UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	*	16-MD-2740
	*	Section H
Relates to: All Cases	*	May 22, 2019
	*	10:00 a.m.

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ORAL ARGUMENT BEFORE
THE HONORABLE JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

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MORNING SESSION

(May 22, 2019)

THE COURT: Just give me a second. You-all can sit down.

MR. MOORE: Thank you. Good morning, Your Honor. Douglas Moore, defendants' liaison counsel and local counsel for Sanofi.

Very quickly on the batting order for today's motions. Thank you, Your Honor, for allowing us to proceed with the motion to exclude the expert testimony of Dr. Linda Bosserman. First, Ms. Byard will be arguing that. We will then proceed with the learned intermediary motions, which Mr. Ratliff will argue. We will present our position on those two motions, and then the plaintiffs will present their position on those two motions for the interest of lack of repetition and efficiency.

We will do the same thing with the statute of limitations, which Mr. Strongman will present for the defendants, and then the presentation will be made on those two motions by the plaintiffs. Then I will address the Rule 72 motion and will do so in five minutes or less.

THE COURT: Thank you.

Ms. Byard.

MS. BYARD: Good morning, Your Honor. Adrienne Byard for defendant Sanofi.

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We are here today on an expert challenge because the prescribing doctors in this case did not testify in a manner that would convincingly persuade a jury that Sanofi misled them to prescribe Taxotere to Tanya Francis and Barbara Earnest. Instead Dr. Carinder described Taxotere as a good drug, Dr. Verghese described Taxotere as a drug that's effective, and both doctors reiterated that they still use the medicine today.

So what do you do when you are not able to elicit testimony from the local doctors accountable to the patients who are the plaintiffs in this case? Well, in an ingenious move by our opponents, you find a doctor to dress up as the prescribing physicians and offer expert testimony that substitutes what was actually said with what in a different world, under different facts and counterfactual hypotheticals, a doctor might have said.

Unfortunately for the admissibility of this specific informed consent opinion of Dr. Bosserman, the best and only accurate evidence that the jury should hear comes from the horse's mouth. It comes from Dr. Carinder and it comes from Dr. Verghese.

The only opinion that's at issue in our motion, Your Honor, is that of informed consent. The opposition, the briefing in this case, is sort of like ships passing in the night. I'm not quibbling with Dr. Bosserman's credentials, her

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qualifications.

THE COURT: Okay.

MS. BYARD: Yes. We are not. We will certainly cross-examine her at trial about this endeavor to make cancer treatment profitable and her background in that regard; but for the purposes of the motion, we are not seeking to exclude her on that basis.

We are also not saying that Dr. Bosserman can't come in and talk to the jury about the background of this medical issue. We are not saying that she can't come in to talk about treatment, about diagnosis, about treatment options. It's this case-specific informed consent opinion that we think offers a counterfactual hypothesis that cannot be tested and that is extremely misleading to the jury.

Basically, Your Honor, what she does is she says if this risk truly exists, this thing of permanent alopecia -- she's not saying that it does. She's not saying that Taxotere causes permanent alopecia. But if you take the assumption that it does and then if you assume that Sanofi knew about it -- she is not offering that opinion, that's not her -- and then you assume that the doctor didn't know about a risk that existed -- and she is not offering that opinion -- had the doctor then relayed that risk information to the patient, had the patient then refused to take Taxotere, had the doctor then offered an alternative, what would the patient ultimately have chosen to

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do. It's on that house of cards that this informed consent, this case-specific informed consent opinion rests, and that's the narrow basis for which we are challenging Dr. Bosserman.

What is, Your Honor, this informed consent methodology? I will candidly tell you that in 12 years of doing pharmaceutical defense, I have not seen an informed consent expert in a product liability case. I would offer that if the Court were to search the product liability precedent, there will not be a published standard for an informed consent opinion; that this informed consent opinion is an animal on alien soil in the product liability context. It's not a methodology that's published somewhere. It doesn't have a rate of error. I can't test it. There's no checks and balances on the opinion.

We asked Linda Bosserman, then, we said, "What is this methodology?" and she conceded that she's just summarizing what she has read in the depositions. That's the method that she is applying. Sure, she has the background, the experience, but the method for coming to an informed consent opinion is just reading and summarizing.

As far as we can discern -- and I will show this to you later -- this method might as well be fortune-telling. We would offer to you that the conclusions that --

THE COURT: I'm just curious.

MS. BYARD: Yes. Yes.

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THE COURT: There is a standard of care regarding elicitation of informed consent.

MS. BYARD: That's right.

THE COURT: Okay.

MS. BYARD: That's right, and it comes from the --

THE COURT: I know this is not --

MS. BYARD: Yes.

THE COURT: -- the case before us --

MS. BYARD: Yes.

THE COURT: -- that these motions are based, but indeed if the oncologist were deceased --

MS. BYARD: Yes.

THE COURT: -- would there be an argument that this sort of opinion testimony would be appropriate? Because there would be at least, well, this is objectively what the standard of care is and this is what they should have been done.

MS. BYARD: So there definitely is a line of precedent for an objective standard for what a reasonable doctor would have done with an adequate label. There are cases that allow you either to do it objectively or subjectively, but the precedent that we pointed you to and that we found has not allowed that objective evidence in. Moreover, Dr. Bosserman's opinion doesn't fit that objective standard. She does not come out and say that a reasonable doctor --

THE COURT: I understand.

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MS. BYARD: She doesn't do that. She doesn't say Dr. Verghese was unreasonable if he would have decided not to warn her about permanent hair loss. Because what Dr. Verghese says is that he would have warned her of the risk of permanent hair loss with Taxotere or Taxol, which is what Dr. Bosserman is saying he could have offered her.

THE COURT: Right.

MS. BYARD: So even if you allow objective evidence about what a reasonable doctor would do, there's not an indictment by Dr. Bosserman that what they had to do was warn of the risk and then not prescribe this medicine or not default to the patient preference. She doesn't go that far. So it doesn't fit the exceptions where there might be some room for a counseling role in our product liability doctrine.

Because really what our product liability doctrine turns on, Your Honor, is the label. It's a question of me, Sanofi, as a manufacturer, the warnings that I passed along to that doctor, were they good enough, were they strong enough. So we pulled the jury instructions from *Xarelto* as an example, and you will see here that it's an adequate warning or instruction.

Then we go on to show you how deep in the weeds the issue really for the jury legally is this label. More jury instructions from *Xarelto*: The label must contain language that's adequate to reasonably inform the prescribing or

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treating physician. And then we talk here about communicating the warning or instruction through a label or package insert or other communications or literature.

What Linda Bosserman doesn't do is she doesn't offer a labeling opinion. She didn't rely on the label. She didn't reference the label. She looked at the label through Dr. Feigel's report, but she says, "I'm not a labeling expert. I'm not offering any labeling opinions.

Unfortunately, because she's not actually addressing the label in any way, shape, or form, the precedent that you have to look to -- that I think you are probably referencing too -- is med mal. It's a med mal standard. It's not a product liability standard. They are asking us to accept expert testimony where there are no standards for product liability.

So at the end of the day I say let's hear it from the horse's mouth. Let's hear it from the doctors, the local doctors who were accountable to these patients and these women, and let's not dress it up as expert testimony. Let's let the jury make the inferences that Dr. Bosserman would like to decide for them.

So I would like to do a little song and verse on "you know you have a problem when" as sort of the catchphrase. I would submit to you that you know you have a problem when your expert submits an errata to a simple, single question and

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answer that is paragraphs and paragraphs and paragraphs long. I wish I could tell you that this was the only question that elicited this type of an errata response, but it's not.

Okay. So let's back up for a second. Here's the question that's posed by Jon Strongman, my partner:

> **"QUESTION:** It's speculative to know what risks Ms. Earnest or Ms. Durden or Ms. Francis really would have accepted back in 2009 and 2011, correct?
>
> **"ANSWER:** I don't know what they would have decided, but they clearly were willing to weigh information provided in making their final decision with their oncologist."

Very straightforward to me. "I can't say what they would have decided. They would have had more information." Big deal. The jury can come to that conclusion on their own. Here is the errata that we get. If I were the Micro Machine Man, I couldn't read this in response to that question in that deposition.

What's really fascinating is this line: "As I testified, my expert testimony is properly to help the trier of fact to understand the evidence so they can determine a fact issue." She goes on to say, too, earlier -- she says they would have chosen a different chemotherapy regime had they been informed of the risk of PCIA, permanent chemotherapy-induced alopecia. That's not the doctor's testimony. That's not. But

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this certainly wasn't the answer that Mr. Strongman heard back in response to his very, very simple question.

For a medical doctor to say, "Oh, I'm properly helping the trier of fact understand the evidence so they can determine a fact issue," you know you have a problem when the errata sheet has to say, "We are not drawing the ultimate conclusion that it's the jury's position to draw. That's not what we are doing." It's sort of a "lady doth protest too much." If you are having to say, "I'm just trying to help the jury understand the facts. I'm not drawing the ultimate conclusion for them," they are saying that because that's precisely what Linda Bosserman is trying to do.

If this were the only example of her errata sheet -- this is just Volume 1, paragraphs and paragraphs with this "assist the trier of fact," "help the jury" legalese. Volume 2, she gave us another eight, nine, ten paragraphs long about her testimony, trying to undo what she did, which was render her testimony inadmissible on informed consent.

I would like to take an indulgence to step aside for a moment and talk about why we care more about what the local doctors say than Linda Bosserman and why it's misleading to offer her testimony as an substitute for theirs or even in an additive way.

So Tanya Francis, at the time that she goes to sit down with Dr. Verghese, a woman in her situation, she has

10:31 either felt a lump, her partner has felt a lump, she has felt discharge or heat from the area. She has been worried. She has talked to family. She has gone to her general practitioner, who's referred her for secondary care. They have given her a mammogram. She knows she has breast cancer.

She sits down and she is staring down the barrel of radiation, surgery, chemo, and she is talking to her doctor about what she can do to live. They are talking about what her options are with her past medical history. They are talking about where she is in her life and what matters to her. They are talking about her anxiety, her fear. They are talking about the palliative care that's available to her.

They are weighing all the sources of information that the doctor has, all of his clinical experience about what her best chance for survival is, and what the alternative side effects are. Sure, there may be hair loss, but what about leukemia? What about septic death? What about neuropathy? Are you a violin player or a cellist? What is your life like? Do you have a history of diabetes? What are the risk factors in your personal medical care that I need to weigh in making this decision? It's a personal moment, and it's an individualized medical judgment.

That's why the proposition in this intensive risk counseling scenario of substituting an expert for the local doctor is not one that we should allow. It's within this

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context that this proposition that Bosserman offers, of simply subbing out Taxotere for Taxol, is too speculative and something that we have to instead just rely on what the doctor said, the local doctor.

We'll see, from the testimony that Mr. Ratliff will talk about in more detail, that at the time that Barbara Earnest was being treated by Dr. Carinder, for example, the way that we dose Taxol was not every week. It wasn't approved, and so we dose Taxol less frequently with a very, very, very high dose.

So at the time, based on the medicine available for administration, neuropathy was a concern for Dr. Carinder that he would not have prescribed that medicine to Barbara Earnest. Why are we going to hear from Linda Bosserman about today's standards, today's available medicines, what could be done today when we have Dr. Carinder's testimony saying that in 2011 Taxol was not an option? Really for our purposes what I think matters most is at the end of the day, like Dr. Verghese, he would warn of the risk of permanent alopecia with both, with Taxol or with Taxotere.

So we asked Linda Bosserman. We said:

"QUESTION: And as we have discussed, you certainly cannot say that had Ms. Francis received AC-Taxol that she wouldn't have permanent hair loss today, correct?

"ANSWER: Correct."

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We asked about Earnest:

"QUESTION: You can't say with certainty that if Ms. Earnest had been prescribed AC-Taxol that she wouldn't have permanent hair loss today, correct?

"ANSWER: Correct."

So instead of substituting in this rich, this personal, this individualized patient-doctor relationship from the local prescribing doctor, we cannot allow Dr. Bosserman to parachute in and put her expert gloss on what would have been done in her hypothetical facts that don't exist in the case.

Informed consent, I think to your point, Your Honor, does have --

THE COURT: I think what my concern was, if in this circumstance the treating physician were unavailable for a variety of reasons -- it could be illness, it could be just for a variety of reasons -- would it be appropriate to have an expert to provide some objective standard about what would be appropriate in terms of having the physician have these very frank discussions regarding the potential benefits and risks with any chemotherapy treatment?

MS. BYARD: Yes.

THE COURT: I know we are talking about --

MS. BYARD: Yes.

THE COURT: -- very specific --

MS. BYARD: Yes.

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THE COURT: -- plaintiffs --

MS. BYARD: Yes.

THE COURT: -- whose physicians are indeed available.

MS. BYARD: Right.

THE COURT: Are you telling me --

MS. BYARD: Yes.

THE COURT: -- that there are no circumstances -- and that's probably an unfair question because that's not before me --

MS. BYARD: We have to look at it.

THE COURT: -- where perhaps there would be a need to have an objective expert say the treating oncologist should indeed provide the basis of informed consent, and that would require the treating physician give this information?

MS. BYARD: Yes. Yes. I think --

THE COURT: I know that's not what's before me today.

MS. BYARD: Yes. We would have to look at it in context.

THE COURT: Yes.

MS. BYARD: We would have to look at it in context. I would have to think through it in a different way, but I think we can set aside that issue.

THE COURT: I understand, but that has --

MS. BYARD: And only because Linda Bosserman doesn't do that objective test. She does not apply the objective

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standard in her testimony. She doesn't say a reasonable physician with an adequate labeling would not have done X, Y, or Z. She doesn't second-guess.

THE COURT: I just want to make sure.

MS. BYARD: Yes.

THE COURT: I want to go back and make sure I understand that there is no objection -- and I think you said clearly --

MS. BYARD: Yes.

THE COURT: -- you had no objection to her credentials and --

MS. BYARD: Correct.

THE COURT: -- the appropriateness of her testimony regarding fundamentals of breast cancer treatment --

MS. BYARD: Absolutely.

THE COURT: -- describing the various forms of treatment, how that generally plays out over the course of breast cancer treatment. So there's no objection to --

MS. BYARD: On the same page. On the same page. There is not an objection. It's the case-specific informed consent opinion.

So I kind of did this exercise in an old-school way, you know, with my paper calendar sitting beside me. If I was thinking about what of her report came in, for instance, Your Honor, I didn't cross through anything until we get 16

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pages into her report. So there's the entire background that I don't think is touchable. I don't think her credentials lend any credence to the idea that those opinions should be excluded. I certainly intend to offer Dr. Glaspy or Dr. Miletello on our part to come through and do a lot of that same -- hopefully not repetitive, but that same legwork.

To the point of the reasonable medical care and what a doctor would do with an adequate label, we wanted to make sure the issues in the case were narrowed through the written discovery. As an example, Tanya Francis, we asked her does she contend that she received inadequate medical care from any of the practitioners she saw; unequivocal no. We asked her if she contends that Dr. Verghese failed to properly warn her of the possible complications related to the use of Taxotere; unequivocal no.

The scenario, I think, that Your Honor envisions where there might be a link in the chain or some objective testimony that a reasonable doctor wouldn't have done what they did in these circumstances, you know, that they were hoodwinked by Sanofi, that they were hoodwinked and they wouldn't have done it had they had an adequate label, that's not the claim that's being made in the case. Really in the LID context, Your Honor, what we are talking about is the label.

THE COURT: Wait a minute.

MS. BYARD: Yes.

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THE COURT: Go back. Possible complications related to the use of Taxotere, I guess that is assuming that he related the complications that were part of the labeling.

MS. BYARD: So I think to make the plaintiffs' case, you have to say that, sure, the link between Sanofi and the doctor, that duty was not fulfilled.

THE COURT: Right.

MS. BYARD: But then you have to say, by consequence, the link in the chain between the doctor and the patient wasn't reasonably fulfilled either. Now, it could be because of virtue of the information that was available.

THE COURT: Right. Right. Okay.

MS. BYARD: That's what I'm asking her in the written discovery, if that's the claim. That's a question and answer.

THE COURT: All right.

MS. BYARD: So we go to the label.

THE COURT: Let's proceed.

MS. BYARD: So we go to the label in the pharmaceutical context, and I would have expected -- Mr. Strongman asked this question of Dr. Bosserman eight times more often than I would have felt comfortable because I thought for sure at some point she would say, "Well, I do have an opinion on the adequacy of the label, actually." Maybe she answered it in the negative the first four times, but the fifth or sixth time she needs to, for her testimony to come in on

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this, and she doesn't.

She keeps saying over and over again, "No, not on the label, not me. I'm not the expert. I'm not about the label." She says that over and over and over again. Again, the jury instructions, that's what we are here about; we are about the label. So what she is doing, then, in the end, Your Honor, is dressing up as the doctor and trotting out this hypothetical with different risk information that may or may not actually be the case, might actually be true.

I would tell you, Your Honor, that I would love to bring in a very well-credentialed female oncologist to redo the prescriber testimony and fit my theory of the case. I would love to hire out the fact witness testimony nine times out of ten and control it, but that's not the case that we have to try. The case that we have to try is rich. It's factually nuanced. The doctors' experiences are varied. Their knowledge of the literature is different. It's not a hired-out opinion.

We asked Dr. Bosserman:

> **"QUESTION:** Is the best place to understand what Ms. Earnest would have done in this situation, what Dr. Carinder would have done, is it to go to Dr. Carinder? Is it to go to Barbara Earnest?
>
> **"ANSWER:** Yes, yes, yes, go to the horse's mouth."

Dr. Bosserman can't pretend to stand in for that testimony.

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Here's a concrete example. So applying technology that's only available now in 2019, she uses online calculators.

THE COURT: I think you might want to reserve a little time.

MS. BYARD: Okay. Okay. These cool caps that weren't available -- so here's my "you know you have a problem when," and I will speed through the rest of these. You know you have a problem when, number two, the sequel, instead of just offering the doctor's testimony, she says:

"I'm reading the intent of the discussions."

"I'm extracting in the tone of Mr. Earnest's deposition."

"I'm taking it in context."

"I'm looking at what all their interpretation of the situation is."

This is what the jury does with the testimony. This is what the jury does with the testimony of Ms. Earnest's husband. This is what they do with the testimony of the doctor. She cannot stand up and testify for the jury what the intent was, how they should contextualize it, how they should weigh it. That is 100 percent supplanting the role of the jury.

You know you have a problem when the opposition in this case relies time and time again not on the facts of the

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testimony of the doctors themselves, but on Dr. Bosserman's reiteration of it. Here is an example. In her report Dr. Bosserman says that the oncologists have testified that they would have used a Taxol regimen had their patients expressed a preference based on the risk of PCIA. That's not what the doctors actually said.

That's the second problem. So they're supplanting the jury, but she is also misleading the jury by trying to parrot this testimony, because what he says is both of them cause hair loss. He says, "If there's a report of one being permanent, I would apply it to the other one too." He doesn't say he would have given her Taxol. He says, "If permanent hair loss is a concern with one, it's a concern with the other, and I would have warned her of both."

THE COURT: Okay.

MS. BYARD: More examples, okay, and I will --

THE COURT: Ms. Byard, I think --

MS. BYARD: Yes. Okay. Perfect.

So the last thing we would point out, Your Honor, is how she has cherry-picked examples from the testimony. The *Grenier* decision we have talked about. That's where you can do an objective test, but I would implore the facts of that case to both. The *Grenier* case says it would have been fine if it had come from the doctor who treated the plaintiff. It didn't come from the doctor. It came from the

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expert. The *Huffman* decision is similar.

So let's just look at her ultimate opinions, and I will conclude with this. So her ultimate opinion, Your Honor, is that this information about these risks of permanent chemotherapy-induced alopecia, that had they been communicated via the product label, the marketing pieces, the correspondence, or the sales representative, it would have changed the discussion. That's what she says, it would have changed the discussion. The problem is, Your Honor, she didn't look at the product label. She didn't look at our marketing pieces. She didn't look at any correspondence or sales rep -- the doctors said that they didn't rely on sales representatives.

Then she says it would have changed the discussion. The only way that she can say it would have changed the discussion is by supplanting the jury's job and weighing the doctor's testimony. The only way she does it is by shaping the facts of that testimony in a way that is not consistent with the record evidence.

For all those reasons, we would say the case-specific informed consent opinion ought to be excluded. Thank you.

THE COURT: Thank you.

MS. JEFFCOTT: Good morning, Your Honor. May it please the Court. My name is Emily Jeffcott. I'm here on

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behalf of the plaintiffs.

Your Honor, I don't believe there's too much dispute here. As you mentioned, defendants have conceded two important points: (1) that Dr. Bosserman is qualified to be an expert in these cases; and (2) defendants don't challenge Dr. Bosserman's general opinions.

Specifically, I point to page 3 of Sanofi's reply. Defendants don't challenge Dr. Bosserman's opinions on the science of cancer, the development of treatment plans and that "decision-making process of oncologists and their patients." What it appears that Sanofi challenges is the application of those general opinions to the facts of these cases. Specifically, Sanofi claims that --

THE COURT: Ms. Jeffcott, I have to tell you. I think as I read the report -- because I like to do that before I read the briefing -- I thought this is very beneficial, the initial part that lays out the diagnosis, the formation of a treatment plan, and the decision-making process. I think that's important. What does Dr. Bosserman bring to us when she begins basically summarizing the plaintiffs' testimony?

We have the doctors that are going to say, "This is the conversation I had." What does Dr. Bosserman do? We have got these people, and they are going to testify, "This is the conversation I had with my patient. If I knew that permanent alopecia was indeed a risk, I would have told her

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that, and then we would have had another conversation." Bosserman was not in that room, so tell me what she brings.

MS. JEFFCOTT: Sure, Your Honor. That really actually brings me to my first point, which is regarding the relevancy of Dr. Bosserman's opinion --

THE COURT: That's what I want to know.

MS. JEFFCOTT: -- regarding these specific plaintiffs.

Sanofi wants to make this about common sense, that it's within the common sense of the jury, of the layperson, to understand the treatment options and these treatment discussions between Ms. Francis and Ms. Earnest and their oncologists, and that they can listen to the testimony and that they can understand essentially the progress of events.

Now, I think the reality before us, though, Your Honor, is that breast cancer, its varying diagnoses, the various treatment options available to them and the application and discussion of those treatment options and how and what Ms. Francis and Ms. Earnest, in the discussion with their oncologists, what they ultimately decided, that's a lot of information. It's complicated and it's not common sense.

Your Honor, Sanofi cites to the *Peters* case in support of their decision. In the *Peters* case, there the expert sought to opine that off-loading a vessel during a

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rainstorm with 4- to 5-foot waves, where diesel fuel had spilled all over the deck, was dangerous, and the court there said, you know, it's within the common sense --

THE COURT: I want to go back to my initial question, which is we've got -- I have to tell you. As I was thinking about this, I thought there are circumstances where I could see this is absolutely relevant. That would be if the oncologist were unavailable. So we would then have to have somebody to come in and say, "This is what an oncologist would do under these circumstances," but we have the actual oncologist that had that discussion.

While it's complicated, I don't know if the discussion that these two oncologists had with their patients is more -- maybe it's the same discussion. That's where I'm at a loss. We have the people that had the discussion. Very frankly, they had to have a discussion in a manner that their patients understood it. Why wouldn't a jury understand that?

MS. JEFFCOTT: I have two responses to that. The first one, I want to refer back to Judge Fallon's decision in *Xarelto* regarding the *Orr* case. I argued that and I participated in that trial.

There was a unique circumstance where the prescriber testified that he wasn't sure whether or not he would follow the instruction and do the additional testing. That was what we wanted added to the label. So Judge Fallon

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permitted us to bring an expert who would provide essentially that reasonable person standard in order to provide that objective information to the jury about what a reasonable doctor would have done in those circumstances. That certainly didn't supplant but it added to the context of what the doctor in that case could and should have done.

The second part of the response, Your Honor, is that the issue of the diagnosis and the various treatment options, as I said before, is complicated. I want to point to, for example, Ms. Francis' diagnosis.

There she was diagnosed based on pathology reports of Stage 1 tubulolobular breast cancer that was progesterone and estrogen positive receptor, along with being HER2 negative and having a low grade Ki-67. Your Honor, to me -- and I think to a lot of people -- that could be considered alphabet soup, word salad. Without breaking that down, without explaining that diagnosis, there can be a misapplication, a misunderstanding of the significance and severity of what that diagnosis means.

THE COURT: I don't think they are objecting to her explaining it.

MS. JEFFCOTT: Respectfully, Your Honor, I do think they are objecting to explaining what that diagnosis is in the context of Ms. Francis. They are seeking to exclude all of her opinions with respect to anything specific to Ms. Francis. It

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goes beyond just explaining her diagnosis, Your Honor, but it's also explaining the various treatment options available to Ms. Francis.

This is where, I think, also her testimony becomes all the more important because Sanofi wants to make this case about life and death; that without Taxotere these women would have faced essentially certain death and, therefore, it would be unreasonable for an oncologist and their patients to weigh the risk of permanent alopecia against taking Taxotere.

Respectfully, this isn't a zero-sum game. There were other treatment options available to these women, and Dr. Bosserman will provide context of that by going through the NCCN Guidelines, which she has done, and applying the discussions that Ms. Francis and Ms. Earnest had with their oncologist, that it conformed to those discussions, that back-and-forth.

That's particularly important because to a layperson -- who may come to this case with their own understandings about breast cancer. They may think breast cancer means the Komen foundation, and they may have people that have survived or loved ones that have died. But the reality is that there is a big difference between metastatic breast cancer and early stage breast cancer. In particular, there is a difference between the different treatment options

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that these women had available to them and understanding those different treatment options and how all of those pieces fit together.

Now, Sanofi spent some time, I believe, discussing the learned intermediary doctrine and how that applies in this case. My colleague, Mr. Schanker, will next up go into further detail, but I do want to mention -- and there was some discussion of case law before, Your Honor, that wasn't mentioned in the briefing or the reply brief.

In the cases that were cited in the *Daubert* motion, none of those stand for the proposition that a plaintiff who decides not to take a drug based on an adequate warning and informs her physician of that, that that's somehow --

THE COURT: I'm really trying not to conflate and, frankly, that's a different matter.

MS. JEFFCOTT: I understand, Your Honor.

THE COURT: As to these specific plaintiffs, the treatment options available, wouldn't that be left to the treating oncologist as to what they would have done as opposed to some independent oncologist to say, "Well, this is what I would have done"? Because the reality is when Ms. Francis visited her physician, if indeed he had the information and he conformed his behavior and changed his behavior and said, "I'm going to tell you that this runs a risk of permanent alopecia,"

10:55

and she says, "I need to know what other options are out there," wouldn't we look to the options that he would have offered her as opposed to some independent expert? If that's the case, that we are going to look to what those physicians would have recommended, why would we need Dr. Bosserman to tell us that?

MS. JEFFCOTT: Absolutely. We are not arguing that Dr. Bosserman is going to substitute or wear the dress of a doctor. Dr. Bosserman is more focused on the exchange between the patient and the oncologist, the back-and-forth, that discussion of treatment options and how those conform to NCCN Guidelines.

That's particularly important in this case, Your Honor, because I think typically to the layperson the discussion between a patient and their physician can be one-sided. When I go to a doctor, my doctor will make a recommendation, I take it. But when it comes to breast cancer and the NCCN Guidelines, which Dr. Bosserman was integral in implementing, it's much more than that.

We see it with both plaintiffs that there were discussions back and forth, multiple meetings in which treatment options were discussed. It's that focus, that narrow focus in which Dr. Bosserman wishes to explore. She's not substituting her judgment for that of the doctors. What she did -- and this actually brings me to my second point regarding

10:57

the reliability of her opinions.

Sanofi states that she is cherry-picking testimony to conform to her opinions. That's not what she did. She testified that she reviewed all of the plaintiff depos, their treating oncologists, and even additional depos. She also reviewed the pathology reports, the surgical reports, and she took that information, extracted the parts about that decision-making process, and evaluated whether that decision-making process conformed to NCCN Guidelines.

That's what makes her opinions not only reliable, but relevant, because it demonstrates the exchange, the back-and-forth, the discussion of treatment options, the discussion of side effects; that it's not just about life and death, that it's a discussion of toxicities, it's a discussion of side effects, what these women were willing to weigh. That's the totality of her opinion.

Now, in a seeming contradiction, Sanofi argues then that not only did she somehow cherry-pick, but then she just summarized the depos and the medical records. If you look at the footnotes that Sanofi references for that claim -- it's footnotes 11 and 12 in their motion -- and you read them, it states much more than that.

As I said before, she reviewed all the depositions, she extracted the parts that she believed about that decision-making process, she compared them to NCCN

10:58

Guidelines, and then she even went a step further and validated those opinions -- those of her own and of the methodology employed by the oncologist -- against those online database tools, which a similar version existed at the time that these women were being treated. That's much more than merely summarizing depo testimony and medical records.

Now, in Sanofi's brief -- I'm not sure Ms. Byard mentioned it, but Sanofi states that Dr. Bosserman's opinions are unreliable because she acknowledges that there are case reports of permanent alopecia with other chemotherapy drugs, including Taxol. Your Honor, to me that actually is a hallmark of the reliability of her report that she is considering these additional drugs and evaluating whether or not there could be an instance of permanent alopecia and whether or not that would be at issue. She found that, based on those case reports, that's not something that she would rely on.

Furthermore, regardless of whether other drugs have instances of chemotherapy [verbatim] is not an issue that's at bar before the Court. This is a failure to warn case under Louisiana law. The focus is on Taxotere and whether or not it caused permanent alopecia in these plaintiffs.

We are not alleging a design defect. We are not alleging that there had to be a safer alternative design. Here the focus is squarely on Taxotere. If we are required to go beyond that, we are allowing trials to turn into mini trials.

11:00

Your Honor, for those reasons Dr. Bosserman's testimony is not only reliable, but relevant. Thank you.

THE COURT: Thank you.

MS. BYARD: So, Your Honor, we feel like there's again ships passing in the night. I think Your Honor understands we are not challenging the general opinions, the background, the diagnosis, the treatment options at all; it's just the case-specific informed consent opinion. I think we would be remiss if we didn't point out a couple things about opposing counsel's argument.

When I hear "more focused," I hear "better credentialed." It doesn't mean that we substitute in the doctor's testimony for that of their hired expert.

Unlike *Xarelto*, Your Honor, Dr. Bosserman is not offering a reasonable doctor standard. You won't see that standard applied anywhere in her report. She does not say a reasonable doctor in this situation with an adequate label would have done X and that would have been different than what these doctors did. It's just not anywhere in her report. It's not anywhere in her testimony. It's not *Xarelto* and it's not admissible.

She suggested to you that Dr. Bosserman conformed her opinions to the NCCN Guidelines and that part of this idea of what the prescribing decision should have been was running it up against the NCCN Guidelines. I think, as the

11:01

record makes clear from the actual local doctors, that at the time to dose Taxol weekly was not an option.

What Dr. Bosserman comes up with in her machine from 2018 as the treatment recommendation was not something that NCCN Guidelines would have allowed those doctors to do at the time. So it's not true that her testimony was validated as a methodology against some objective standards because the standards that would have allowed her treatment recommendation today are not the ones that applied at the time.

Finally, Dr. Bosserman did not even read the consent forms in these cases. So to say that she has applied a reliable methodology applying reliable standards that speak to the informed consent standards that have been created by the medical community or that are appropriate within NCCN Guidelines, to suggest that method --

THE COURT: Let me ask you a question.

MS. BYARD: Yes.

THE COURT: Is there any objection to Dr. Bosserman speaking to the specific diagnoses of Ms. Francis or Ms. Earnest in terms of whether or not they were estrogen receptors, progesterone receptors, and what does that mean?

MS. BYARD: No.

THE COURT: I think I asked that question and then -- okay.

MS. BYARD: Yes. No. No, it's truly the

11:03

case-specific risk information, what different risk information would have led to different prescribing opinions. This case-specific informed consent opinion that she offers is the heart of our challenge.

I think that's it, Your Honor, unless you have further questions.

THE COURT: Thank you. No.

MS. BYARD: Thank you.

THE COURT: I think now we are going to learned intermediary.

I will tell you-all we have an en banc meeting at noon and I have to go.

MR. RATLIFF: Are you telling me to be quick, Judge Milazzo?

THE COURT: Yes. We were supposed to tell you-all that there were seven minutes per side per argument, and apparently that memo didn't get out.

MR. COFFIN: Your Honor, to be clear, we were aware of the five minutes per side on the Rule 72, but there was not a communication --

THE COURT: I know. So we may have to just take a break for an hour. I'm sorry.

MR. COFFIN: We can try to shorten it.

THE COURT: I have to be at this one.

MR. RATLIFF: Give me a minute, Your Honor, to get

11:04

the slide deck up.

Your Honor, Harley Ratliff for Sanofi. As Mr. Moore indicated, I'm going to cover the learned intermediary for Earnest and Francis. I have conferred with Mr. Schanker. He is going to cover them when I'm done with both of them, so I will try and move through both of these as quickly as possible.

THE COURT: Okay.

MR. RATLIFF: Your Honor, as you know and as Ms. Jeffcott said, this is a failure to warn case.

THE COURT: Right.

MR. RATLIFF: The crux of the allegation is Sanofi failed to warn of a particular side effect; therefore, all 12,000 plaintiffs have a particular injury. That would be the case for Ms. Earnest. That would be the case for Ms. Francis. That puts us squarely into, as you know from our discussion on the *Mills* argument, the learned intermediary.

In Louisiana, in this district, it's a two-prong test. Plaintiffs must satisfy both of those prongs: (1) that the warning was inadequate, the warning that was given at the time of the treatment was inadequate, and the doctor did not know of the risk; and (2) that the failure to warn, Sanofi's failure to warn, was the cause in fact and the proximate cause. So but for the inadequate warning, the treating physician would not have used Taxotere.

11:05

THE COURT: Is it would not have used or would have conformed his conduct?

MR. RATLIFF: Your Honor -- and this was a discussion we had during the *Mills* argument -- I would say that the great weight of the evidence in this district and in the Fifth Circuit is that it's not use the product; that but for the inadequate warning, the doctor would not have used the product.

Now, the plaintiffs cite two cases they say are opposite of that, that it would change the conduct in terms of the counseling information or that the doctor would have provided a different warning.

THE COURT: I tell you why I think about that, Mr. Ratliff. When I go to the doctor and I have an earache, he might give me amoxicillin or Rocephin. We don't have a discussion.

MR. RATLIFF: Right.

THE COURT: The people that I know that took chemotherapy, that's a very different discussion that you have with your doctor for, I think, very obvious reasons. There is a very rich conversation about risks and benefits and what this may mean to you long term, what are the downsides.

I understand learned intermediary. Would he have prescribed the same thing? Well, yes, if I thought something, I might still prescribe amoxicillin. But in my view -- and maybe you need to just explain this to me -- I

11:07

would think when you are prescribing a chemotherapy regime, there is a more robust conversation between oncologist and patient.

MR. RATLIFF: Your Honor, that may very well be the case. There may be a more robust discussion. I don't think that point, though, is necessarily relevant to the learned intermediary doctrine.

THE COURT: But doesn't it go to conforming your behavior, whereas when a doctor looks at the risks associated with a chemotherapy drug and --

MR. RATLIFF: Your Honor, I think all that goes to is the decisional calculus of the doctor and what they are going to convey to a particular patient on an individualized basis.

THE COURT: Okay. Fair enough. What they would have conveyed to the patient.

MR. RATLIFF: What they would have -- and that's in the doctor's discretion.

THE COURT: Then the patient makes an informed decision.

MR. RATLIFF: Correct, Your Honor. That's part and parcel of the learned intermediary is the doctor is the one who takes that information and forms their "decisional calculus." That's the language that's used.

THE COURT: Because sometimes, I have to tell you, when you read about learned intermediary, the question is,

11:08

well, would the doctor have prescribed it. Well, maybe it would have been his first recommendation. The question as to whether or not he would have prescribed it is whether he had buy-in from his patient and consent to proceed down that road.

MR. RATLIFF: I agree, Your Honor. I do think that we talked about this a little bit last time, as it talks about what goes on in that discussion.

THE COURT: Sure.

MR. RATLIFF: We are talking about chemotherapy, and no one has asserted in any of these pleadings that either one of those patients simply would have refused chemotherapy or any option. So this isn't a situation of --

THE COURT: Right.

MR. RATLIFF: -- "Mr. Ratliff, you can take an anticholesterol drug with all these side effects or maybe you should run more and have a better lifestyle."

THE COURT: Right. Right.

MR. RATLIFF: These are my two options. Take it or don't take it. So I think we are a little bit different there.

All I would say is that the great weight of the law in this district talks about it in it would not -- the doctor would not have prescribed the product. The two cases that the plaintiff cite saying, no, Sanofi's construction of that is too narrow, one was *Xarelto*, which that is different than this case. The doctors testified that, yes, they still

11:09

would have prescribed Xarelto, but that's not the issue. The issue is if they had known about this PT test, they would have used that PT test, still prescribed Xarelto, but avoided the injury.

The other case they cite, *Frischertz*, was the one outlier case that says, "I would have given a stronger warning," and most importantly -- and this is a point that is missing in the *Earnest* case -- "I would have given a stronger warning," and the patient came forward with affirmative evidence that if given that warning, they absolutely would have not taken that drug.

THE COURT: Right.

MR. RATLIFF: Your Honor, I would say that is not the standard in this district. I would say even if you accepted that case as applicable here, it's not applicable to these particular facts as it relates to Ms. Earnest and Ms. Francis.

So getting back to the idea of was the Taxotere label inadequate, was it adequate, I don't think that's a discussion that we have to resolve here today. We think it's adequate. We think it's always warned of hair loss. There's never been any restrictions on it. Fine counsel here think I am wrong.

In this issue, though, for Ms. Earnest, we don't have to get to that point because whether the label was adequate, whether it was inadequate, was it the medical or

11:10

legal cause of Ms. Earnest's injury, and the issue here, Your Honor, is this. Dr. Carinder, her oncologist, testified that he had read the Taxotere label once, when it first came out on the market. That was 1996. He estimated it to be '99 or 2000. So in the 10 years, the 11 years, maybe the 12 years between the one time he read the label, where the warnings would be about hair loss -- whatever that adequate warning plaintiffs' counsel say it should be, whatever FDA has said it should be -- he never read the label. That, Your Honor, gets us into no matter what was in the label, no matter what Sanofi put in the label --

THE COURT: He did read it one time.

MR. RATLIFF: He read it one time, Your Honor. What plaintiffs do not put in their opposition, nor can they, is that reading it one time in 2000, that there should have been a warning in 2000 about permanent hair loss or whatever they might say it is. They don't make that argument in their opposition, Your Honor. They certainly cannot because their own labeling expert, Dr. Kessler, says best case scenario the label should have been updated in 2006, as late as 2009. That's why you do not see that in their argument, this idea that, well, sure, you read it in 2000, that's good enough.

The reality, Your Honor, is this. Between 2000 and 2011, Sanofi could have put a black box warning in bold print, "Taxotere causes permanent hair loss." Dr. Carinder

11:12

would not have reviewed it. Sanofi could have cribbed directly from the master complaint and said, "Taxotere causes severe, disfiguring, permanent alopecia and hair loss." Dr. Carinder would not have read it. Your Honor, Sanofi could have put in the warning any time between 2000 and 2011, "Don't give this drug to Ms. Earnest. It's going to cause all of her hair to fall out and it's never going to come back." Dr. Carinder wouldn't have read it or conveyed that to Ms. Earnest.

Case after case after case, Your Honor, has said that plaintiffs' presumption, the heeding presumption that they talk about in their opposition, it's a rebuttable presumption.

THE COURT: Right.

MR. RATLIFF: One of the things that rebuts it is if the warning -- the stronger warning, the more adequate warning, whatever that might be, if it would have been futile. So if a doctor doesn't read it, it's futile; they lose. If the doctor even knows of the risk but doesn't read the warning, they lose. If the doctor doesn't know of the risk but doesn't read the warning, they lose.

I believe it's the third case down. Even if the doctor just says, "I don't recall reading the label," courts have said routinely that breaks the causal chain, and that's a fact the plaintiffs' opposition concedes. This is from plaintiffs' opposition, the "presumption may be rebutted with evidence showing that an adequate warning would have been

11:13 futile under the circumstances," just as here.

I would like to thank plaintiffs' counsel for citing a case that we did not cite, which is *Bloxom v. Bloxom*, which is the classic case in Louisiana of a person whose Camaro burned down, filed a lawsuit, and the court said, "That's all great and wonderful, but there's no evidence that you ever read the owner's manual. There's no evidence you read the warning. Case cannot go forward."

That's exactly the case that we have here with Ms. Earnest and, as I will talk about more briefly, with Ms. Francis as well. This issue right here, Dr. Carinder's unwillingness to read the label, no matter what that warning would have been, is dispositive.

Now, Your Honor, even if you want to take that aside, you want to put it over here and say, "Mr. Ratliff, I get you. I want to move on to what happened," plaintiff must still show that Dr. Carinder, her oncologist, would not have prescribed Taxotere to Ms. Earnest in 2011 -- that's our relevant time, 2011 -- had he received an adequate warning. Your Honor, there is simply no evidence before you that Dr. Carinder has ever testified that he would have changed his prescribing decision in 2011 before he prescribed this to Ms. Earnest. That evidence is devoid from the record.

Now, the plaintiffs, their whole opposition, what it rests on, Your Honor, what is cited time and time again

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on page 137 and 138 of Dr. Carinder's deposition, is his response to this question:

"**QUESTION:** Would you prescribe Taxotere to Ms. Earnest again if she presented with you today?"

In fairness to Dr. Carinder, he said:

"**ANSWER:** No. I would give her a different drug today, partially because of what I have heard on the media of permanent hair loss, but partially because there is now an alternative treatment available, Taxol every one week, which reduces the risk of neuropathy."

Your Honor, while it is fascinating what Dr. Carinder would do today, what he might do tomorrow, what he might have done last year, that is not the question before us. It's would he have changed his prescribing decision in 2011. You can read through his entire deposition, and you will not find any of that testimony. That's because the plaintiffs did not ask the question they should have asked.

They should have taken the 2015 label, the current label that says cases of permanent alopecia have been reported, shown that to Dr. Carinder and said if that had been the label, the current FDA-approved label that mentions permanent alopecia -- "If that had been the label in 2011, would you have prescribed Ms. Earnest a different product? Would you have given her a different chemotherapy?" And even, Your Honor, to be generous to what you mentioned, "Would you

11:16

have changed your counseling decision? Would you have given her a different warning?" That question, Your Honor, was not asked, that evidence is not here, and that is a threshold issue as it relates to Barbara Earnest's case.

The other thing that is left out of plaintiffs' opposition, Your Honor, is -- and we talked about this last time in the *Mills* argument -- was there a safe and effective alternative in 2011. Dr. Carinder testified there was not. There are two options -- we have now heard about them a lot -- Taxotere, Sanofi's product, and there's Taxol, the other taxane. Those are the two options in adjuvant chemotherapy.

Here is what Dr. Carinder said in 2011, Your Honor. Not today. 2011. "We didn't have paclitaxel approved for using it weekly back in the day when Ms. Earnest was treated." That's changed now. That indication is approved now. He said, "I used docetaxel more because you had less risk of infusion reactions, a severe side effect, and you had less neuropathy. If you can avoid the neuropathy and the infusion reactions, of course I'm going to use Taxotere."

Do you know who had severe neuropathy then and who has severe neuropathy now? Ms. Earnest. So at the time the regimen that was available was Taxotere. The regimen plaintiffs say she should have been given, Dr. Bosserman says she should have been given, was not available and not approved, and came with significant side effects.

11:17

Likewise, Your Honor, Dr. Carinder conceded even if she had received a different option, there's no way to say she would be alive today. Even if she was given a different chemotherapy regimen, there's no way to say her hair would be any different than it is today. There is no evidence that there was a viable option that was equally efficacious that also might not have produced the same hair loss that Ms. Earnest is alleging she has today as a result of Taxotere.

This gets to the other question that you were asking about, which is if you change your counseling decision, step one. That's the *Frischertz* case that they rely on. The second part of that, Your Honor, is the patient has to come forward with evidence that they would have changed their decision.

THE COURT: Right.

MR. RATLIFF: They would not have taken Taxotere. You will find nowhere in plaintiffs' opposition, because it is not in the evidence, that Ms. Earnest has ever testified that she would have done something different, and by doing something different meaning not taking Taxotere. Not that "I would have thought about things" or "I might have considered different side effects," that doesn't get you there; that you would not have taken the product. That's the evidence that was submitted in the *Frischertz* case that got them over that hurdle.

Here is what Ms. Earnest said about what she

11:19

would have done or what she did do. She said, "I was going to do whatever I was told. I would do whatever Dr. Carinder told me to do." She was not asking follow-up questions. "If you tell me I'm taking this, if you tell me I'm doing radiation, if you tell me I'm doing chemotherapy, I'm doing what Dr. Carinder tells me to do."

These are the risks that Ms. Earnest consented to when she took Taxotere. She knew it could cause death. She knew it could cause paraplegia. She knew it could cause brain damage, cause bleeding. It could cause damage to vital organs. She accepted all of those risks when she took Taxotere. She knew they were significant, she accepted them, and she went forward with Taxotere.

One of the things, Your Honor, that you mentioned previously or we talked about previously was the idea that a patient now 10 years out from taking chemotherapy can look back in hindsight and say, "Well, if I had known this, accepting all of these risks, that would have changed my mind. This one risk would have changed my mind," the benefit of hindsight bias. But Louisiana has articulated -- and certainly this isn't a med mal situation -- that you have to use an objective standard. You have to use a reasonable patient standard.

That's something to be thinking about both in this case and in the *Francis* case. It's not necessarily what

11:20

the patient says 10 years down the road when they are cancer free and they can look back at the risks and say, "That would have changed my mind." It's what would an objective patient do at the time when presented with all these risks --

THE COURT: Is that something to be decided at summary judgment? I understand what you are saying, and that's a really good argument to make at trial of this matter. But if I have testimony from someone saying, "I would have done something different. I would have sought a second opinion" --

MR. RATLIFF: Your Honor, this is just a cherry on top of my argument right here. So this is what Ms. Earnest actually testified to: She said she was concerned about neuropathy, which is what Dr. Carinder testified was a worry with Taxol; she did not seek a second opinion for chemotherapy treatment; and she does not know that she would have taken an alternative chemotherapy, even if presented with the option, based on the side effects of that drug.

The answer she gave was: "I don't know what I would have done. I don't know if I would have taken a different drug." That's the missing element of the one case they rely on in this district that says a change in the counseling will get you over the hump as long as you have a change in what the patient would do.

THE COURT: Right.

MR. RATLIFF: So anyways, Your Honor, I would say

11:21 plaintiffs bear the burden to show that a proper warning would have changed the decision of Dr. Carinder in 2011. That evidence is not here, and that's not even considering the fact that he doesn't read the label and has not read the label in the last 11 years.

I get to Ms. Francis. I will try and race through this because I know plaintiffs' counsel wants to talk too. The same two-part test. Dr. Verghese -- which Ms. Byard talked about. Many of the issues here are the same, but there are some subtle differences between this and *Earnest*, one particular one.

One, we have the same issue of Dr. Verghese testifying he does not recall the last time he read the label. Importantly, he doesn't consider what's in the label "meaningful" to treatment. So the idea that he has not read the label gets us right back to the courts that have said any adequate warning, any stronger warning, whatever plaintiffs might suggest the warning should be, that makes it futile.

That's one part of it. He has never read the Taxotere label in its entirety. He doesn't think it's relevant to treatment. He doesn't recall the last time he read it. That alone, we believe, is going to be dispositive in *Francis* just as it was in *Earnest*.

The other thing that we have seen in plaintiffs' opposition is the idea that sales reps can come in and somehow

11:23 circumvent the learned intermediary doctrine. Dr. Verghese addressed that to plaintiffs' counsel's question and said, "I don't rely on sales reps from drug companies to tell me what are meaningful side effects. I get those on my own." So if you look at he doesn't read the label, he doesn't rely on sales reps, that right there would not change whatever warning Sanofi put into the label.

The second part, Dr. Verghese was certainly aware of and warned patients that their hair may not grow back. He knew of the risk. He knew there was a risk with chemotherapy. When a prescribing physician was aware of the possible side effects of the drug yet chose to use them regardless of the label, as a matter of law the warning was not the proximate cause of the plaintiffs' injury.

This is a situation where Dr. Verghese was asked by plaintiffs' counsel, "Is it your general understanding with Taxotere that alopecia is temporary?"

He says, "It's common, but I would not call it temporary. I never tell people it's temporary. *Temporary* is not the word I would use when I counsel patients, patients like Ms. Francis, about the side effects of hair loss with Taxotere or any chemotherapy."

He describes what his counseling procedure is. He says, "It's not appropriate to expect normal hair growth. I don't use the word *temporary*." In fact, he goes so far as to

11:24 say, "You know what you should do -- because you don't know if your hair is going to grow back because I only see 80 to 90 percent of patients' hair grow back -- you should go out and take preventative measures and make yourself a wig because your hair may return differently." So he certainly was aware that there was a risk with multi-agent chemotherapies, the same type of multi-agent chemotherapies Taxotere is used with and that it was used with Ms. Francis.

Similarly to Ms. Earnest, there is not the testimony in this case, in the *Francis* case from Dr. Verghese, that had there been a different warning, he would not have prescribed the product, he would not have given her a different product. That question, just like in the *Earnest* deposition, was never asked.

"Dr. Verghese, here is the current label. Here is the FDA-approved label that mentions permanent alopecia. Would you have changed your prescribing decision?" The question was not asked and there's no testimony on it and there's no evidence in the record for Your Honor to consider. That is something that the plaintiffs must show, that they would have changed their prescribing decision.

What Dr. Verghese did testify to was that the Taxotere regimen that he prescribed was the most studied, it was the preferred treatment, it had gone to a tumor board with 10 oncologists who said this was Ms. Francis' best option, and

11:25

this is the one he would recommend to Ms. Francis for the best case of survival.

So was there a safe and effective alternative option for Ms. Francis? Your Honor, there's no question about it. When Ms. Francis testified in her deposition, she said, "If he had told me that Taxotere causes hair loss, I would have sought a second option." I'm not going to pretend like that testimony does not exist, but there is a salient point here that I think Ms. Byard brought up, which is Dr. Verghese said she had three options: the Taxotere option, which he found to be the preferred, best option; a dose-dense AC followed by Taxol, which he said was -- I forget the exact words -- debilitating; and then an AC followed by weekly Taxol, a third option.

I think what is paramount here and what is important to consider is that Dr. Verghese testified repeatedly that if there was a risk of permanent hair loss with Taxotere, that same risk would be present with the only other option, the Taxol option, and he would give the same warning as it related to Taxotere or as it related to Taxol.

So when we talk about the patient counseling decision, if you want to take the learned intermediary that far -- if you want to say it just doesn't require changing the product but changing the patient counseling information -- I think what balances out against Ms. Francis' deposition

11:27

testimony that was not available when her deposition was taken is that her prescribing oncologist's opinion was, "If it appears in one taxane, I'm going to give the same warning to the other taxane."

So now Ms. Francis is presented with the issue of there are two options. And to Dr. Verghese, her prescribing physician, they both have the same risk of permanent hair loss to him. I think that is sort of the unique element to this case, that even though the case that plaintiffs cite we believe is an outlier -- we do not think it's accurate, we don't think it is what tracks the majority of the Eastern District and Fifth Circuit about using the product versus counseling information -- the reality is she would have got the same counseling information as to both alternatives. There was not an alternative, Your Honor, that didn't have a risk of hair loss, permanent hair loss. That, Your Honor, I would say is what gets us, the defendants, over the hump and is dispositive of the learned intermediary as it relates to the *Francis* case. Thank you, Your Honor.

THE COURT: Thank you.

Mr. Schanker.

MR. SCHANKER: Good morning, Your Honor.

THE COURT: Good morning.

MR. SCHANKER: I'm Darin Schanker on behalf of Barbara Earnest and Tanya Francis.

11:29

Your Honor, your questions really demonstrated -- you hit the nail on the head. Defense is conflating this concept of a prescribing doctor recommending a drug and actually prescribing a drug. There's a big difference between that. What the defense is really kind of trying to gloss over is ignoring the important concept, which you touched on in your questions, of patient choice. You can't dismiss patient choice from the Louisiana interpretation of the learned intermediary doctrine, and really that's what the defense is doing.

As we break down their argument here, you can see that that is the big flaw in their legal analysis, which I would like to go through, and then there's a couple of factual inaccuracies that are clear in the record that I would like to make sure and clarify for the Court.

I will try to stay organized and clear with regard to Tanya Francis and Barbara Earnest since we are making both of these arguments at the same time. By the way, Dr. Verghese is the way we pronounce the prescribing doctor for Tanya Francis.

THE COURT: I'm glad to know that because I didn't know.

MR. SCHANKER: Yes. We have heard several different pronunciations and Dr. V, but Dr. Verghese is how we pronounce it.

11:30

So really what defense has put forward is this overly strict interpretation of the learned intermediary doctrine that we saw in the briefs and heard in the courtroom. Really what they would have you believe, the defense would in their arguments, is if Dr. Verghese, if Dr. Carinder today prescribed Taxotere, then we can't satisfy the learned intermediary doctrine, and that's simply not what the doctrine is.

Specifically, the cases that are cited in the briefs -- the *Willett* case, the *Huffman* case, the *Rhodes* case -- the learned intermediary doctrine under Louisiana law basically says that if the doctor is given an adequate warning that the doctor would not have prescribed the drug. Would not have prescribed the drug. It's not using the word *recommended*. It's would not have actually prescribed the drug.

Looking back retrospectively in this specific case, in the *Francis* case and in the *Earnest* case, when we walk down the logical steps of the record, would the doctor actually have prescribed the drug or not? Clearly there's a question of fact on this issue, and that's why these motions should be denied.

Specifically, we also heard counsel for the defense dismiss the *Xarelto* case and the *Frischertz* case, at least in the *Frischertz* case claiming it's an outlier, when the fact is that those cases are clearly interpreting what went on

11:31 in the situations we have here with *Francis* and *Earnest*. They get into the nuance of the heeding presumption which we heard mentioned, that particular analysis that's laid out in those important cases -- that are district court cases right out of this courthouse, Your Honor -- and that's that the doctor would have acted differently, changed his or her advisory, deferred to the patient's wishes. That gets into this patient choice concept, which the defense has been ignoring.

So specifically what I would like to do is go through the record on both Francis and Earnest, walk through the record specifically on Francis and Earnest just step by step and see do we satisfy learned or not.

THE COURT: What do we do, Mr. Schanker, with Ms. Earnest's physician -- I don't remember his name -- who said, "I don't read the labels"?

MR. SCHANKER: Right. So Dr. Carinder read the label in 1999, 2000, in his mind when he started using the drug Taxotere. It doesn't mean that he doesn't stay updated. In the 21st century, how the doctors stay updated, are we expecting the doctors on a yearly basis are going to go back and read the label of every single drug that they prescribed? Or might it be, as Dr. Carinder lays out clearly, that doctors in the 21st century get updates? Online updates from ASCO is what Dr. Carinder specifically refers to. That's the American Society of Clinical Oncologists.

11:33

Dr. Carinder explains that he get updates on label changes in that specific manner. As a matter of fact, that's how he found out in 2015, the record is clear, that as well as media attention, how he determined that the label had changed and that there had been a warning of permanent irreversible hair loss associated with Taxotere.

That right there is evidence of how Dr. Carinder would have -- let's say that that label would have been changed, as the plaintiffs claim it should have been, years and years earlier, prior to 2011, when he provided this treatment to Barbara Earnest. Dr. Carinder would have had knowledge and would have warned accordingly.

By the same token, Dr. Verghese, it was brought up by counsel -- if I may, Your Honor, since we are on that topic -- that Dr. Verghese doesn't read the entire label. You had the privilege of having the label in the record, the hundred-plus pages of the label. What Dr. Verghese explains is there's really important stuff in that label from an oncologist's standpoint and then there's stuff that's not so important.

What Dr. Verghese does is he reads the important parts of the label, that that goes to risk/benefit analysis and effectiveness, efficacy for a patient, and also that he knows about updates to the label as well. Dr. Verghese claims that he knew that this information about permanent hair loss had

11:35 started to surface in -- he estimated four years prior to his deposition. The deposition was in 2018. So Dr. Verghese learned sometime around 2014 or so of this risk of permanent hair loss and then began advising patients accordingly. So the factual argument that the label change would have made no difference is in no way supported by the record, and there's certainly a question of material fact that survives summary judgment on that particular factual issue.

The defense goes on to articulate with regard to the *Tanya Francis* case -- we heard this -- that Dr. Verghese did not know about permanent -- oh, specifically, I'm sorry, that Dr. Verghese had knowledge of permanent hair loss -- that Dr. Verghese had knowledge of permanent hair loss, the defense claims, back at the time that he treated Tanya Francis in 2009. Black and white, the record of Dr. Verghese's deposition is clear to the contrary.

Specifically, on pages 105 and 106 of his deposition, Your Honor, Dr. Verghese is asked by counsel:

> **"QUESTION:** At the time you were treating Ms. Francis in 2009, did you have any reason to believe that Ms. Francis may experience something aside from temporary hair loss?
>
> **"ANSWER:** No."

Clear question on the issue:

> **"QUESTION:** Did you have knowledge about permanent

11:36

hair loss?

"ANSWER: No."

So as we work through that analysis of the steps of learned intermediary specifically for Tanya Francis, if Dr. Verghese had been informed by Sanofi, by the defendant, if Dr. Verghese knew, what would he have done with that information? Would he have advised the patient, which is what the standard of learned intermediary law lays out?

Dr. Verghese says on page 48 of his deposition, "Yes, I would have advised the patient." How do we know that? Because Dr. Verghese specifically explains that if he is aware of a permanent side effect, that's a big deal, and he tells the patient about that. So clearly, following the logical steps, if Dr. Verghese had been informed by Sanofi that there's this permanent risk, this hair loss permanent risk associated with Taxotere, he would have advised the patient.

So the next step in the learned intermediary analysis then is, okay, so Tanya Francis is informed. What does she do with that information? Tanya Francis specifically states that she would have told -- on page 287 of her deposition that she would have said, "I want another option." She was interested in an option that doesn't cause this risk of permanent loss. That was important to her.

Dr. Verghese then explains that he would have advised her of other options. This is very important, other

11:37 options, because we heard defense counsel basically put a false choice before you, that it's either Taxotere or Taxol.

Now, Taxol is a viable option for Tanya Francis on the NCCN Guidelines -- which, by the way, there are a dozen other combination therapies that are listed aside from the one that Tanya Francis took, and you have this in the record. I believe it's Exhibit B, Your Honor, the 2009 NCCN Guidelines for Tanya Francis. Of those dozen or so options, half a dozen of those don't involve Taxotere, and there are three of those, three or four, that don't involve Taxotere or Taxol.

So to try to put forward a concept that there were no options available other than Taxotere or some concept of some other drug that might cause hair loss is just not what the record supports in this case. Tanya Francis had other options available to her. Dr. Verghese explains if a patient asks about it, he actually goes and does the research. The research, the record is clear that there is nothing in there containing side effects of permanent hair loss with other drugs aside from Taxotere. Dr. Verghese would have honored Tanya Francis' request.

So the long and short of it, when you go back to the legal analysis, is would Dr. Verghese then have made a different prescribing decision. As we walk through the steps, it's clear that Dr. Verghese would have recommended and then ultimately prescribed a different drug than a Taxotere-based

11:39 combination and, therefore, summary judgment is survived in this case, the motion.

A similar analysis, Your Honor, for Barbara Earnest and, again, patient choice here. It's not a situation where the doctors are holding these women down and injecting them with the drug against their will. It's a choice. So Dr. Carinder makes it clear. Dr. Carinder did not know about the risk of permanent hair loss. On page 41 of his deposition, the question is asked:

"QUESTION: In 2011, were you aware of any chemotherapy drugs at all that carried a risk of permanent hair loss?

"ANSWER: No."

Dr. Carinder had no knowledge that Taxotere caused permanent hair loss when he prescribed it back in 2011, contrary to assertions by the defense.

So what would Dr. Carinder have done with this information? He indicates if he knew about it, he would have warned Barbara Earnest. That's on page 166 of his deposition. Page 166, 167, he says he would have given her a choice.

Now, we heard about this choice of Taxol, and Dr. Carinder does say that today, looking back retrospectively -- on page 138 in his deposition, looking back retrospectively, today he would prescribe Taxol. He also says that the dosages that were available back in 2011 might have

11:41 led to neuropathy, and he would have advised the patient of that, but then that's patient choice again. He doesn't say that Taxol was off the table, that a Taxol-based therapy was off the table. Dr. Carinder says, "I would have given her the choice."

Barbara Earnest then, contrary to what we had asserted by counsel -- in the record that you have, in her deposition, Barbara Earnest specifically addresses the issue of what she would have done if she had been given the information by Dr. Carinder. I'll just read that, Your Honor. That's specifically on page 102 of her deposition, the record that you have, this question to Barbara Earnest:

"QUESTION: Did you tell Dr. Bianchini that if you had known this treatment caused permanent baldness, you would have asked if there was another drug that could cure your cancer that did not cause permanent baldness?

"ANSWER: Yes. If I knew that it caused -- if I knew that drug I was taking caused permanent baldness, anybody would.

"QUESTION: And that's something you told Dr. Bianchini?

"ANSWER: Yes.

"QUESTION: And so it's your opinion in 2018 that that's something you would have said to Dr. Carinder in 2011?

11:42

"**ANSWER:** Yes."

So the record is clear Barbara Earnest indicates that she would have asked for another option that didn't carry with it the risk of permanent hair loss.

Then working through the exchange, Dr. Carinder indicates he would have honored that request. We get to the same point again that the prescribing medication would have been different than Taxotere. From a factual standpoint, learned intermediary is satisfied, and we survive summary judgment.

Your Honor, we heard counsel make a distinction specifically between lines of cases that were cited, the *Xarelto* case and the *Frischertz* case. In their reply brief, for the first time they raise the distinction between, you may recall, a preventible risk and an unavoidable risk, and claim that in this case what we are dealing with is an unavoidable risk, which I found interesting being that we have *Daubert* motions that have been filed that say that there is no causation with regard to Taxotere, but now in this motion we have an argument that Taxotere causes an unavoidable risk.

Aside from that, as we move forward on that issue, if we even accept that law that they cite, which is *Thomas v. Hoffmann-La Roche*, a 1992 Fifth Circuit case interpreting Mississippi law not Louisiana law -- but if we even accept the unavoidable risk compartment that they are

11:43

trying to place this analysis in, the analysis specifically asks the question: Was the risk high enough that it would have changed the treating physician's decision to prescribe the product in this case? So was it a high enough risk that the docs would have acknowledged it, done something about it, advised about it, and potentially changed the prescribing pattern, the drug that was prescribed?

We have evidence in this case, again, from both doctors that certainly the risk was high enough. They have indicated, both Dr. Carinder and Dr. Verghese, that if they knew about this risk of permanent hair loss that they would have advised the client of it, so that risk is absolutely satisfied.

A couple other points, Your Honor. We heard about sales reps and sales reps making visits, and we saw some testimony on Dr. Verghese's opinion concerning sales representatives. In the record you also have testimony from Dr. Carinder concerning sales reps.

We see Dr. Verghese says, "I don't listen to sales reps," and certainly that's his prerogative.

Specifically with regard to Dr. Carinder, Dr. Carinder indicates that if it's a respected sales rep -- and in his depo in the record you have he is talking about Ruth Avila, a particular sales representative that he had a professional relationship with that visited him often -- that

11:45 he would absolutely accept that information. If Ruth Avila, sales representative, had told Barbara Earnest's prescribing doctor, Dr. Carinder, about this risk of permanent hair loss, that's something he would have taken seriously.

So he indicates that is another avenue -- we have this kind of narrow perception the defense is trying to create that the doctors have to be poring over these labels on a regular basis to stay updated, ignoring the fact that in the 21st century there's other avenues for them to get updates, other avenues for drug companies to let them know what's going on with regard to a label.

Your Honor, basically that covers the issues that I saw as important and imperative. If you don't have any questions or comments, then thank you for your time. On behalf of Barbara Earnest and Tanya Francis, plaintiffs respectfully request that you deny defendants' motion for summary judgment. Thank you, Your Honor.

THE COURT: Thank you.

MR. RATLIFF: Your Honor, may I address just a few quick points?

THE COURT: Quick points.

MR. RATLIFF: Yes. Your Honor, to address the point that Mr. Schanker raised about the fact that Dr. Verghese and Dr. Carinder, while they may not have read the label -- and in Dr. Carinder's case hadn't read the label for a decade -- that

11:46

there are other avenues of information, anticipating that, I wanted to read back to you something from one of the cases that we cited about this exact issue that Mr. Schanker raised.

"Plaintiff instead speculates about other ways an adequate warning might have reached Dr. Collini and altered her decision. She suggests, for example, that a modification to MCP's warning label might have come up in conversations with other physicians or have been discussed at a continuing education seminar. Certainly those scenarios are possible. Ultimately, however, without any summary judgment evidence to support them, they remain nothing more than possibilities."

That's exactly what we have here, Your Honor.

THE COURT: Isn't that a little different from Dr. Verghese's testimony saying, "I was aware of this because of notices on ASCO's website," which talks about warnings from the manufacturers? That's a little different to say, "I might have talked about it at a cocktail party after some continuing education seminar."

MR. RATLIFF: For example, Dr. Carinder, I know it was represented that he learned about the label change from ASCO. There's nothing in the testimony that says he learned about a label change. He said, "I heard about permanent alopecia from media reports, from litigation, and I followed up with ASCO," whatever it might be, but nothing about the actual substance of the label. So what he is hearing from attorney

11:48

advertisements is not a substitute for actually reviewing the label back in 2011.

With Dr. Verghese, I would say it is the same thing. He learned about something from ASCO. I don't know how the testimony you are looking at -- I don't recall him saying, "I learned about the label change. I learned about a difference in the label."

"I just learned that there was a risk of permanent alopecia or a potential risk of permanent alopecia with Taxotere," which he says was in 2014. The label for Sanofi, for Taxotere, to add permanent alopecia was added on December 12, 2015. So whatever he is learning from ASCO is not something that's coming from Sanofi and is not something that is derived from the label.

The only other point, I think, Your Honor, I would make is this. At the fundamental level, the duty of the manufacturer, the duty of Sanofi, runs to the doctor. The duty to warn runs through the doctor. The idea of just "informed consent, informed consent," that undoes the entire learned intermediary doctrine is not accurate. Here's what I say. Simply because you would have asked for other options, that doesn't get you down the road to saying, "I would have taken another drug that would not have produced the injury I'm alleging here."

That maybe gets you a little bit down the way,

11:49

but it doesn't get you to the point of saying, "Had I been able to get another drug, there was another drug that had not this risk and, therefore, I don't have that risk." So simply the constant use of "informed consent, informed consent" as if it is an elixir for the heavy burden of learned intermediary, it just does not get plaintiffs to that point.

The last thing I will say, Your Honor, and then I will close is I think one thing you need to be aware of certainly in the *Earnest* motion and the testimony that was elicited about the sales rep, Ruth Avila, elicited from Dr. Carinder about would he have changed his warning at the time -- and you will see this in the opposition and you will see it as well in the depositions -- all of those questions were asked to Dr. Carinder in the opposition with a qualifier.

"If you had been told that Taxotere causes permanent hair loss in a significant patient population, would you have given a different warning? If Ruth Avila had told you that Taxotere causes permanent alopecia in a significant patient population, would you have listened to Ruth Avila?"

Well, Your Honor, plaintiffs have not quantified what a "significant patient population" is or even what that term means. To the doctor, does it mean 90 percent? Does it mean 80 percent? Does it mean 50 percent? That's certainly not the language that is in the label today, which just says cases of permanent alopecia have been reported, not that

11:50

Taxotere causes permanent alopecia in a significant patient population, whatever that might be. So there is no evidence to support what are essentially counterfactual hypotheticals posed to Dr. Carinder.

I could probably walk into any doctor's office and say, "Well, if you knew Drug X caused you to all grow a third eye in 100 percent of patients, would you advise patients?" Well, certainly a doctor is going to say that. So I want you to be aware of that when you are looking back through the briefs and looking at the evidence that's done, is that much of that testimony in the *Earnest* case is built upon sort of a hypothetical foundation that doesn't comport with the evidence and doesn't comport with reality.

THE COURT: Thank you.

MR. RATLIFF: Thank you, Your Honor.

THE COURT: Who is handling the prescription issue?

MR. COFFIN: Mr. Nolen is for us, Your Honor.

THE COURT: I am sorry. We dropped the ball. I should have told you that there were going to be time limits and that didn't happen. I have got to be at this meeting. It's from 12:00 to 1:00. We are going to be at recess until five after 1:00. Is anybody catching a plane before then? Maybe that will make you talk faster. Do you have a plane to catch?

MR. NOLEN: At 3:30, Your Honor.

11:52

THE COURT: Oh, you will be out.

MR. STRONGMAN: My flight is at 3:30 too.

THE COURT: Okay. You see, you guys are really going to talk quickly. I'll be back as soon as I can. 1:00. Court is at recess.

(Lunch recess.)

* * *

AFTERNOON SESSION

(May 22, 2019)

THE COURT: Court is in session.

Mr. Strongman.

MR. STRONGMAN: Thank you. Good afternoon. Again, I will try my best to be brief.

THE COURT: Especially since you have a flight.

MR. STRONGMAN: Absolutely. Thank you, Your Honor. Jon Strongman on behalf of Sanofi.

Your Honor, these two cases present very similar prescription questions, both in terms of the facts and the law. Frankly, they parallel the same types of prescription questions that we already addressed in the *Johnson* argument, very similar situations with both Ms. Earnest and Ms. Francis as we saw with Ms. Johnson; namely, Ms. Earnest and Ms. Francis were both, as they say in the briefs, painfully aware of their hair loss within six months after stopping chemotherapy. That's undisputed. That's in 2012 and 2010 respectively.

Both Ms. Earnest and Ms. Francis always believed that chemotherapy was the cause of their hair loss. Again, that's undisputed. Both Ms. Earnest and Ms. Francis also knew that Taxotere was part of the chemotherapy regimen that they received. Despite the fact that they were painfully aware of their hair loss, Ms. Earnest and Ms. Francis did not do anything to investigate the injury or the damage for many

01:03 years.

THE COURT: Let me ask you something, Mr. Strongman.

MR. STRONGMAN: Yes, of course.

THE COURT: I read Ms. Francis' deposition with care. It seems to me she says, "I knew my hair wasn't growing back. I went to my oncologist appointment. I talked to the PA, and she said, 'You need to see your family doctor.' I see my family doctor and she says, 'Maybe you need to see your dermatologist.' The dermatologist says, 'I think there's things we can do for this,'" and she is taking these shots.

It doesn't seem that she has an awareness that it's permanent. She knows she's lost her hair, but she is still thinking, from the way I read her deposition, that, Listen, this is not over yet and this could still be a temporary condition. I'm taking these shots, and I don't know if the shots -- I don't know what they are. I don't know. Maybe they were B12 shots -- that if you could just get your body healthier, your hair will grow back. How is that a recognition that this is a permanent condition?

MR. STRONGMAN: Well, there's two things to that. So the first thing, Ms. Francis ultimately sought some treatment --

THE COURT: Yes.

MR. STRONGMAN: -- after she filed her lawsuit. So Ms. Francis claims in the briefing and in her deposition

01:04

testimony that what triggered her notice, as they would argue in their brief, was a lawyer advertisement. So whether or not Ms. Francis has a firm belief that her hair loss is permanent or that it could improve or that her hair has continued to grow back -- which it has. She has a significant amount of hair. So the fact she hasn't come to a firm conclusion as to the full extent of it is not what the law requires.

The law requires that when she is aware that there is something that isn't right, she must do what she needs to to investigate. I think the quote under Louisiana law is "plaintiff is responsible to seek out who may be responsible" once you know something isn't right. So Ms. Francis may have determined that her hair has some opportunity to improve, which it very well may and maybe it is improving. That doesn't mean she wasn't on notice to bring a lawsuit.

THE COURT: Well, I guess my question is -- because this is a little different. This case isn't somebody that got run over by a Coca-Cola truck and lost their arm, where we know that's one thing. This lawsuit is: When did you understand it wasn't temporary? That's what my concern is, at what point did it change from this may not be a temporary condition, this is a permanent condition, and I think that's a continuum and why prescription issues -- we call it prescription issues --

MR. STRONGMAN: Understood. Right.

THE COURT: Prescription issues are so fact intensive

01:06

in this case.

MR. STRONGMAN: So I think when you look at both Ms. Earnest's case and Ms. Francis' case -- so we are going back to, for Ms. Francis, 2010, when she had stopped using chemotherapy; for Ms. Earnest, 2012.

THE COURT: Right.

MR. STRONGMAN: They both testified and knew that their hair was not as they wished it would be.

THE COURT: Right.

MR. STRONGMAN: They knew that their hair regrowth was not what they wanted. So at that point, while I understand there's a continuum towards what your final conclusion may be, the reality is once you have determined that what your expectation was and what has happened are apart, you were on notice to investigate.

So the fact that there may be a continuum between what we are in here today calling temporary and permanent, the reality is plaintiffs in this litigation don't either have all their hair or no hair. That isn't the circumstances that any of these plaintiffs present with.

THE COURT: Right.

MR. STRONGMAN: What they are presenting with is a claim that their hair is not what they believed it would be. So when there is a reasonable constructive knowledge, I think would be the word to use under the law, that your hair has not

01:07

grown back to your expectation and you knew that the reason your hair was missing was because of chemotherapy that you were then on notice to do an investigation.

What we know for both Ms. Earnest and Ms. Francis is that that investigation did not happen until after they filed the lawsuit. So clearly it can't take filing a lawsuit to trigger the statute of limitations or the prescription period. That doesn't make any sense.

So what we know is that there was certainly enough -- and I think in the brief the word that is used by both plaintiffs is "painfully" aware of their circumstance with their hair, going back to 2010 for Ms. Francis and 2012 for Ms. Earnest. So you're talking about years. We are not talking about missing the prescription period by a day or a month. We are talking about years.

Certainly there's evidence in the record that makes it clear that both Ms. Francis and Ms. Earnest understood that their hair was not as they expected and that they knew something was wrong and that that triggers under Louisiana law a duty to investigate, and neither plaintiff did.

The other thing that's critical is Louisiana law has actually addressed this temporary/permanent distinction in some regard. We have cited to you in our briefs the *Fontenot* case. This quote is out of there, where the plaintiff's contention is largely that "The doctor told me that this was

01:09

temporary, but if it's permanent, it's different," and the court said --

THE COURT: The gravamen of this complaint --

MR. STRONGMAN: Right.

THE COURT: -- is that it wasn't temporary; it was permanent.

Again, I read the *Fontenot* case, and I know that was a back surgery gone bad. I think they dropped a drill. This case, that's what this case is, when did it cease becoming temporary, and now that's the issue. So I think that's distinguishable.

Everybody loses their hair in chemotherapy. Well, we can say the vast majority of women that undergo chemotherapy, and men too -- I shouldn't say just women -- will lose their hair. The crux of this case is that it's permanent, and so the question in my mind is at what point did you realize this is no longer a temporary problem, but it's a permanent problem. That was not the case in *Fontenot*. The facts, I think, make that very different.

MR. STRONGMAN: So the other issue at play here is the standard. Under Louisiana law the standard is an objective one, not a subjective one. So it deals with what a reasonable person would think or believe or feel the need to investigate.

THE COURT: Right.

MR. STRONGMAN: Plaintiffs cannot overcome the

01:10 prescription period just by saying, "Well, I have this enduring hope that my hair will come back." That's not reasonable after four years, five years, six years. So a reasonable interpretation, a reasonable person would be on notice to investigate, if nothing else, under the terms of the complaint as it's pled, which defines the injury here.

The plaintiffs' complaint, it defines the injury as an incomplete hair growth six months after the cessation of chemotherapy. So to take those allegations on their face as the definition of the injury, you are at least into a territory where you have triggered a notice to do an investigation.

THE COURT: Let me ask this question. This is interesting to me because we have 11,000 cases, give or take. There is this master complaint. When you look at the face of the complaint, yes, but do we do any individualized assessment, where we look at the facts beyond that complaint to what the subjective knowledge was of the plaintiff and then whether or not their belief was reasonable, before we make a determination as to when prescription runs as to that particular plaintiff? Is that awkwardly worded?

MR. STRONGMAN: Absolutely.

THE COURT: I'm just hoping it was clear.

MR. STRONGMAN: I certainly understand and do not disagree with the Court that this is not an issue that we are asking you to decide for every single case at one time.

01:12

THE COURT: Okay.

MR. STRONGMAN: I understand that.

THE COURT: Let's go back to Ms. Francis. I guess this is because I'm seeing she is actively receiving treatment thinking this treatment should be successful. "My hair is going to come back, and so I'll going to wait it out longer." Then I wonder when is the magic point where you realize this is as good as it's going to get and --

MR. STRONGMAN: I understand that. I think the critical component for Ms. Francis' treatment is that it didn't happen until after she filed her lawsuit. So we are talking about a situation where that is not what she did to investigate whether or not she had a claim. It's not what she did to try to figure out what was going on. She already filed a lawsuit, and the same goes for Ms. Earnest. There is a timing component to it.

Certainly what we know is that both plaintiffs -- I think this is an important issue that plays into this, too, specifically with Louisiana law, is that both plaintiffs' claims, as the Louisiana law sets out, are prescribed on their face, which means that the plaintiffs bear the burden of showing that we have an exception.

THE COURT: Right.

MR. STRONGMAN: So the types of questions that Your Honor has asked, frankly, are questions that the other

01:14

side has the burden of answering, not the defendants. So when you're dealing with Louisiana law and that burden shift, which we have at play here, it's different. It really is a question that when there's an absence of evidence and when there is an open question about when this happened or when that temporary to permanent shift happened, that has to cut against the plaintiff's claim when it's prescribed on its face, which we have here due to the fact that the injury, as defined, occurred years and years before the plaintiffs filed their respective lawsuits.

So that's another reality that Louisiana law presents that I think is an important one to consider when trying to answer that question, but I certainly understand that there are and can be fact-specific issues that come up in every case that have a bearing on this question. Certainly Sanofi isn't asking you to disregard or discount that reality.

A couple of points I wanted to make. We covered the law with the *Johnson* case last time. I don't think there's much we need to cover on that again unless Your Honor has some questions.

Just for the record, a couple of points on Ms. Earnest:

"QUESTION: Again, did you ever think your hair loss is due to anything other than chemotherapy?

"ANSWER: No.

01:15

"QUESTION: You always thought the condition of your hair was related to the chemotherapy, correct?

"ANSWER: Correct."

The wrinkle with Ms. Earnest's case that, frankly, makes the statute of limitations motion in her case perhaps stronger for the defense than even in the *Francis* case is that Ms. Earnest had notice in her possession before she started chemotherapy of, at least as described in the information that she had, rare reports of permanent hair loss, which is essentially the same information that the plaintiffs claim triggered the whole litigation by being added to the Taxotere label.

So Ms. Earnest was provided this handbook by her doctor before chemotherapy. Now, it's very clear right here if you were to go look through the handbook -- it is a big handbook, but if you look through the index, it's not hard to navigate. If you want to know information about the drugs that you are taking, it's easy to find. Ms. Earnest had this handbook. She knew she was taking Taxotere and certainly was on notice that there were rare reports of permanent hair loss based on this book.

Now, Ms. Earnest may claim that she doesn't remember reading it, "I didn't read it cover to cover," etc., but I think the law supports -- and in some ways, again, to come back to the *Riviera* case a little bit -- when the

01:17 plaintiff is in possession of knowledge, the fact that it's in a drawer or hidden but not looked at doesn't entirely eliminate the fact that it exists and that it was available to them. So the Ms. Earnest case is, if anything, even stronger on the statute of limitations because she had information at her fingertips. Just like Ms. Francis, Ms. Earnest didn't investigate for years.

There were a couple of points that I saw in the briefing that I wanted to address, one being Dr. Carinder. So there's a lot of talk in the hypothetical about, well, Dr. Carinder didn't know X or Y; so had Ms. Earnest gone and talked to Dr. Carinder, he wouldn't have had any information to share with her. First of all, the Louisiana law says that isn't a requirement. You don't need a doctor to tell you you have a claim. That's first.

Second, this conversation never happened in reality. Ms. Earnest never went to Dr. Carinder and asked this kind of question, and you can see it here. Ms. Earnest was asked point-blank:

"QUESTION: You never had a conversation with Dr. Carinder where he said, 'I didn't know that persistent hair loss with docetaxel was a possibility'?

"ANSWER: No, I never had a conversation with him like that.

"QUESTION: You never had a conversation with anyone

01:18

outside of the attorney-client relationship to that effect, correct?

"**ANSWER:** Correct."

So what we know for both Ms. Francis and Ms. Earnest is that they sat and passively waited for years. The only thing that changed was a lawyer told them that they may be entitled to benefits. That's the only thing that changed, lawyer advertising.

We certainly can't be in a situation where the plaintiffs' lawyers can drive the entirety of the prescription question in every lawsuit simply by putting out advertisements when they choose to. We know that under the law of Louisiana you don't have to wait and sit on your hands until the lawyer tells you you have a claim. That is well-settled, but that is exactly what happened in both of these cases.

I'm happy to answer any questions that Your Honor has, but at the end of the day the burden of proof is on the plaintiff to prove an exception; namely, the discovery rule. What we have here is a situation where both plaintiffs knew of their injury and damage. They waited years before filing suit and didn't do an investigation in the interim like Louisiana law requires. As a result, because of those realities and the burden on the plaintiff, both claims are prescribed and were filed well outside of the one-year prescription period.

01:20

THE COURT: Thank you.

MR. NOLEN: Good afternoon, Your Honor. Rand Nolen for Tanya Francis and Barbara Earnest.

To start with, Your Honor, I would just say this. If we are to logically follow what Mr. Strongman just told the Court, we know that at some point prior to 2009 Sanofi changed their labeling for Taxotere and put in the label that it causes permanent hair loss and then went out and told doctors across the United States and perhaps the entire world that that was true so that they could tell patients, but they didn't. Those aren't the facts at all.

In fact, even today Sanofi in both briefs say that they don't even concede that Taxotere causes permanent hair loss, and yet Ms. Francis and Ms. Earnest are supposed to know that Taxotere ingestion caused their hair loss. That's what the argument is. They are supposed to be on some sort of notice that they have permanent hair loss as a result of taking Taxotere, yet in both cases neither of their chemotherapy doctors ever told them that was the case.

In fact, they both testified -- Dr. Verghese testified that he did not warn of a risk of permanent hair loss because he didn't know Taxotere was associated with permanent hair loss. In Ms. Earnest's case, her oncologist, Dr. Carinder, testified that he did not discuss permanent hair loss with Barbara because he didn't know that permanent hair

01:22

loss was associated with Taxotere.

THE COURT: Yes, but I think the question is: When were these plaintiffs aware that "I have sustained permanent hair loss"? I think they both have said that they related it to chemotherapy at the time.

MR. NOLEN: Right.

THE COURT: The law in Louisiana is you can't sit on your hands; you have to do something. My question is: When did you realize that it was permanent and what did you do?

MR. NOLEN: In both cases, Your Honor, the plaintiffs have testified that they knew that they had hair loss associated with their chemotherapy use and that it was temporary. In both instances, that's their testimony. They believed that it was temporary. In both instances, Your Honor, they started regrowing some amount of hair after their chemotherapy ended just as they thought and had been told by their doctors would occur.

So what then happened, though, was that time passed and their hair didn't come back in very thick. It didn't come back in nearly the same. In fact, they have permanent hair loss on their scalps, they don't have eyebrows, and they don't have eyelashes. So you have almost a signature injury with the eyelashes and the eyebrows, and yet that's not warned of anywhere in the Taxotere label.

Under the doctrine of *contra non valentem*, the

01:23

issue is when the tort victim knows or should know of the causal association between the product and the injury and know that they are the victim of a tort. That would be impossible in this situation. So you have tort impossibility because the manufacturer has consistently denied, at least up until 2015 when they made a change to their own labeling in December, that their product was associated with or caused permanent hair loss.

So why is it that the tort victims in these instances aren't entitled to rely upon what the manufacturer says? Should they just presume that the manufacturer is not telling the truth? Should they just presume that their doctors, when they told them their hair loss was temporary, either didn't know or had been lied to? We can't just presume that.

There is a big distinction, Your Honor. I know the Court wants to ask me a question. I don't mean to cut off the Court, but they raised the *Fontenot v. ABC Insurance* case. That's a completely separate case. That's a bad back case, just as the Court observed, where the drill slipped. The doctor tells the plaintiff that the drill slipped, says that you have some --

THE COURT: I know. I already went through that with Mr. Strongman. This is my issue.

MR. NOLEN: Okay.

01:24

THE COURT: I don't think under Louisiana law there is a requirement that a manufacturer fess up and say, "We did something wrong," for prescription to run. That's just not the law at all. I think that the question is when are you on notice that you have sustained an injury or an event.

That's what, as I appreciate it, this complaint is: We were never told that permanent alopecia was a side effect of Taxotere chemotherapy treatment. We weren't told that, but it happened. We should have been told that so that we could make an informed decision as to whether or not we wanted to choose that course of treatment.

I think the issue in my mind is when did these people understand that this was no longer a temporary condition, it was a permanent condition, and then it triggers, if you will, a duty to investigate. That's the law, as I appreciate it, unless you have hidden something or it is impossible to discover, and that's when *contra non valentem* comes in. *Contra non valentem* doesn't excuse the duty to investigate.

MR. NOLEN: Your Honor, back to that impossibility issue, how would a plaintiff know what is in the files of Sanofi when it's not disclosed and it's not in the label and when it's not being promulgated to the medical community?

THE COURT: She shows up at her doctor's office and says, "What do you mean? My hair didn't grow back. You said

01:26

it would."

MR. NOLEN: Right.

THE COURT: That's an investigation.

MR. NOLEN: Let me go a little farther than that, then. So that's the "excite the attention" that's described in *Campo v. Correa*. So what the Louisiana Supreme Court said in *Campo* is, "We cannot expect that patients will self-diagnose," a direct quote from there. The plaintiff cannot be in the position of self-diagnosis.

THE COURT: Right.

MR. NOLEN: So in this instance, in these two cases, Your Honor, you don't have any evidence at all that a doctor told them that they were going to have permanent hair loss. That doesn't occur. We have almost exhausted -- I think we have exhausted discovery in the cases. You don't have any evidence that any of the physicians that they saw ever told them they were going to have permanent hair loss. You don't have any instance where the manufacturer ever publicized a risk of permanent hair loss or that people would have permanent hair loss.

In Ms. Francis' case, you have her going to her doctor in 2012, actually, and saying, "Doctor, can we do something to help me hair grow back?" which would indicate -- I can tell you I've got this giant bald spot back here. I'm very painfully aware of it because my wife points it out to me

01:28

regularly. I don't go to the doctor asking for some kind of medicine to put on it because I understand that I have male pattern baldness and I'm bald in the back. I know not to go and ask, "Is there anything out there for me, Doctor?" because I know that that's not something that can be cured at this point in medical science.

That is the opposite of what Ms. Francis did, where she goes and says, "My hair is not coming back exactly like I thought it would. Can you help me?" and nobody gave her any solution, nor did they tell her ever that it was a permanent condition. The reason, of course, they didn't tell her that it was a permanent condition is because nobody had told them.

Now, I saw the Court writing down something during the Barbara Earnest part of Mr. Strongman's presentation, particularly when he put up the little handbook, that nurse handbook that has that indication in there about reports of Taxotere, and several things about that.

One, that is over a 200-page book. The doctor, who was a surgeon, who had provided that to Ms. Earnest did not, in fact, read the entire book himself. In fact, his testimony is, "I never read the entire book." What he did do was refer her to the pathology section, which she got --

THE COURT: Right.

MR. NOLEN: -- which she actually reviewed, but she

didn't have a clear recollection of that. She knew she had not read the entire publication. It's like a textbook in some ways, and it deals with a lot of different issues.

We know that that didn't happen because that's her testimony. So we have testimony to that effect, that she didn't read it. We have testimony from the doctor who gave it to her who said that he didn't read it. We have got that, so then the issue becomes why does that book say that. I don't know. I don't know that anybody knows why it says that; because at the time that it would have been given out, that was not something that had been widely reported in either the medical literature and was not being said by the manufacturer.

So what I think we can probably presume is that report comes from some sort of anecdotal understanding that that nurse practitioner who wrote the book had. But otherwise there's no evidence, Your Honor, that Ms. Earnest ever saw that or understood it to mean that she wasn't going to have her hair grow back. That was an issue that had been raised.

The other case that was cited as sort of the case in Louisiana law that was going to be problematic was this *Carter v. Matrixx* case. It's a Zicam case that was decided on undisputed facts. Curiously, in that case the plaintiff actually doesn't raise the issue that when *contra non valentem* is raised that it typically turns on fact issues and, therefore, is a determination that the jury should make.

01:31

In the opinion itself, what the court says is these are really undisputed facts and the individual, the lady who suffered from a Zicam injury -- which was she took Zicam and lost her sense of smell and sense of taste -- admitted that she, in fact, had lost it immediately after and over any period of time it had never returned. She sought treatment for that early on and told doctor after doctor -- I think there's three doctors in that case that she went to and said, "I seem to have permanent loss of senses as a result of taking Zicam." So that's a major difference.

We do not have in this case just as in the *Fontenot* case. We don't have the same situation where in *Fontenot* the plaintiff was going to different doctors saying that he had suffered a nerve injury that was not resolved, a permanent nerve injury, and he wrote it down in two different places more than a year after he had suffered the injury.

In Zicam we had that instance where she is going and seeking treatment saying, "I seem to have permanently lost my sense of smell and my sense of taste." We don't have that in this case. You cannot point to anywhere where these ladies are admitting that they somehow know, have divined that they have permanent hair loss.

It's counterintuitive also. If they were seeking any treatment for a permanent condition, then it's counterintuitive. Right? Because you don't go to the doctor

01:33

if your arm has been cut off and say, "I need some treatment because I want my arm to grow back."

THE COURT: Are you telling me that prescription, then, never runs?

MR. NOLEN: Well, the courts of Louisiana have answered that question on many occasions. They have imposed prescription on pretty much every case that I'm aware of that's been reported. It seems to me, though, that in certain circumstances where you have an affirmative hiding of information, nondisclosure, that for at least during the period of time that that information is being withheld, not provided, then the answer is prescription shouldn't run. There are a multitude of cases where when you have sort of that affirmative withholding of information and not disclosing that something is a permanent condition versus a temporary condition that prescription does not run because you have information that is being withheld.

In fact, in the case that we just talked about, the *Fontenot v. ABC Insurance* case, the Court specifically found that the surgeon had not committed a fraud or deception because the surgeon had fessed up immediately that there was this accident and told the gentleman that he thought that it would resolve over time. It did not resolve, and the individual kept going and trying to seek treatment to help with his permanent nerve injury. It did not resolve.

01:35

In that case, though, the man knew that he had been the victim of a tort of negligence, because the drill had slipped, the day after his surgery where the drill had slipped. He knew he was the victim potentially of a tort, so that's why the one-year prescription period runs against that individual. This is a different case because we have even until now the defendant saying that "Our product does not cause permanent hair loss" and not until the end of 2015 warning about it.

Now, in both these cases the suits were filed within that period of time, in the 2016 time period, but the point of it is that there is an impossibility point here, because it's not being widely reported by anybody that there's permanent hair loss associated with this drug. The manufacturer is not putting that in the label. The manufacturer is not telling physicians. Their detail people aren't telling physicians.

THE COURT: So I'm going back to, I think, the first question I asked based upon what you are arguing. Are you telling me that prescription didn't run until they changed the label? Is that the position you are taking?

MR. NOLEN: No, I'm not taking that position because we actually --

THE COURT: When does it start running?

MR. NOLEN: We actually know in both instances how these individuals, Ms. Francis and Ms. Earnest, learned about

01:36

the potential for permanent hair loss, and it wasn't the label change. In both instances it was an advertisement, an attorney advertisement. Ms. Francis, she saw it on Facebook. In Ms. Earnest's case, I think she saw it on TV.

That would have been their first notice because that's the first time they had any idea that their hair was never going to come back. That was the first possible notice that they had because there's no evidence of any other notice to them. I'm not tying it to the label change at all. They didn't even know about the label change.

Does the Court have any other questions?

THE COURT: No. I think I'm good. Thank you.

MR. NOLEN: Happy to answer them.

MR. STRONGMAN: Your Honor, just one minute.

A couple of points I wanted to make. Now, with regard to Ms. Francis, her hair has continued to grow back and change over time, so that's one circumstance. Ms. Earnest, I believe, has been clear that her hair condition has remained the same since 2012, so that's an entirely different circumstance altogether.

I know that you're wrestling with the idea of this line between temporary and permanent, and the reality is that we don't need to make a determination on that exact issue today for everybody because what we know is that these two cases -- you know, whether that line is one year, two years,

01:38

three years, in both of these cases it's beyond that.

THE COURT: I think that's an individualized assessment, what somebody thinks after you have a surgery and -- I've got this ongoing problem with my foot. I might give it two years before I go to the doctor because I just am the eternal optimist, and I have friends that would be there the next week. At the point that you realize this is as good as it's going to get --

MR. STRONGMAN: Again, under the reasonableness standard, waiting four years, six years is not reasonable to make that inquiry.

I know Mr. Nolen talked about self-diagnosis. Well, the curiosity here is that what we --

THE COURT: I know what you are going to say.

MR. STRONGMAN: Well, I will say it anyway. What we have here is not self-diagnosis; we have lawyer diagnosis. What we certainly can't have in the law is something where all it takes is a lawyer telling you you have something for the statute to run and for people to file lawsuits.

So it is clear, based on these cases, that the plaintiffs have the burden, and they just can't meet it, to prove any kind of exception. They are barred under the prescription on their face, and there isn't anything under the law to save them.

THE COURT: Thank you.

01:39

I know you-all have flights to catch. Please feel free to leave.

MR. MOORE: You have given me five minutes to make this argument, Judge, and I intend to keep my remarks within that limit. Douglas Moore on behalf of Sanofi. I am addressing the Rule 72 motion as it relates to Judge North's minute entry on an in camera inspection on documents related to the stem cell issue.

I think I can speak for all counsel in this room that we are all impressed and appreciate very much Judge North's management of discovery in MDL 2740. He has approached it with diligence, with commitment, and he renders his rulings with unmistakable clarity. It has been a Herculean task, and both sides have received rulings that they do not agree with. This is one of those for Sanofi.

We didn't know it at the time, but the stem cell saga in this case really relates back to the time that the plaintiffs filed a Rule 72 motion on Judge North's ruling as it relates to the pathology production. You affirmed that ruling under sort of different reasoning, but you reached the same result.

In this Rule 72 motion, we are asking you to reach a different result. We think that the issue in this case is very simple: Are we entitled to the discovery of facts and data provided to Dr. Thompson related to the work that he was

01:41

doing in this case? We think the case law is unequivocal. We think the answer to that question is yes. We have two issues with Judge North's ruling, which was rendered without the benefit of any briefing. It was simply an in camera review because we were on a tight time frame.

It's apparent from the minute entry and also from his ruling on our motion to compel, which was cited in their opposition, that Judge North views any communication involving a lawyer, as it relates to experts, to be off limits following the 2010 amendments to FRCP 26.

We don't think that's the correct law. We think that there are numerous exceptions. We have cited them in our papers. One of those is a circumstance when facts or data are considered and contained in the communication from the lawyer, that communication becomes discoverable.

That's the second issue that we have with the minute entry. Judge North determined that information contained in some of the materials that he looked at were not discoverable because Dr. Thompson did not rely on them. Reliance is not the standard, under Rule 26, for disclosure of an attorney communication that includes facts or data considered.

Consideration is a much lower standard than reliance. The case law that we cited to the Court establishes it basically means that they looked at it, that they reviewed

01:42 it, that they were provided that information for their consideration. So if an attorney says, hey, expert, look at this article, look at this information, review these materials, that becomes discoverable at that time. It doesn't matter if the expert says: I don't like it; or I don't cite it; or I'm not going to include it in my opinion.

So those are the two problems. There is no carte blanche rule against disclosure of attorney communications after the 2010 amendments, and the second is that the standard is consideration and not reliance. We think that's where the minute entry is incorrect.

So how does all of that apply to the materials submitted in camera? Well, for most of it, I have no idea because we weren't given a privilege log. We weren't given really a lot of information about what it was because of the timeline that we were on. But there is some information that we received both before and after Judge North's ruling that makes us firmly believe that there is information contained within the in camera production that contains facts and data that should have been produced to us.

I'm specifically referring to the video that was shown to Dr. Thompson. We asked him at his deposition, after Judge North's ruling, what that was about. He testified:

"QUESTION: So plaintiffs sent you a video about a stem cell researcher giving a lecture?

01:44

"ANSWER: Yes."

The issue of stem cells is obviously at issue in this case. Dr. Thompson tested the plaintiffs' tissue for the presence of stem cells. He was obviously shown this video of a lecture from a consulting expert. When you link up a consulting expert and provide information to a testifying expert, the provision of that information becomes discoverable.

It doesn't matter if he doesn't think it's relevant. It doesn't matter that he doesn't rely upon it. If he is provided information, if he reviews it, if he looks at it, if he thinks about it, that becomes discoverable and something that we should have.

I haven't seen the videos. All I know is what Dr. Thompson said in his sworn testimony. It's a video of a stem cell researcher giving a lecture, and we know that stem cells are at issue in this case. So we would ask, at a minimum, that the videos be produced to the extent that they are conveying facts and information to Dr. Thompson.

I have 15 seconds, and in those 15 seconds I make one more request, and that is that in the surreply provided by the plaintiffs, they included a September 3 email that was not given to Judge North. It was identified in his invoices. We knew about it. We asked about it. They said they couldn't find it. The expert that it was sent to had a copy of it, and they gave that to you.

01:45

THE COURT: Yes.

MR. MOORE: We have not seen it. Judge North hasn't seen it. Judge North hasn't ruled upon it.

THE COURT: I will tell you this is the situation, because Judge North contacted me about that and said --

MR. MOORE: We raised it with him.

THE COURT: We spoke.

He said, "This is on appeal to you. I don't know if you have reviewed it. There is this other issue. Do you want me to handle it and then send it to you?"

I said, "I think that's the antithesis of judicial efficiency. If I've got it, give it all to me at this point," and he happily agreed.

MR. MOORE: Okay. That was the question we had for him, and he indicated he was going to raise that with you.

THE COURT: We visited about that, and so that's how it ended before me. I know that he has not seen it.

MR. MOORE: So the 10 seconds on why we think we are entitled to that email, they admit that it is an email that does not involve a lawyer. It is not privileged. Their argument for not producing it is that, well, it's about a different study that these two experts were talking about, and that's not relevant to the opinions that were issued in the case.

It's clearly about stem cell research. Our

01:46

experts had to give over discovery about other research that they had done outside of the case because it may be relevant to the opinions they were rendering, and we furnished that information. That should apply to this communication as well.

We think that if it's about stem cells, stem cells were obviously considered by Dr. Thompson. He tested for them, didn't like the results, so he didn't put them in his report. We still think that's relevant, and we think we should have access to that as well. Thank you.

THE COURT: Thank you.

Mr. Lambert, let's see if you can go five minutes without breathing.

MR. LAMBERT: Good afternoon, Your Honor. Palmer Lambert from Gainsburgh Benjamin, co-liaison counsel for plaintiffs.

In Magistrate Judge North's order of April 1, Rec. Doc. 6616, His Honor correctly determined that the work product protections of Rule 26 apply to protect the documents submitted in camera by the PSC. Because Judge North's legal conclusions were not incorrect and because his application of law to facts was not clearly erroneous, the Court should not reverse his decision.

The 2010 amendments to Rule 26 are clear. Sanofi is only entitled to facts or data considered by the witness in forming the opinions to be expressed. Those last

01:48

few words about "forming the opinions to be expressed" are generally omitted from all of the citations in Sanofi's position.

It goes without saying, Your Honor, the PSC is frustrated with the allegations of impropriety that permeate the original memorandum, the reply memorandum, and the sur-surreply memorandum submitted by Sanofi. I do want to address some of the issues that are raised in those briefs.

In February of this year, it became apparent that the PSC's dermatopathology expert made a mistake. He admitted to making a decision on his own to withhold six slides that were stained with cytokeratin and Ki-67. The PSC had no reason to believe these slides had been sent to Sanofi as we produced Dr. Thompson's bills two months before, in December, that identified these stained slides.

On January 11, Sanofi's dermatology and dermatopathology experts issued their reports without any mention of the cytokeratin and Ki-67 slides. Since the PSC was made aware of this mistake, the PSC agreed to a four-month continuance of the trial, to put up four of its experts for supplemental depositions, answered numerous questions posed by counsel regarding the handling of these six slides, provided certain email communications -- including lawyers on them -- to document the chain of custody, and provided declarations of two consultants regarding the same, regarding their handling or

01:50

nonhandling of these materials. After all of that supplemental discovery, it remains clear that there is no stem cell study that was conducted by the PSC.

Sanofi suggests three invoices, line items related to August 15, September 3, and October 24 emails, provide support for its contentions. However, when the timeline of events is considered, it is clear Dr. Thompson did not consider any such communications in forming his opinions.

Dr. Curtis Thompson issued his dermatopathology reports in April of 2018. All of these communications which are complained about in Sanofi's position postdate that report. None of the PSC's experts, including Dr. Thompson, considered these six stem cell slides in forming their opinions. The existence of these slides and discussion surrounding these slides is completely irrelevant to any of the plaintiffs' experts and their opinions in this case.

In his April 3 deposition -- oh, that's really small. I'm sorry, Your Honor -- Dr. Thompson addressed the reason why these slides are irrelevant and not appropriate for any opinion. He said, "For sure, it wouldn't have been included in the dermatopathology reports because there's no support, published support, even professional experience that these have any utility in diagnosis."

Dr. Tosti also was deposed. We do not have that transcript in the record, but she also stated that these six

01:52 slides have no utility without a full study that has controls and hundreds of participants.

Despite all of this, Sanofi continues to preargue *Daubert* issues throughout this briefing, including making incorrect statements about what plaintiffs must prove to meet their general causation burdens.

As late as this past Sunday, we had a six-hour deposition of Dr. Jerry Shapiro, defendants' dermatology expert. He admitted he is not an expert in stem cells or stem cell staining, never ordered cytokeratin-15 or Ki-67 staining, didn't know whether such staining had any reliability, and had not done any research regarding the utility of those stains. Such testimony corroborates both Dr. Thompson's and Dr. Tosti's testimony that these stem cell slides have no utility in this case.

Sanofi also incorrectly states that Dr. Thompson shared this information with Dr. Feigel. It's just not true. The deposition testimony that they cite for that premise says, "I just remember talking about the -- my findings again, my professional interpretation of the slides, and nothing beyond that. It was simply pathology discussion."

What he was talking about on page 335 of his February 26, 2019, deposition is the H&E slides, not the cytokeratin and Ki-67 slides. When he was deposed again on April 3, he was asked the same line of questioning. I'll just

01:54

skip to the end of the line. He says on page 503 at line 11 "seriously doubt we had any discussion in that direction." The suggestion is that he testified that he believes he discussed his findings from trial plaintiffs' stem cell stains with Dr. Feigel. It's just not true. That's not what the deposition testimony says.

In fact, the day before the April 17 email that they suggest Dr. Poole is providing information that Dr. Thompson somehow relied upon, the day before that email, on April 16 -- which happens to be my birthday -- he says, "We processed the three biopsies, and I have examined the initial H&E sections, which all do show features consistent with permanent alopecia after chemotherapy."

I have included Dr. Poole's affidavit here because she also says that she never even looked at these slides of the plaintiffs. She was just asked to receive them and then send them over to Dr. Curtis Thompson.

The August 15, 2018, invoice entry is another issue that Sanofi raises. The line item says "planning a stem cell study at CTA Labs." Well, CTA Labs is Curtis Thompson's lab, and there were discussions with the PSC about what could possibly be done. That's part of the PSC's diligent investigation of this case, and it's not something that Sanofi should be allowed to invade.

All of the circumstances surrounding these

01:56

emails and the discussions about stem cells can only be characterized as the PSC's diligent investigation of issues surrounding hair loss. The sanctity of the work product privilege over communications between lawyers and their experts should not be invaded in this case.

THE COURT: Thank you.

MR. LAMBERT: Unless Your Honor has any questions, that's all I have.

MR. MOORE: I reserved no time, Judge, so I have nothing further.

THE COURT: Thank you. Let's meet in the jury room. I know you-all mentioned some concerns with Sam, and maybe we can resolve that now. Court is adjourned.

THE DEPUTY CLERK: All rise.

(Proceedings adjourned.)

* * *

CERTIFICATE

I, Toni Doyle Tusa, CCR, FCRR, Official Court Reporter for the United States District Court, Eastern District of Louisiana, certify that the foregoing is a true and correct transcript, to the best of my ability and understanding, from the record of proceedings in the above-entitled matter.

/s/ Toni Doyle Tusa
Toni Doyle Tusa, CCR, FCRR
Official Court Reporter