understand that, sir?
A. Yes.
Q. You're not testifying to the jury that those side effects couldn't have caused problems for patients, are you?
A. As I said, that's more of a medical expertise required to understand patient situation to see if it will or will not.
Q. That would require a medical doctor's opinion?
A. Yes.

MR. MARKETOS: No further questions. Thank you.

THE COURT: All right. Thank you, Mr. Marketos.

Dr. Patel, you're excused from the trial. Thank you.

THE WITNESS: Okay. Thank you.

(Witness excused.)

THE COURT: Before the next witness, Counsel, can I see you for one moment, folks, just before we call the next witness?

(Sidebar discussion as follows:)

THE COURT: Remind me, this is your witness?

MS. BROWN: Yes, Your Honor.

THE COURT: I should also allow them to know that,

look, the defense is calling a witness out of order, I permitted that for witness availability issues. And he'll also testify remotely. Then I'm going to say that they're not to consider any of that other than they should evaluate this witness as if the witness is testifying in the courtroom. I think that's the only fair instruction to give. But I also want them to understand that this is not Relators' witness. And that you're directing now, and they're on cross. And this is just being done because I made a determination to do that. Does that make sense?

MS. BROWN: It does.

MR. MARKETOS: That's fine, Your Honor.

THE COURT: Yeah, just so they have a sense.

MS. BROWN: Appreciate it. Thank you, Your Honor.

(End of sidebar discussion.)

THE COURT: Folks, just briefly on the next witness. So the next witness is actually being called by the defense out of order. And, well, there's two issues, one is, I'm allowing this witness to be called out of order because the witness has an availability issue for when Janssen is calling their witnesses. So I'm going to allow them to call this one witness ahead of time in the Relators' case, but also I'm permitting this witness to testify remotely by video. You are not to consider that in any way really whatsoever other than you should evaluate this witness's testimony as if the witness is

testifying in the witness box. So you should just consider all the same factors that you would evaluate any witness that's been testifying before you, but it's going to be done by video.

The only other thing is logistically this is a defense witness being called early because there was an availability issue and I made a determination to allow this one witness to come early to testify.

So I just wanted to make sure you understand that we're switching roles a bit. Janssen's counsel is going to be doing direct examination of this witness. Relators' counsel is going to be cross-examining. And Ms. Brown will be doing the redirect. So we're reversing it. It's only for this one witness. And then we go back into the regular course and the Relators continue to present their case.

With that, Ms. Brown, do you want to call this next witness?

MS. BROWN: We do. Thank you very much, Your Honor. We call via video Dr. Ricky Hsu.

THE DEPUTY CLERK: Good afternoon, sir, can you hear me?

THE WITNESS: Yes, I can.

(Witness sworn.)

THE DEPUTY CLERK: Please state your name for the record.

THE WITNESS: Ricky Hsu.

MS. BROWN: May I proceed, Your Honor?

THE COURT: You may, Ms. Brown.

DIRECT EXAMINATION

BY MS. BROWN:

Q. Dr. Hsu, good afternoon. My name is Alli Brown. I'm a lawyer for Janssen. Can you hear me, sir?

A. Yes.

Q. Okay. Do we need to turn up the volume or you're okay proceeding?

A. If you could turn up the volume a tiny bit, that would be very helpful.

Q. Dr. Hsu, I'm just going to switch to this microphone, is that better?

A. It's much better. Thank you.

Q. Sure, no problem. Let me just bring my stuff over.

MS. BROWN: And then, Your Honor, may I proceed?

THE COURT: You may.

BY MS. BROWN:

Q. Okay. Dr. Hsu, I think we're ready to go. Everything okay on your end?

A. Yes, it is.

Q. Okay. Sir, would you introduce yourself to our jurors, tell them who you are and what you do?

A. Sure. So as you know, my name is Ricky Hsu. I am an internal medicine physician. Been in practice in the field of

internal medicine with an emphasis in HIV medicine for the last 26 or so years. My current role is the national medical director for the AIDS Health Care Foundation.

Q. Dr. Hsu, what is the AIDS Health Care Foundation, sir?

A. The AIDS health care foundation is actually the largest provider of HIV care in the world. We're in over 40 countries and take care of about 1.3 million people affected by HIV. In the US we have roughly 50, 60 clinics that take care of about 60,000 people with HIV.

Q. And can you tell us a little bit about what you do as the medical director for the AIDS Health Care Foundation?

A. Sure. So I am responsible for establishing the clinical standards for all of the doctors, nurse practitioners and PAs in the organization. I also develop some policy regarding a variety of different disease states. And involved in education.

Q. Okay. Do you treat patients, Dr. Hsu?

A. Yes. Actually, 70 percent of my time is in direct patient care. About 20 percent is administrative. And 5 percent in clinical research.

Q. Okay. And, sir, can you tell us just a little bit about where you went to medical school and how you decided to get involved in the field of HIV care and treatment?

A. Yes. So I did go to Harvard. And I initially was going to pursue a potential MD Ph.D. program because my undergraduate

work as well as my after undergraduate work was in actually basic -- what you call basic science, and it was always in the infectious disease space, microbiology, HIV, and immunology.

And after my second year of medical school there was clinical. I decided to abandon the Ph.D. portion and concentrate on the MD portion because I really enjoyed patient care and direct patient interaction.

In terms of HIV itself, as I mentioned, from a research standpoint I was always interested in infectious disease area and I've worked with people like Tony Fauci in his lab for HIV, but personally this was coming around at a time in the, you know, early '90s where basically HIV was still a death sentence at that point, and there were not very many, I guess, options for a number of our patients. And I had -- I, myself, being a gay male, had a number of friends and very close people that were affected by HIV and who passed away from the illness itself.

Q. Fair to say, sir, it's an area of care that is important to you both personally and professionally?

A. I would definitely say so, yes.

Q. All right. And have you devoted now more than 20 years of your professional life to treating patients in this area?

A. Yes. My training and residency, many fellowships and current practice have all been in this area.

Q. And you mentioned working with Dr. Fauci, was that work

that you did as part of a government laboratory or where did you work with Dr. Fauci?

A. Yes, I worked in his lab -- NIH lab doing HIV research.

Q. And that's the National Institutes of Health, Dr. Hsu?

A. That's correct.

Q. Do you also currently hold a teaching position at NYU, sir?

A. Yes, I do.

Q. And what do you teach there?

A. So general internal medicine and primary health care. So we do have medical students. We also really invite any residents who would like to come in and rotate through our office. But we also let them know if anyone has any particular interest in LGBTQ care or HIV care, that our facility is more than happy to teach the students.

Q. Sir, have you published in the scientific literature about issues regarding HIV?

A. Yes, I have, probably over 50 papers or so in the area.

Q. And have you similarly lectured to other doctors at conferences and other professional events regarding your experience and knowledge in the area of HIV?

A. Yes. I do attend most of the national and international HIV conferences and have lectured in multiple conferences as well.

Q. And, Dr. Hsu, final background question, and I don't mean

to embarrass you, sir, but have you been recognized with awards and recognition for your work in the area of HIV?

A. Yes, I have. I've gotten a few honors and currently help evaluate and review journal articles for a number of potential publications in the field.

Q. Dr. Hsu, the reason we asked you to come testify here in this case, do you understand that this is a lawsuit being brought by sales representatives who worked at Janssen, and the time period at issue is about 2006 to 2014?

A. Okay. Yes, I do.

Q. And there are claims being made in this case, Dr. Hsu, about Janssen's speaker bureau and about claims that sales reps were making off-label promotion claims to doctors like you. Do you understand that, sir?

A. Okay. Yes, I do understand that.

Q. Okay. And I want to start by talking with you first about Janssen's speaker bureau, okay, sir?

A. Sure.

Q. You, Dr. Hsu, were a member of Janssen's speaker bureau for a period of time; is that correct?

A. That's correct.

Q. Okay. And was Janssen the only company for whom you served on a speaker bureau?

A. No. I actually served in all the speaker bureaus for all the companies. I think the number of patients I see gave me a

broad exposure to a number of different drugs, and I think a lot of the speaker bureaus are -- speakers are chosen in a speaker bureau because of their ability to convey information in a short and concise and understandable way to providers. So I also spoke for Glaxo ViiV, Merck, Abbott, and Bristol-Myers, Gilead and Serono and Thera.

Q. Dr. Hsu, why did you make the decision to serve on the speaker board of Janssen as well as some of these other companies?

A. So a few things. I mean, I think one of the things I really do enjoy and I actually find it not, shall I say -- I would judge for myself. It would not be a good program if I present a program and people don't go home with some type of learning point that they gained from me. So I do like, obviously, eduction -- it's my current role -- and I do like providing education to others.

I have to say, being part of the different speaker bureaus also really forces you to be up to date with the latest data for almost all of the products that are out there, including those products in development. So having that knowledge, also just kind of, I would say, kept me on my toes in terms of just my understanding of HIV and its multiple aspects of use.

Q. It sounds like, Dr. Hsu, it was both a benefit for you professionally, but you also hoped to educate some of your colleagues; is that right?

A. Absolutely.
Q. Okay.
A. And I won't be mistaken about it. You know, it's also nice, of course, getting compensation for the work, but it is hard work that you spend a lot of hours, you know, plodding through slides and trying to get them ready for hopefully an interesting discussion at the lecture.
Q. And we heard, Dr. Hsu, that some of the speaker programs lasted a couple of hours. Is that consistent with the programs that you did, sir?
A. Yes. So oftentimes, especially the dinner programs, do last a couple hours. Most of the times the slides themselves roughly would be 45 minutes and you always want to leave at least 15 minutes for questions. But usually, as questions went on, sometimes we'd extend to two hours if people were interested in the topic area.
Q. Dr. Hsu, do you have to spend time preparing to give your presentation at these events?
A. Absolutely. You know, I mean, I think a good amount of time oftentimes was utilized on personal hours after general work where we would -- you know, where I would go through the slides, try and really understand them, try and figure out how to present it in a manner that could be clinically useful for a provider and to also understand the competitive landscape should that information get brought up.

Q. Do you recall, Dr. Hsu, signing a speaker contract with Janssen prior to your engagement on the speaker program?
A. Yes. Every year we are required to sign a speaker contract.
Q. Okay. And I'm going to move that into evidence right now, sir. And I'm going to try to do it without slowing us down here. Just a minute.
MS. BROWN: Your Honor, counsel indicated no objection to D-4187.
MR. MARKETOS: No objection, Your Honor.
THE COURT: So admitted.
(Exhibit D-4187 admitted into evidence.)
BY MS. BROWN:
Q. And, Dr. Hsu, I have what we've admitted into evidence now as one of the contracts that you signed with Janssen. I understand you would have done this every year, sir, is that about right?
A. That's correct.
Q. And one of the things you agreed to in the contract was to undergo speaker training, is that accurate?
A. Yes, every year there was a speaker training.
Q. Yes. And you also agreed, sir, that you would be of course compensated for your time preparing and presenting, correct, sir?
A. Yes, that is correct.

Q. And did you understand and agree that that compensation would be set at fair market value?
A. Yes.
Q. And did you understand and agree in the contract that that compensation was not meant to obligate you, sir, to use our medicines?
A. Absolutely. I actually would not. There was actually a situation where there was one company that I did speak with that actually broached that topic area and actually asked and told me that I was part of the speaker bureau, however, my prescriptions were not on par with the usual speakers on the speaker bureau. And I actually found that extraordinarily offensive and did report that to the company's manager. That was not Janssen. Different company.
Q. I understand, sir. You're telling a story about another company's speaker bureau; is that right?
A. That is correct.
Q. And you understood that company to be suggesting that your participation in their speaker bureau was tied to how much you prescribed of their drug?
A. Yes. And pretty much all the other companies have not tied speaking to prescriptions. It was just this one company that I was rather shocked that they actually brought it up.
Q. And did you say you reported that, sir, to the company?
A. Yes, I did.

Q. Did you ever have that experience with Janssen?
A. I did not.
Q. Okay. Would you have continued to serve on Janssen's speaker bureau if you believed your participation was dependent on how much of Prezista or Intelence you were prescribing?
A. If it was dependent, I would have severe reservations in being part of the speaker bureau. I would try and discuss this with whoever is making that comment, and if that was definitively the case, I would probably feel it went beyond my line of ethics.
Q. Do you understand, sir, that the allegations in this case are that Janssen paid speakers like you to prescribe more Prezista and Intelence?
A. I am not aware and have not ever experienced feeling any pressure to prescribe a particular drug to be part of the speaker bureau. Except for that one company I mentioned.
Q. Do you understand, sir, that the amount of money Janssen compensated you was set at fair market value pursuant to the contract that you signed?
A. Yes, I am.
Q. And do you understand that pursuant to the open payment regulations, that payment was made public on a website that anybody could access?
A. Yes, I am. I am aware of it.
Q. Okay. Did you agree, sir, in the contract that you signed

with Janssen, to present information at these speaker events that was consistent with the approved slide decks the company provided?

A. Yes, that is part of the training that Janssen provided and so that is what we indeed followed.

Q. Did you understand you had the ability, if someone asked you a question outside of that slide deck, to answer it, but then you had to return to the approved slide deck?

A. Yes, I am aware of this.

Q. And based on those speaking engagements that you did for Janssen, did you follow those policies?

A. Yes. I think a lot of providers naturally I think, people in the field of HIV generally are pretty passionate about figuring out what the optimal drugs are for the patients to help them adhere and maintain their drug therapies. So in the early years, even up to the early 2000s, in this period came about there were a lot of, I guess, innovative or off-label methodologies of treatment that would naturally come up in discussion because of, you know, what was presented at the conferences. The conferences -- at every conference there was something pretty significant or new or interesting that came about. So these topic areas did oftentimes come up. I, like we were trained, would state that this is an off-label issue. It's an off-label indication for the drug. Making that quite clear. Address the question with whatever data or experience

we had, and then return to the original slide deck.
Q. Were you, Dr. Hsu, visited in your office or at your institution by Janssen sales reps regarding Prezista and Intelence?
A. Yes.
Q. And do you understand the claims in this lawsuit are that our sales reps, when they visited doctors, including you, promoted those medicines off-label? Do you understand that, sir?
A. That's the claims in this lawsuit.
Q. Yes, sir.
A. That's what I understand.
Q. Yes. Do you, based on your memory and your experience, believe that Janssen sales reps came to your office and promoted Prezista and Intelence to you off-label?
A. I do not think so. They were -- I think the sales reps have been very good in discussing just on-label information. What the provider talks about in his or her office on their own is up to that provider. And so if the provider brings up off-label information, they, you know, would just ask that provider's experience and why they would not actually promote it themselves.
Q. Did you recall receiving visits from a Janssen sales rep named Nancy Bartnett?
A. Yes, absolutely. Nancy, honestly, is one of, in my

opinion, this one provider's opinion, an extraordinarily bright representative who knew the information regarding her drug as well as multiple other competitor's drugs and some of the latest data at the conferences better than a lot of providers knew information.

Q. What about a Janssen sales rep named Tim Mcsherry, do you recall receiving visits from him?

A. Yes. Also extremely nice. And, yes, we did get along.

Q. And in terms of any Janssen sales rep that visited your office, do you recall them promoting Prezista and Intelence to you for use in off-label ways that were not indicated in the label?

A. The Janssen representatives themselves did not promote that. They may have asked me how I utilized it and how I felt the drugs were useful and I may have volunteered on my own off-label information. But I usually do say, you know, in my own office that I know this is off-label, but this is why I think this is supported based on so and so study.

Q. Do you, Dr. Hsu, and did you during the time period in this case make decisions in your own medical judgment to use Prezista or Intelence in an off-label manner for your patients?

A. Yes. On my own clinical judgment, I did use Prezista and Intelence in an off-label manner.

Q. And why would you, as an HIV expert and doctor, why would you make that decision, sir?

A. So I think it's really mainly because of what we've learned from other drugs that have been in development. For example, one of the reasons why I use a good amount of Prezista is because, unlike many providers, a lot of my patients have been with me 25 -- some 20, 25 years from the beginning, and they've gone through a number of different medicines and have become resistant to them so have few options. And it's a protease inhibitor that is utilized for those patients who have a good amount of resistance.

Kaletra is a protease inhibitor that was the first protease inhibitor that really showed that a protease inhibitor that's very potent could still be utilized in a patient who wasn't so good at adherence, yet not have resistance be developed. And Kaletra was approved, I think, around 2000 or so, first for highly experienced patients, and then a few years later it was approved once a day for first-line therapy for treatment-naïve patients.

Very similarly, Prezista was compared to Kaletra and it showed the same results, if not even superior results to Kaletra, and also similar showed extraordinarily good efficacy in experienced patients. And having that ability potentially to use in naïve patients did indeed make sense because naïve patients are generally much more easy to treat than experienced patients.

And regarding the use of Prezista occasionally in naïve

patients to help preserve treatment options was off-label early on, 2006 when I think Prezista got approved, later it was approved in that indication. But I did consider using it earlier on in that manner before it got officially approved.

Q. Dr. Hsu, would you ever allow a sales rep's promotional message to hijack or override your independent medical judgment about what's best for your patients?

A. No, I wouldn't. I would definitely not feel comfortable and would not want that person in the office if they couldn't at least understand or listen to some things I was saying to influence and unfairly try to pressure me to practice a certain way.

Q. If sales reps from Janssen were in your office regularly promoting Prezista and Intelence off label, would you report that to the company or to somebody?

A. If they actively promoted it without someone bringing it up, yes, I would potentially do that.

Q. Do you recall a Janssen sales rep named Jessica Penelow?

A. I knew Jessica with a different last name.

Q. Jessica Finkelstein?

A. Yes, I knew her as Jessica Finkelstein.

Q. Okay. And similarly, sir, do you have any memory of Ms. Finkelstein, now Ms. Penelow, coming into your office and promoting these medicines for Janssen in an off-label way?

A. No, she did not come to my office and promote these

medicines in an off-label way.

Q. Just a few final questions, sir.

One issue that has been a big topic for us in this trial is lipids as they relate to the use of protease inhibitors.

Is that a topic you generally have some knowledge about, sir?

A. Yes, I do.

Q. Do you, Dr. Hsu, as an expert in the area of HIV, understand that all protease inhibitors can have an impact on lipids?

A. Yes, yes, I do.

Q. How did you, Dr. Hsu, view Prezista's lipid profile in your medical view?

MR. MARKETOS: I'm sorry, Your Honor, objection.

THE COURT: Sidebar.

MS. BROWN: I'll withdraw.

THE COURT: No, I need to see you guys anyway.

MS. BROWN: Dr. Hsu, we just have to run up and speak to the judge. We'll be right back.

THE COURT: They can walk. They don't have to run. Don't give the doctor the wrong impression about judges.

(Sidebar discussion as follows:)

THE COURT: Just remind me, though, is he testifying as an expert?

MS. BROWN: No, he's testifying as a doctor who may

--

THE COURT: But you're saying in your questioning "as an expert in HIV." It sounds like he's testifying as an expert witness in the case. I thought he was a fact witness.

MS. BROWN: I apologize. He is a fact witness, Your Honor. I meant just because he has such impressive credentials, but I'll rephrase.

THE COURT: Credentials is one thing, but he's not an expert. So you're going to have to clarify that.

MS. BROWN: I will do that.

MR. MARKETOS: He's not disclosed as an expert.

MS. BROWN: I can rephrase the questions.

THE COURT: Guys, slow down.

MR. MARKETOS: I want to be clear, Your Honor. She's trying to elicit an opinion about a lipid profile from him as a medical doctor. She's trying to get an expert opinion in. That's not allowed.

THE COURT: Let me hear from you, Ms. Brown, because it sounds like that's exactly what you were doing.

MS. BROWN: Not meaning to do that, Your Honor. I will rephrase the question and make clear --

THE COURT: What is the question?

MS. BROWN: That he had an independent understanding in his medical judgment of the medicines he was prescribing and their lipid profiles. That's it.

THE COURT: Is he going to go into lipid-friendly is not off label and this is --

MS. BROWN: No, no. I just am establishing that doctors like him who treat these patients understand generally the lipid profile of this class of medicines. They have independent knowledge that every medicine in this class can raise lipids.

THE COURT: And that's it?

MS. BROWN: Yes, sir.

THE COURT: And you're going to also fix the expert issue.

MS. BROWN: Right now.

THE COURT: So your objection is sustained, but you're going to clear it up. Okay.

(End of sidebar discussion.)

BY MS. BROWN:

Q. We're back, Dr. Hsu. One thing I want to make clear. I was calling you an HIV expert, but to be clear, you're participating here not as a, quote, expert witness for Janssen. You are a fact witness, and you were on our speaker bureau.

Do you understand that, sir?

A. I do understand that.

Q. Okay. And when we left off, sir, we were talking about physicians' knowledge generally about protease inhibitors and their lipid profiles.

Do you remember that, sir?

A. Yes.

Q. And is that -- I apologize, sir. Go ahead. Let me just rephrase the question to make sure I keep us on track.

Is that something, sir, when you make a prescribing decision, you consider your independent medical knowledge and experience when prescribing medicines in that class?

A. Yes. So prescribing protease inhibitors, always, you know, there are advantages and disadvantages with each and every drug that's out there for HIV, similarly to other non-HIV drugs. But with the protease inhibitors, a number of them have caused some elevations in lipids, both in total cholesterol, triglycerides, and the LDL, bad cholesterol.

In comparison to some of the earlier protease inhibitors like Kaletra and Crixivan, there seems to definitely be some advantage of Prezista very similar to one of the, what we call, second generation protease inhibitors called Reyataz, where both of them had more favorable lipids than the first generation of protease inhibitors; however, it still causes mild elevations in lipids.

Q. Finally, Dr. Hsu, just from your point of view, sir, as a doctor who was visited by Janssen sales reps, based on your experience, did the Janssen sales reps who visited you promote these two medicines, Prezista and Intelence, to you affirmatively off-label?

A. No, they did not, not that I recall at all.
Q. Finally, sir, based on your participation in Janssen's speaker bureau, were you of the understanding that Janssen was paying you to increase your prescriptions of Prezista and Intelence?
A. I was and am not at all aware that my being involved with the speaker bureau had anything to do with my prescription volume.

MS. BROWN: Dr. Hsu, thank you very much for your time. I'm going to sit down, and the lawyer for the other side will come up.

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

MS. BROWN: Thank you.

THE COURT: Mr. Marketos.

MR. MARKETOS: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. MARKETOS:

Q. Dr. Hsu, good afternoon, sir.
A. Good afternoon.
Q. My name is Pete Marketos. I represent the Relators, Jessica Penelow and Christine Brancaccio. You understand that they were representatives for Janssen during the time period from 2006 to 2014? Were you aware of that?
A. Okay. I knew they were part of the Janssen sales force. I don't recall the time period.

Q. Thank you, Dr. Hsu.

And you actually, as I understand it from your testimony, you recall Ms. Jessica Penelow, but you knew her as Ms. Finkelstein; is that right?

A. That is correct.

Q. And, sir, I never have had a chance to speak with you.

You've had a chance to speak with Janssen's lawyers about this case; is that right?

A. That is correct.

Q. Okay, sir. And did Janssen's lawyers tell you what this case is about, Dr. Hsu?

A. Yes, they did.

Q. Okay. Dr. Hsu, were you aware of the fact that Janssen's promotional speaker bureau during the time period from 2006 to 2014 held almost 9,000 speaking events?

A. No, I'm not aware of that.

Q. Were you aware, Dr. Hsu, that during that time period, Janssen paid more than 335 different doctors to give speeches on that promotional speaker bureau?

A. No, I'm not aware of marketing practices. I would expect that to be fairly similar to other companies.

Q. You would? You would expect other companies to have held almost 9,000 programs during that same time period?

A. I would think so.

Q. Okay, sir.

A. Just a guess.
Q. I understand, sir.
You mentioned, Dr. Hsu, that you had one experience with another company, and you found it offensive because that company was suggesting that your participation on the bureau was tied to your prescriptions.
Do you recall that testimony?
A. Yes. Yes, I do.
Q. Now, I understand that you, sir, would sign a contract on an annual basis to speak with a number of companies, and Janssen was one of them, correct?
A. That is correct.
Q. And at the end of each year, you would then sign another contract, including nine years in a row for Janssen, correct?
A. Correct.
Q. And that was, of course, for both Prezista and Intelence?
A. For myself -- I don't recall exactly when we started talking about Intelence, the exact time period, but I did sign yearly contracts to speak on behalf of both.
Q. Understood, Doctor.
And like you said, it's nice money; is that fair?
A. Yes.
Q. And to be clear, sir, Janssen paid you, in cash money in the form of checks $300,000 during that time period, right, sir?

A. In nine years, yes, I guess so. I'm not aware of how much they paid me absolutely.
Q. Well, Janssen has continued to pay you, sir, money over the last eight years as well, which is available under the Sunshine Act, correct?
A. That is correct.
Q. And since 2016, Janssen has paid you an additional $300,000; is that right?
A. If that's what the Sunshine Act states, that's correct. I did not look at the reports myself.
Q. All right, sir. And to be clear, that's separate and apart from the amount of money that you get paid to be on a speaker bureau. Janssen has paid you for items of, like, consulting fees and other source of payments not related to a promotional speaker bureau, correct?
A. Yes. That does include research, and I am part of the Janssen's presidential advisory board while Janssen had that process. So they had selected -- they select about ten, I guess, influential providers in the area to help them understand their medicines, to help guide their research, and to actually help do the research.
Q. Yes, sir. So Janssen has paid you to be on advisory boards, correct?
A. Yes, and research as well.
Q. And I'll go through them one by one if you bear with me,

Doctor.

They paid you to be on advisory boards, correct?

A. Yes.

Q. They've paid you for research, correct?

A. That's correct.

Q. They've paid you for consulting, correct?

A. I think that is part of the advisory boards, but maybe it might be separate.

Q. Is the amount of money that you have received directly from Janssen, sir, over $1 million?

A. I do not think so.

Q. All right. Somewhere between 600,000 and a million; is that right?

A. I would be a little surprised, but possibly. I think a lot of that money also is reimbursement for all of the expenses of, you know, hotels, flights --

Q. Yes, sir.

A. -- car services.

Q. I'm sorry. I don't mean to speak over you, sir. I just want the jurors to understand.

You get paid money directly from Janssen in the form of honoraria is what they call it? That's --

A. Yes.

Q. -- checks directly to you for speaking, right?

A. That's correct.

Q. And those amounts have totaled more than $300,000.
Do you agree?
A. In nine years, possibly, yes. I'm not keeping track of it.
Q. And since, right, sir? It wasn't just for that nine-year time period.
You've been paid by Janssen several hundred thousand dollars since 2014, correct?
A. If that's what your records do show, that is correct.
Q. And I don't want to misrepresent anything, sir. I'd like to know if you're aware of the fact that the Janssen that is in this courtroom has paid you more than $300,000 since 2014?
A. Since 2014?
Q. Yes, Dr. Hsu.
A. As honoraria, I do not think that's correct.
Q. In any form or fashion since 2014, sir, they have paid you more than $300,000, correct?
A. I do not think it was honoraria for speaking, and I think they gave me, I'm guessing, for research. We don't -- you know, all the research funds just go back into our company, the health care foundation company. So I don't know. And I also thought this case was about the years 2008 to 2014.
Q. Yes, doctor.
A. I'm just curious why we're talking about beyond 2014.
Q. I was just wondering if Janssen was paying you today, sir,

if you're receiving checks from Janssen even today.
A. I am not being paid by Janssen. Janssen disbanded their HIV group, including all of their promotional talks, their research, as well as their advisory boards, roughly two years ago.
Q. Thank you, Dr. Hsu. I appreciate that. It's important that we know. One of the reasons, Dr. Hsu, that you found it offensive that one company had tied your speaking and getting paid to speak on a bureau to their prescriptions was because that's unethical.
Would you agree?
A. I would say so, yes.
Q. It's unethical because if somebody is -- if a company, a pharmaceutical company is paying a doctor to speak on a speaker bureau and they tie those payments to the level of prescriptions for that doctor, it seems like a kickback.
Do you agree?
A. I would agree with that, yes.
Q. Are you aware of the fact, Dr. Hsu, that Janssen was tracking your prescriptions after it paid you to be on the promotional speaker bureau for Prezista and Intelence?
A. I do -- I am aware that all pharmaceutical companies track doctors' prescriptions. I can't remember the name of the program, but there is a program where all pharmaceutical company representatives do know -- actually, I think Viiv

stopped that process maybe ten years ago where the reps are not aware of prescription practices of the provider, but for all other companies, they do do that. I am aware of that. Yes.

Q. I'm sorry, Dr. Hsu. Let me take it back to Janssen for the time being.

Are you aware of the fact that Janssen the company was tracking your prescriptions for Prezista and Intelence after it started paying you to be a speaker?

A. I think that like all other pharmaceutical companies, whether it be Janssen or not, all our prescriptions are being monitored and tracked.

Q. And were you aware, Dr. Hsu, that during that time period, the sales force for Janssen was tracking the amount of prescriptions of Prezista and Intelence that you wrote, sir?

A. Yes, I think I was aware of that. And as I was saying, I'm aware that all companies, with exception of ViiV, have their representatives know how many prescriptions the doctor is writing.

Q. All pharmaceutical companies do that; is that right?

A. That I'm aware of, yes.

Q. All right, sir. And were you aware of the fact that Janssen would remove speakers from their promotional speaker bureau if they didn't prescribe enough Prezista and Intelence?

A. I am not aware of that policy. It could have happened, but I was not aware of it.

Q. You weren't aware of it, sir, because you had a high level of prescriptions of Prezista and Intelence during the time period from 2006 to 2014, so with you, that issue was never raised, fair?

A. Yes, but it's hard to jump to the conclusion, at least in my mind, that because I wasn't dropped from the bureau that someone else was dropped from the bureau because of their prescription.

Q. Yes. I understand, sir. You might have wanted to hear the testimony of the president of the company stating that speakers were removed from the program if they didn't prescribe enough of the drug; is that fair?

MS. BROWN: Your Honor, I object. That misstates Mr. Mattes's testimony. It also lacks foundation here.

THE COURT: I'll sustain the objection.

MR. MARKETOS: I'm sorry, Your Honor.

BY MR. MARKETOS:

Q. Dr. Hsu, are you aware of whether or not the president of the company in this case has attested to the fact that the company Janssen would remove speakers if they didn't prescribe enough drug? I'm just asking if you're aware of that.

MS. BROWN: I object as misstating the testimony.

THE WITNESS: No.

THE COURT: Do you have the transcript?

MS. BROWN: We can get it, Your Honor.

THE COURT: Let me see it.

MS. BROWN: Okay.

THE COURT: I'll sustain the objection for now. Why don't you continue with your examination.

MR. MARKETOS: Thank you.

BY MR. MARKETOS:

Q. Let me just ask it this way, sir.

If, in fact, that were happening, if, in fact, it were true that the company Janssen were removing speakers from the speaker bureau if they didn't prescribe enough drug, that would concern you enormously, wouldn't it?

A. It would concern me if the reason why they were removed -- not because of the number of drugs that, you know, they prescribed. It would be unethical in my mind to directly link being part of the speaker bureau to direct the number of prescriptions a provider writes.

I think if a provider does not have experience with the drug -- so let's just say hypothetically they may be writing one or two or five prescriptions of Intelence so had very little experience with it or do not know the data regarding it, that drug, then I could understand why that person wouldn't be on the speaker bureau, because they wouldn't be able to convey the information.

However, if you have two cases of two providers that wrote the same amount of drug, one who was on the speaker bureau, and

one that was not on the speaker bureau and one was removed because their prescriptions dropped, that would be of concern and would be ethically, in my mind, concerning.

Q. Thank you, Dr. Hsu.

It would be in your view unethical for a company like Janssen or any pharmaceutical company to remove a speaker from a speaker bureau because they weren't writing enough prescriptions for the drug, fair?

MS. BROWN: Objection, Your Honor. Asked and answered.

THE COURT: I'll overrule it because it's a long answer. I need him to clarify.

THE WITNESS: I'm sorry. Should I answer that?

THE COURT: Yes, you should, Dr. Hsu. This is the judge. You can answer it.

THE WITNESS: Okay. So I think it would be unethical if a provider -- if Janssen removed someone from a speaker bureau because they -- I guess their prescriptions -- how should I put this. This is an interesting question.

If we had adequate -- if a provider had adequate experience with the drug and was able to convey that information and they were taken off the speaker bureau because they had a drop in their prescriptions, I would have problems with it ethically.

BY MR. MARKETOS:

Q. Yes, Dr. Hsu, because then it would seem like the payment of money was being made in exchange for prescriptions, right? That's why you would have a problem with it?
A. Potentially, yes. Yes, I would think so.
Q. Now, you attested to the fact, sir, that as I understand it, off-label conversations came up with some frequency during the speaker engagements that you hosted; is that right?
A. Yes.
Q. All right. And as I understand it, sir, that would be because somebody from the audience asked a question --
A. That's correct.
Q. -- that prompted an off-label response, right, sir?
A. Yes.
Q. Because in order to speak off label at a promotional speaker event, you're not permitted to do so unless an unprompted question comes from the audience, right, sir?
A. That is correct.
Q. Okay. Do you know whether or not Janssen was using plants in the audience at the speaker engagements that you attended in order to prompt discussions about off-label prescriptions for Prezista and Intelence?
A. I'm not aware that was a tactic used.
Q. If that were, in fact, a tactic that was deployed by the sales force nationwide in order to prompt off-label discussions about these two drugs, that would be enormously concerning to

you, would it not?
A. Yes, it would.
Q. That would be an unethical way to obtain and spread off-label information about a drug in violation of the law, right, sir?
A. I would think so, yes.
Q. And, sir, you mentioned that you remember Nancy Bartnett. Do you recall testifying about her?
A. Yes.
Q. And do you recall that she was very -- I think you said she was bright and had lots of data; is that right?
A. Yes.
Q. And Nancy Bartnett had a lot of data and so did Tim McSherry, right, sir?
A. I think they both did, but Nancy was particularly -- she particularly knew the data from all the conferences better than a great majority of people.
Q. From all the conferences and all the studies that she shared with you, right, sir?
A. That we talked about, yes.
Q. Do you know how many of those conversations that you had with Ms. Nancy Bartnett included discussions about off-label studies?
A. Well, with myself she oftentimes would ask me what my experiences were and why I felt or thought the way I did. And

so, you know, we would discuss that.

Q. Yes, sir. And you said, as I understood it, that Janssen's sales representatives, including the Relator in this case, Ms. Penelow, never marketed to you or promoted their drugs to you off-label. Do you remember having that conversation?

A. Yes.

Q. Sir, you were actually on the early access program for Janssen's drug Prezista. Do you recall that?

A. I actually do not, but thank you for reminding me.

Q. Do you remember that now, you were part of an early access program to evaluate the long-term safety and tolerability of Prezista back before the drug was even launched? Do you recall that?

A. Honestly, I do not. I'm usually part of almost every extended access drug, if it's available.

Q. I'm sorry for interrupting, sir. Sorry, it's a little bit difficult.

A. Go ahead.

Q. You actually learned during the course of your training and being on the early access program that Prezista did not have a good lipid profile, do you recall that?

A. It has a decent lipid profile, but there are some downsides to it. It's not as good as other drugs, some other drugs.

Q. Yeah, it's not as good as other drugs that were available on the market. And Prezista's label stated that there were adverse and serious adverse reactions with respect to hypercholesterolemia and hyperlipidemia, right, sir?

A. Yes.

Q. And, in fact, at one point at Cabrini Hospital, Ms. Nancy Bartnett told you that Prezista had great lipids and that it was the same as Reyataz, and you found that odd because you were -- you had learned that Prezista did not have a good lipid profile like Reyataz. Do you recall that?

A. I actually do think it had similar lipids like I mentioned in my last testimony. I put them together as the second generation protease inhibitors. So significantly better than the first generation protease inhibitors like Kaletra and Crixivan, but still with some lipid elevations. And it does depend on the person, some people are more predisposed than others for lipid elevations.

Q. I apologize for interrupting, sir. I asked a different question. Would you like me to restate it?

A. Yes, please.

Q. Yes, sir.

You were actually in a conversation with Ms. Nancy Bartnett at Cabrini Hospital, do you recall that, where she stated at the time that Prezista had great lipids and were the same as Reyataz; and you stated in front of Ms. Penelow that

you found that odd. Do you recall that conversation?
A. I do not recall that conversation now, sorry.
Q. You don't recall finding that conversation or that statement by Ms. Bartnett to be odd because you had learned through the early access program that Prezista had lipid issues associated with that drug? You don't recall that?
A. No, and it's not through the early access program. I think through the clinical studies it shows a mild elevation in lipids that is very similar to Reyataz and certainly better than a lot of the prior -- pretty much all the prior protease inhibitors. I would be surprised if she said it was great because I think she would be aware that there is some elevations very similar like there are some elevations to Reyataz.
Q. So is the answer to my question, Dr. Hsu, you don't recall that conversation taking place?
A. I do not recall that conversation specifically.
Q. One of the reasons that the sales representatives who called on you from Janssen would not promote the drug off-label as having a good lipid profile is because you were educated on the drug and knew that it did not have one at the time. Do you recall that?
A. The company's -- the representatives have been very good to not promote things off-label. So I don't think any -- I'm not aware, at least that comes to memory, of any representative

that was promoting things off-label.
Q. All right. Sir, one of those people you said was not promoting the drug off-label was Ms. Jessica Finkelstein, now Ms. Penelow, right, sir?
A. Yes.
Q. It's your testimony that Ms. Penelow has not promoted Prezista and Intelence off-label; is that right?
A. Not that I recall. I do not think she did.
Q. At least not to you, that's what you can tell us?
A. Yes, not to me.
Q. There were 335 other doctors on that speaker bureau, and thousands of attendees, you're aware of that, right, sir?
A. Sure.
Q. All right. And to the extent that off-label information was shared during those speaker bureaus, that off-label information would have reached hundreds or thousands of other doctors, right, sir?
A. I'm trying to figure out which off-label information.
Q. Well, any off-label information that was discussed during those bureaus would necessarily reach the audience, do you agree?
A. Not unless it was actively discussed from the audience members and it was a reactive discussion. But as I was mentioning, a lot of people go to these conferences, especially during this period of time, in the early 2000s, where --

Q. I'm sorry, Dr. Hsu, do you remember my question, sir? I'm sorry to interrupt but we've got five minutes left before letting the jurors go. If you wouldn't mind, sir, I just have some questions that I need you to answer, okay?
A. Sure.
Q. All right. If off-label discussions were held, took place at these speaker bureaus, they reached thousands of audience members. I'm not asking about how or why the conversations started. If off-label discussions took place, they reached thousands of audience members. Do you agree?
A. Yes, I do.
Q. Is it my understanding, sir, that you are currently serving on a -- what did you call it? What board are you currently serving on for Janssen?
A. The Presidential Advisory Board is a group of ten physicians in the US that evaluate studies and drugs in development. That was disbanded about a year and a half, two years ago.
Q. All right. Sir, that was a paid position?
A. Yes, it was.
MR. MARKETOS: If we take a look at RX-376.
We're going to offer RX-376, Your Honor. My understanding, there's no objection. This is the MedForce data.
THE COURT: Ms. Brown, do you have that before you?

MS. BROWN: I don't. Can I see it on my screen? I don't know what it is.

THE COURT: Mr. Marketos.

MR. MARKETOS: Yes, I don't know if you can see it on the screen.

THE COURT: We have Dr. Hsu on the screen.

MS. BROWN: I'll just reserve, Judge. I don't want to hold us up, Judge. No objection, it's fine.

THE COURT: Do you have something over there?

MS. BROWN: It's okay. No objection.

THE COURT: All right. It's admitted.

(Exhibit R-376 admitted into evidence.)

MR. MARKETOS: I'll also offer the AHM data, Defendants' Exhibit 4533, and 1039, Relators' Exhibit, which is the 902 affidavit.

THE COURT: Is there some way you folks can show these folks what those exhibits are without the monitors?

MR. MARKETOS: Yes, Your Honor. It's actually a defense exhibit. It's called the AHM data, and it's just a business records affidavit attendant to it.

THE COURT: It's their exhibit.

MS. BROWN: That's fine, Your Honor.

THE COURT: So admitted.

(Exhibit D-4533 admitted into evidence.)

BY MR. MARKETOS:

Q. I'm going to show you a demonstrative, Dr. Hsu. If you can see the screen, just let me know if you can see that, sir?
A. No, I cannot.
Q. It's going to come on. This is going to be Demonstrative Number 1.
MR. MARKETOS: If you could share that.
BY MR. MARKETOS:
Q. There we go, sir.
Sir, what I'm showing you is a demonstrative that shows the accumulative amount of payments that you, Dr. Hsu, received from Janssen during the time period from 2006 to 2014 on the speaker bureau. Do you see those amounts increasing over time from 2006 to 2014?
A. Yes, I do.
Q. Okay. We'll take a look at Demonstrative 2, if we could?
MS. BROWN: Is it possible to get a copy of your demonstratives, Counsel?
MS. WENDEL: Yeah.
MS. BROWN: Thank you.
BY MR. MARKETOS:
Q. Dr. Hsu, what I'm showing you here, sir, is this is the amount of money that you were paid by Janssen during the speaker bureau. And then in blue we have the cumulative reimbursements for prescriptions that Janssen received from the prescriptions that you wrote for Prezista and Intelence. Do

you see that, sir?

A. Yes, I do.

Q. As you see, sir, Janssen got a significant return on the amount of money that it paid you to speak on the speaker bureau?

MS. BROWN: I object, Your Honor, argumentative.

THE COURT: Overruled. I'll allow it.

BY MR. MARKETOS:

Q. Janssen obtained a return on investment from reimbursements from the government compared to the amount of money that it paid you to speak on its bureau. Can you see that, sir?

A. Yes. I do have to dispute that in the sense that my practice has grown. In 2006, I was in private practice as a solo practitioner, along being with St. Vincent's, NYU, I can't remember which one. And as the years have gone by, my practice now has doubled in size. So I don't see a doubling in scripts.

Also, in terms, if you look at anyone's prescriptions of the drug, as any drug comes about, it increases exponentially as we get more and more experienced and as it gets -- as it, you know, replaces the older generation of medicines that were inferior to it.

So all the Kaletra drugs, all the Crixivan, and many of the other drugs are being switched to Prezista because Prezista is a new drug, first in 2006 when it's approved, but of course

it's going to grow as people get more experience with it, and of course the indication from a twice a day experienced drug to people who are on first line therapy --

Q. Dr. Hsu, do you remember my question, sir? I'm sorry.

A. Sir, you're showing data that is completely irrelevant. It's not related to how much I'm being reimbursed. It's completely related to. One, a new indication for the drug from experienced to naïve. And as I find offensive in that Gilead, that other representative who tried to tie prescriptions to profit that they get from a company, I find your allegations to be extraordinarily offensive as well because you have no idea and no practicing concept of our wanting, as HIV providers, needs to take care of our patients as best as possible. We're in it not to -- because we're being paid by a company. We choose the right drug for the right person because it's the best for them. And you're trying to correlate me being paid, which doesn't -- which includes reimbursement and everything else, and research, expanded access, everything else, you're trying to insinuate --

Q. Dr. Hsu, I'm sorry.

THE COURT: I'm going to let him finish.

THE WITNESS: -- brand-new indication. It's offensive. It's ridiculous. And you should know that yourself.

BY MR. MARKETOS:

Q. Thank you, Dr. Hsu.
A. I'm sorry to be weird about this, but think about it, new indications and prescriptions go up. You're going to have to get your logic in better order.
Q. Thank you, Dr. Hsu.
MR. MARKETOS: Objection, Your Honor, nonresponsive, I'd move to strike.
THE COURT: I'm not going to strike that response, denied.
BY MR. MARKETOS:
Q. Dr. Hsu, I have a question for you, sir, I'm not asking you about your receipt of money. You know that Janssen was tracking its return on investment based on the amounts of money that it paid you?
MS. BROWN: I object, Your Honor, misstates the facts.
THE WITNESS: I am not aware of any of that.
THE COURT: Overruled.
BY MR. MARKETOS:
Q. Thank you, sir.
As I understand it, sir, you would take the tracking of the return on investment that a company paid doctors for their prescriptions, you would find that to be offensive? That's what you just told us; is that right?
A. Yes, if it was a return on investment I would find it

offensive in terms of it being related to why they're on the speaker bureau.

Q. I understand, Dr. Hsu. And you have no idea what Janssen was actually tracking because you haven't seen any of the return on investment calculations that it was performing while you were speaking on its bureau, fair?

A. That's fair.

THE COURT: Mr. Marketos, on that one, is that a good place to stop?

MR. MARKETOS: Yes, Your Honor.

THE COURT: We have more to go, I presume?

MR. MARKETOS: Yes, Your Honor.

THE COURT: Folks, it's 5:00, we're going to adjourn for the day. Just a reminder, tomorrow at 12:30. Folks, I appreciate your patience and the time you've been putting in.

Counsel, remain, I do want to speak with you briefly before tomorrow. And we're going to be ready to go at 12:30 with Dr. Hsu.

THE DEPUTY CLERK: Please rise.

(The jury exits the courtroom at 5:04 p.m.)

THE COURT: All right. Folks, have a seat. Do we need a sidebar?

MS. BROWN: I was just going to ask if we could excuse Dr. Hsu from the video.

THE COURT: Sorry. I didn't realize that we still

had him on the screen. Why don't we temporarily excuse Dr. Hsu.

Dr. Hsu, we're going to be starting at 12:30 sharp, so I presume that counsel will make sure that you're available, set this VTC up at that time.

MS. BROWN: Thank you, Dr. Hsu.

THE WITNESS: Thank you.

(Witness excused.)

THE COURT: All right. Let's go off the transcript.

(Discussion held off the record.)

(Proceedings adjourned at 5:05 p.m.)

CERTIFICATION

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/Shannan Gagliardi, RDR, CRR 5/30/24
Court Reporter/Transcriber

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