## UNITED STATES DISTRICT COURT

## EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	*	16-MD-2740
PRODUCTS LIADILITY LITIDATION	*	Section H
Relates to: 16-CV-17144 17-CV-2689	*	August 16, 2019
T1-C1-2003	*	9:30 a.m.

## ORAL ARGUMENT BEFORE THE HONORABLE JANE T. MILAZZO UNITED STATES DISTRICT JUDGE

## <u>Appearances</u>:

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INDEX	
	Page
Oral Argument	<u>r age</u>
Ilana H. Eisenstein, Esq.	4
Andre M. Mura, Esq.	10
Ilana H. Eisenstein, Esq.	15
Douglas J. Moore, Esq.	18
Christopher L. Coffin, Esq.	24
Douglas J. Moore, Esq.	28

1 PROCEEDINGS 2 (August 16, 2019) 3 Douglas Moore, defense liaison counsel MR. MOORE: and local counsel to Sanofi. 4 We have two motions pending before Your Honor 5 6 this morning, a motion for a certification under § 1292 of 7 Your Honor's summary judgment ruling on learned intermediary and a second motion on a motion to adjourn the trial date. I 8 9 will be addressing the motion to continue. My colleague, Ilana 10 Eisenstein, from DLA Piper in Philadelphia, will be addressing 11 the § 1292. We would like to proceed with the § 1292 first, if 12 that's acceptable with the Court. 13 **THE COURT:** I think that's appropriate. 14 MS. EISENSTEIN: Good morning, Your Honor. 15 Ilana Eisenstein. Thank you for welcoming a new member of the 16 team representing Sanofi, defendant. 17 Your Honor, I'm here to speak on the § 1292 18 motion and why an interlocutory appeal should be granted on the 19 learned intermediary question presented, particularly as it 20 relates to a proximate causation decision in the *Earnest* and 21 the *Mills* decision. 22 Your Honor, I think that the first thing to 23 address is the three factors for interlocutory appeal, and in 24 our view each of them are met and easily met. The first is 25 whether this presents a controlling issue of law, the second is

whether the courts can reasonably or substantially differ on
 that, and the third is whether the resolution of this will
 materially advance the litigation.

I think that, on the controlling issue of law piece -- and I know that Your Honor had mentioned Judge Proctor's decision in *Blue Cross Blue Shield* as one that you wanted us to address.

8 **THE COURT:** Well, I just asked if they had read it 9 because I think he does a nice outline of the law.

10 MS. EISENSTEIN: I agree, Your Honor, and I think 11 that that actually really underscores why this case is 12 different from that case and why this is a controlling issue of 13 law. In that case the issue was whether there was personal 14 jurisdiction, and there were three independent grounds for a 15 decision, one of which was already controlled by prevailing and binding circuit precedent. 16

Whereas here, as I think Your Honor has recognized, the proximate causation issue is not governed by binding precedent in the sense that Your Honor has developed and applied a unique rule in the chemotherapy context that departs from the traditional, standard rule and the learned intermediary doctrine, which is that the doctor's prescribing decision is where the proximate causation chain ends.

When the doctor has testified that he or she
would not have changed the prescribing decision as a result --

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THE COURT: Let me ask you: In the other cases that you cite to that say, listen, the doctor would not have changed his prescribing decision, did any of those cases require signed informed consent by the patient, and isn't chemotherapy different?

6 MS. EISENSTEIN: So, Your Honor, I can't speak to 7 whether signed informed consent was required, but I believe 8 that informed consent is a doctrine that underlies a doctor's 9 responsibility to his or her patient in every case in all of 10 those jurisdictions that I'm aware of. I think that's a 11 prevailing standard of care for physicians, but that's really 12 the point.

In every traditional sense that we're aware of, the standard for learned intermediary stops, proximate causation stops and ends with a change to the doctor's prescribing decision. It doesn't run to a patient's decision -- intentionally doesn't run to a patient's decision to potentially reject that choice or to choose something else based on the patient's own decision-making.

That's potentially a doctrine that Your Honor might disagree with and has disagreed with here, but it's something that certainly presents a difference of opinion on which reasonable judges could differ. That's the really key question here. Standing here today, we are not asking you to reconsider your decision whether or not the proximate causation

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standard was met. What we are asking is -- we think that this is a critical question, one that will control and dispose of significant numbers of cases in this litigation and one in which reasonable judges can disagree and that, I think, Your Honor would recognize --

THE COURT: Oh, I understand --

7 MS. EISENSTEIN: -- is different from the traditional
8 role of learned intermediary.

**THE COURT:** I'm not willing to go that far.

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MS. EISENSTEIN: Okay.

11 THE COURT: I will tell you this. If I should grant 12 this, then what does that do to the case that has been worked 13 up? I know you have set this up in two motions. Why wouldn't 14 we proceed, try the case, and if you lose you bring an entire 15 case to the Fifth Circuit? Your only problem is if you win.

MS. EISENSTEIN: That's exactly the problem,
Your Honor. As you're, I'm sure, painfully aware, this is the
MDL bellwether, the first bellwether case.

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THE COURT: I understand.

MS. EISENSTEIN: The purpose of the bellwether in large part, of course, is to address Ms. Earnest's case, but why it's a bellwether case is to test the legal and factual theories that will help the parties continue to move forward and resolve and better evaluate the cases in the multidistrict litigation as a whole. If we win, none of these -- this

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controlling issue will not be resolved at this juncture. 1 2 If you look at some of the prior MDLs that have 3 extended on beyond the time that they might have, in those 4 cases it was the cases where the defendants have won the 5 bellwether cases consistently. Of course, we believe we are going to win this case. Your Honor will have your own opinion 6 7 about that, I'm sure, and the jury will have its opinion about that when the case gets tried. But if we win the case or if 8 it's otherwise resolved, this issue will remain out there. 9 10 We have a substantial disagreement on the controlling legal question, and we believe it's one of central 11 12 It's not only an essential element of the claim. importance. 13 It's one that's really at the heart of this litigation, which is what is the effect of the warning that plaintiffs assert we 14 15 should have given. 16 So if we don't resolve this at an early stage of 17 the litigation -- and these cases present really ideal vehicles 18 for this question, and that's because the doctors in these 19 cases were quite clear that they would have prescribed Taxotere 20 irrespective of a change in the permanent alopecia warning. I 21 think Ms. Mills' physician was particularly strong in that she 22 had no doubt that this was the appropriate treatment. Really. 23 it was the patient's lack of certainty as to that question that 24 I believe led Your Honor, in your decision, to find there was a 25 genuine issue of material fact.

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So this is an ideal vehicle for this controlling issue. It's one that we can tee up at an early stage. If we don't take this opportunity now to certify these questions, it will be a long time -- and maybe never -- before this issue will be resolved.

6 Mr. Moore is going to address the issues of 7 adjournment and continuance, and we certainly think that it is 8 appropriate to stay and adjourn the *Earnest* trial pending a 9 decision in this case. I also want to urge Your Honor that you 10 don't necessarily have to view it that way. You can decouple 11 this.

12 Mills is also a vehicle to consider, in terms of 13 interlocutory appeal, that's not set for trial. We think, 14 nevertheless, when you are looking at the *Earnest* case and 15 trying that case through and what would be the instructions given to the jury on proximate causation -- because the 16 17 standard instructions include the formulation of law that the defense has advocated. The standard instruction is the 18 19 warnings causation depends on the physician's prescribing 20 decision.

So kind of each phase from the opening to the instructions are going to be guided potentially by what that proximate causation standard is. So it would be, in our view, not an efficient use of time to move forward with the *Earnest* trial under what we think is at least an unsettled proposition

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of law with respect to a key essential element of the claim. 1 2 If there's nothing further, Your Honor, thank 3 you. 4 THE COURT: Mr. Mura. 5 MR. MURA: Good morning, Your Honor. Andre Mura for 6 the plaintiffs. 7 I wanted to respond first to the point that a stav of *Earnest* would be modest. The reason we think the stay 8 of *Earnest* is effectively a stay of the entire MDL is because 9 10 if you were to grant the interlocutory appeal and then stay 11 *Earnest*, what's going to happen is the next bellwether trial 12 proximate cause is going to be an issue. Sanofi is going to 13 move for summary judgment --14 THE COURT: Let me ask you: Could I separate that 15 out and certify *Mills*? 16 MR. MURA: No. We don't think you can because you 17 would have to write a certification order that says that this 18 is an exceptional circumstance and that each of the three 19 elements are met. If you write that order, then it's not 20 appropriate to go forward in *Earnest*. These two issues can't 21 be decoupled. I don't believe the Court can be having a trial 22 in one case at the same time that it's suggesting that the 23 *Mills* case should go up to the Fifth Circuit. That would be 24 very confusing for the Fifth Circuit. It's sort of a race to 25 see who goes first.

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I will say that with respect to the *Earnest* 1 2 case, I don't think the problem is that if Sanofi loses then 3 there isn't an opportunity. If Sanofi loses, that shows that 4 there were genuine issues of disputed fact that the jury resolved in Sanofi's favor, and that shows that this isn't an 5 appropriate appeal for the Fifth Circuit to hear. If you look 6 7 at the cases cited in our brief --8 **THE COURT:** You know what they mean. If Sanofi wins 9 this case --10 MR. MURA: Right, right, right, if Sanofi wins. 11 If Sanofi loses --THE COURT: 12 MR. MURA: Yes. 13 THE COURT: -- certainly --Right, right. 14 MR. MURA: 15 **THE COURT:** -- the Fifth Circuit has an opportunity to review all of my rulings. 16 17 MR. MURA: That's right. 18 **THE COURT:** If Sanofi wins, therein lies the problem. 19 MR. MURA: Which is the final judgment rule and the 20 established standard. 21 THE COURT: Right. 22 MR. MURA: You really have to have an exceptional 23 circumstance to warrant an immediate interruption in the trial 24 proceedings, and here you don't have that met. It will not 25 materially advance the litigation to pause when we are about to

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go to trial. The cases show you should go to trial. You should have a full record. You will have jury findings and you will have an opportunity, then, if there is an adverse judgment to Sanofi, for Sanofi to take a single appeal in which it could raise all the appellate issues. That's the traditional model.

What I was saying is Sanofi said -- they keep 6 7 arguing that there's a controlling question of law. My point was if Sanofi prevails at trial, they will be prevailing under 8 the instructions that the Court gives on the law. 9 If Sanofi 10 prevails, that shows exactly what the Court said, that there 11 are genuine disputes of material fact. The jury would simply 12 be resolving those genuine disputes in Sanofi's favor. That goes to show that this isn't an appropriate appeal because it's 13 14 not presenting a pure question of law.

Now, I have looked at the cases that Sanofi has mentioned. I don't believe any of those -- I think it's overstating sort of the implications of this Court's ruling. All this Court said was that context matters, and a lot of the other cases context mattered. It mattered what the context of the prescribing physician's decision was, and so I don't think there's anything unorthodox about that.

The cases say that you can't show a controlling question of law when you have genuine disputes of fact. There's a line of Fifth Circuit cases saying if a party is going to be insisting on arguing that there are genuine issues

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of disputed fact, then we don't even have jurisdiction to 1 resolve that issue.

3 Now, I don't know that you need to go there because I think nevertheless it sort of dovetails with the 4 5 analysis for the three factors, but I think if you look at 6 their reply brief on page 3, note 1, Sanofi says, "No, no, we 7 are presenting a pure question of law," but then they continue 8 to argue the facts. What they say there is that neither doctor 9 testified with certainty, so they are continuing to argue about 10 what the record says about what the doctor testified. So this 11 isn't an appropriate appeal in which there is sort of a clean 12 record and a pure question of law on which the Fifth Circuit 13 could even rule.

14 Now, as to substantial disagreement, the case 15 law is clear that mere disagreement with a decision is not an 16 appropriate basis to allow an interlocutory appeal. If vou 17 look at Judge Proctor's order, what he was really looking for 18 was a conflict, a conflict in the circuits, a conflict between 19 the courts. They have not shown a clear conflict between any decision of any other court and this Court's on this particular 20 21 set of facts.

22 You don't have a clean sort of disagreement where you could even say, "I disagree with this other court," 23 24 which applied some opposite rule. The Court merely applied the 25 standards for learned intermediary, which are familiar, and a

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misapplication of facts to law does not present a controlling 1 2 question on which there is a substantial disagreement. 3 I think the Court can write an opinion just like 4 in *David v. Signal*, where the judge there said, look, the party 5 asking for an interlocutory appeal has to show all three 6 elements are met. So if any one of those elements are not met, 7 then the interlocutory appeal fails. In that case it was 8 obvious that an interlocutory appeal would not materially 9 advance the litigation. 10 Here I believe that's crystal clear because we 11 are so close to trial in the *Earnest* case. A stay of the 12 *Earnest* case is functionally a stay of the entire MDL because 13 this issue is going to repeatedly come up, and we will never be able to try any other bellwether case. The ordinary rules for 14 15 final judgment support the conclusion that we should go to 16 trial, have a record, and then allow an appeal if there is a 17 needed appeal at that stage. 18 Unless the Court has any other questions --19 THE COURT: No. 20 MR. MURA: Oh, I will mention that in Blue Cross 21 Blue Shield, after Judge Proctor said no, he finally said yes, 22 and then the Eleventh Circuit said no. So it was a great waste 23 of time. There's a strong risk that the Fifth Circuit could 24 simply say no here, and we will be paused and waiting. Given 25 how close we are to trial, that's not sort of a judicious way

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Thank you so much.

THE COURT: Thank you.

4 MS. EISENSTEIN: Can I just respond to a couple of 5 points, Your Honor?

THE COURT: Sure.

7 **MS. EISENSTEIN:** Let me start with the controlling issue of law question. Certainly there are facts that underlie 8 9 the proximate causation question, but the controlling issue of 10 law is what standard is applied to determine whether proximate 11 causation has been established by plaintiffs. Here the 12 controlling issue of law is whether it is the physician's prescribing decision that would have changed or, to quote the 13 Court's decision, whether the jury might decide whether the 14 15 plaintiff's ultimate decision would have changed. Here those 16 are dispositive questions that have to be applied to the facts.

17 THE COURT: I don't want to relitigate my prior 18 decision. Perhaps I'm missing something, but I don't think I 19 upended all of this law. As I read the learned intermediary 20 doctrine, the duty of a manufacturer is satisfied when he warns 21 the physician, and that is his duty.

If for some reason the physician determines not to convey that risk because he doesn't believe that his patient falls within that risk, such as the suicide patient -- and I don't remember the case -- then causation is broken. But in the circumstance where the physician conveys the risk to the patient and says, "I still make the same recommendation," I don't think learned intermediary takes the patient outside of the equation and requires the patient to take this medication.

5 MS. EISENSTEIN: Your Honor, I respectfully disagree 6 because if you look at the jury instructions that are given as 7 to warnings, causation is a standard matter. The jury is 8 typically instructed that causation is broken if the 9 physician's prescribing decision wouldn't have changed.

So if the patient wants to get up and walk out of the office based on the information that she has learned or walk out of the hospital against doctor's advice, even though it is a "but for" causation matter in fact that may have broken the chain of causation, as a matter of law, as a legal principle, courts have not recognized it as such.

16 So I understand that there may be some factual 17 change to the counseling decision as a matter of informed 18 consent or just as the practice that the physician engages in, 19 but as a legal matter under the doctrine, that is not how juries are instructed. That's not how courts typically apply 20 the causation analysis. They stop with the physician and so 21 22 that is -- the cases we have cited, you know, are Georgia law, Louisiana law, but that's typical of the sort of restatement 23 24 majority approach to learned intermediary doctrine as we 25 understand it.

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So I think that that is a different approach. We have seen some more recent cases where they have taken the approach that Your Honor has in the summary judgment ruling, where they have evaluated more closely patient choice, but I think it really is a core issue on which reasonable judges could differ, at minimum. We think that it's an issue on which we would prevail, but we don't have to decide that today.

8 I think that the main question is here it's 9 controlling because it's case dispositive. The fact that there 10 may be ultimately facts that need to be evaluated in light of 11 that legal decision doesn't mean it's not a controlling issue 12 of law, and that's the *Cantu* decision.

13 This is a legal issue antecedent to the factual 14 question. You have to first decide how do you evaluate 15 proximate causation, and then here is a great example of it. 16 If you stop with the physicians, the case would be over. If 17 you evaluate what the patients say they would have or might 18 have done in light of the warning, then Your Honor has found a 19 genuine issue of material fact. You don't get to a factual 20 dispute unless the legal standard is, as the Court has held it 21 to be, to evaluate patient choice.

Just a word on the David case. That was a discovery order that the court resoundingly and probably rightfully said had no chance of advancing the litigation. In fact, if the protective order in that case had been something

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other than what the Court held, it would have delayed the case 1 2 enormously. This is an MDL with, as Your Honor knows, 3 thousands of cases, and this legal question is one that 4 underlies each and every one of them. 5 So the fact that *Mills* and *Earnest* present this 6 question is no surprise. All of these cases that don't get 7 resolved on some other ground are going to ultimately be --8 this will be a necessary aspect of that case. So I don't think 9 that the cases cited on advancing the litigation by plaintiffs 10 really inform the Court. 11 I think that you have to look at the facts in 12 this MDL, the set of cases in this MDL, and it's easy to see 13 that this question is core to a substantial fraction of the Resolving it in an early stage of the litigation will 14 cases. 15 materially advance the ability of the parties to ultimately resolve this case at an earlier stage. 16 17 Thank you, Your Honor. 18 THE COURT: Mr. Moore. 19 MR. MOORE: Thank you, Judge. Douglas Moore on behalf of Sanofi. 20 21 I want to first thank the Court for your 22 patience in hearing oral argument in these last couple of 23 weeks. I think this might be the last time we are making an

THE COURT: Mr. Moore.

oral argument in front of you for at least a couple of weeks.

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1 **MR. MOORE:** At least until we get to our motions 2 in limine at the pretrial conference. 3 I wanted to start off by making an observation 4 to this idea that the whole MDL would be stayed and that would 5 be something that would be prejudicial or bad. As it relates 6 to the § 1292 motion, if Your Honor is inclined to agree with 7 us that this is a controlling issue and that it should be presented to the Fifth Circuit without delay, then we would be 8 asking for an adjournment of the *Earnest* trial to allow that to 9 10 work its way through the appellate court. 11 I don't think that that outcome would be 12 inconsistent with what we are supposed to be doing in an MDL, 13 which is pretrial proceedings. We are supposed to be doing everything except trying cases. So I don't feel like the idea 14 15 that allowing this issue to proceed to the court of appeal 16 would necessarily be inconsistent with § 1407. 17 That said, I want to make it clear to the Court and clear to our adversaries -- because I don't think it's 18 19 clear from either opposition -- that our purpose of filing this 20 motion is not because we want to avoid the *Earnest* trial or 21 avoid a trial altogether. 22 **THE COURT:** I don't think you need to do that. Т 23 have to tell you, Mr. Moore, though, I am not inclined to 24 adjourn the *Earnest* trial. The parties have been keying up for 25 this. I got it.

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MR. MOORE: Let me make two points that I think are important for Your Honor to consider in evaluating whether good cause exists to adjourn this trial date, to continue it. We are not asking that it be bumped off forever. We are just asking for sufficient time for us to receive your pretrial rulings, to evaluate those rulings, to apply those rulings to the evidence that's been gathered in the case, and prepare ourselves to defend it at trial.

9 We filed this motion because as the first 10 bellwether in an MDL, we think we should have an opportunity to 11 do that for the significant issues that remain. As we saw the 12 issues stacking up and looking at their volume balanced against 13 the time that we have left, we became concerned there's simply 14 too much to do with too little time.

15 They have taken the position in their opposition that, "Well, discovery is done. Discovery is done." Do you 16 17 know what they are doing today at 1:00? They are deposing one 18 of our experts for the *Earnest* case. You know what they did 19 last week? Last week they went in front of Judge North and 20 asked him for an order compelling us to give another 30(b)(6) 21 deposition even though discovery against us was supposed to 22 close in December of 2018. We just had a conferral with Palmer 23 this morning about discovery we are requesting of them, deposition examination. Those things are still things we are 24 25 doing and still things we are discussing and fighting with them

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1 about. So the idea that discovery is over, Judge, we are 2 ready, is not really correct. Another point -- and I think this is the most 3 4 significant one. We don't know really what the case is that we 5 are trying in light of what happened at this lectern eight days 6 ago. You said in your preemption ruling defendants have failed 7 to demonstrate that FDA prohibited Sanofi from using stronger 8 language in Taxotere's label. We disagree, but we are not 9 going to argue that. 10 My question is this: What is the stronger language that they are going to stand in front of this jury and 11 12 tell this jury that we should have implemented before 13 Ms. Earnest used this medicine? From jump street in this MDL, 14 it has been their position that the December 2015 label change 15 is inadequate. 16 That has been their position up until eight days 17 ago. That was the opinion that was articulated in 18 Dr. Kessler's report. That is the case that we have prepared 19 to defend. That's the case we submitted a preemption motion 20 That's the case we submitted our countervailing expert on. 21 reports on. Never once have they taken the position that this 22 warning was inadequate because we failed to include a single 23 sentence on page 33 of a 60-some-page label, and there's a 24 reason for that. 25 I've deposed some of the oncologists in the

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bellwether cases, and so I show them the label. I flip to page 33 and I show them the sentence where it says, "Cases of permanent alopecia have been reported." And I ask them, "The addition of that sentence on page 33, in the postmarket experience section of this label, does that materially alter your risk/benefit decision for this medicine?" "No."

7 So the plaintiffs' case has always been, "But 8 wait, Doctor. What if it was a 'Capital W' warning? That's 9 more significant, right? That's a bigger deal, right? That 10 has to be on the front page of the label. That would impact 11 your risk/benefit decision for this medicine, right?" That has 12 been their case from the beginning.

13 What we heard eight days ago from Mr. Mura is 14 that Dr. Kessler is going to get up on the stand in this trial 15 and say, "Oh, no, it could have been in the adverse events section of the label," even though they have always said that 16 17 the December 2015 label change that put this in the adverse 18 events section is inadequate. The reason they have always said 19 that is because they would lose so many cases. Everybody who 20 took the medicine after December 2015, they would be admitting 21 that those cases have no merit. So that's why it's always been about the "Capital W" warning. That's what Kessler's report 22 23 is.

What we heard eight days ago and what they put in their opposition to our motion was, "Oh, no, no, no. You

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1 can look at it. If you look at paragraph 109 and paragraph 123 2 and 133," and whatever they are -- I've read them. None of 3 them say that the 2015 label is inadequate. He gets to the end 4 of his report, he says, "My opinions are as follows: Permanent 5 alopecia is a serious adverse event, a life-altering adverse 6 event that should have been in the warnings section as early as 7 2009."

8 When we says that, he is saying it's inadequate 9 to put it in the adverse events section, which is where it was 10 put in December of 2015. So now we are hearing him say, "Oh, 11 no, no, no. It could be in the adverse events section. 12 Defendants, you should have known that from piecing it together 13 through the tealeaves of reading these six or seven paragraphs 14 out of a 208-paragraph report."

15 That's not the way Rule 26 is supposed to work. 16 If he is going to get up there and give this new opinion, this 17 new failure to warn theory, then we need more time to prepare for that because that's not the way Rule 26 is supposed to 18 19 work. You can't change horses at the starting gate. If they 20 are going to be permitted to change their horse, they are going 21 to take out the "Capital W" warnings horse and put in the 2015 22 label change horse, then we need to move back the post time. 23 So that's our position, Your Honor. We think

that good cause exists in this case. We would ask thatYour Honor adjourn the trial date. We are not asking for a

1 stay as it relates to the issues I just discussed. We think 2 that we could try this case on November 4, on December 1, use 3 the extra time to get the pretrial rulings done, allow us to 4 address and find out from them -- maybe Mr. Coffin will tell us 5 right now whether the December 2015 label change was adequate or whether Dr. Kessler is going to say that or something else 6 7 on the stand. We think we have the right to know that before 8 we try this case.

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THE COURT: Thank you.

MR. COFFIN: Good morning, Your Honor. Chris Coffin on behalf of the PSC.

I would like to first address a couple of the issues that Mr. Moore brought up, and then I will talk more generally about the standard of good cause for the Court to move this trial date.

16 Mr. Moore stated that we are supposed to be 17 doing everything in this MDL except trying cases. I think that 18 is contrary to what the panel believes. I think that's 19 contrary to what the Manual for Complex Litigation believes. 20 Practically, as this Court is well aware, we have to get cases 21 to trial in order to help us with the ultimate goal of this 22 MDL, which is resolution of over 11,000 cases, women who have 23 been diagnosed with cancer, some of whom unfortunately we now 24 know, Your Honor, are dying during the pendency of this 25 litigation.

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The panel and the Manual for Complex Litigation certainly would not support foregoing trials or continuing trials in the circumstances we have here. The facts of this particular case, Ms. Earnest's case, is it was filed about 2 1/2, almost 3 years ago. We have to look at that, but we also, I think, equally as important have to look through the lens of the MDL overall.

8 As Your Honor is well aware, there's over 11,000 9 cases. When Judge Engelhardt had this MDL, the case was 10 originally set for trial in September of 2018. There was a continuance, understandably. Your Honor came on the bench and 11 12 moved it to May, I believe, of 2019 -- or no. Yes, May and now 13 September of 2019. This would be the third continuance in this It is prejudicial to Ms. Earnest and, looking through the 14 MDL. 15 broader lens, to the 11,000.

16 THE COURT: What about Mr. Moore's concern about a 17 changing expert opinion?

18 MR. COFFIN: Your Honor, Dr. Kessler's opinion, first 19 of all, has been --

THE COURT: I thought I was clear in my preemption
motion. I did not deal with the 2015 label at all.

MR. COFFIN: Understood.

THE COURT: Ms. Earnest received her infusions in
24 2011. I'm pretty sure --

MR. COFFIN: 2011? No, it was earlier than that,

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I think it was -- 2011. You are correct. 1 actually. 2 **THE COURT:** So I was looking at a label, as I recall, 3 that was formulated in 2002 and subsequent studies in 2004 and, 4 I believe, 2006 that indicated upticks in permanent alopecia 5 and then some case reports. I thought you-all saw that that's 6 what my ruling was based upon. I was very clear not to say 7 these comments have anything to do with a review of the 2015 8 label at all. That was not before me. 9 MR. COFFIN: Understood. 10 **THE COURT:** Mr. Moore's argument is, "Wait a minute." 11 I'm not sure what Dr. Kessler is going to say, 12 but if he has changed his opinion, we have a problem. 13 **MR. COFFIN:** Dr. Kessler has not changed his opinion, Your Honor. 14 15 THE COURT: Okay. 16 **MR. COFFIN:** As this Court has stated, the experts 17 are going to be held to what is in the four corners of their 18 report and presumably their testimony as it's been given in 19 deposition. If they want to cross-examine -- and I'm confident they will -- Dr. Kessler all day long as to whether he somehow 20 21 changed his opinions in his report or his testimony was 22 different and he wants to show that to the jury, that he is now switching things around and it's not a supportable opinion for 23 24 Ms. Earnest's case, okay, fine. 25 **THE COURT:** Why are we taking depositions now?

09.26

MR. COFFIN: I'm glad you asked that, Your Honor. 1 2 THE COURT: Good. 3 The issue of the 30(b)(6) in front of MR. COFFIN: 4 Magistrate Judge North that Mr. Moore referenced, that's 5 because we have had to go back to Magistrate Judge North to 6 compel the defendants to comply with where we feel they have 7 not complied with the initial 30(b)(6) notice, and we have had 8 to go back and back. That's a contested issue. That's because 9 we believe they haven't complied with it. That's not because 10 of something we did. 11 Dr. Shapiro is being deposed today because there 12 were scheduling conflicts that existed long ago, and by 13 agreement we agreed to put off the deposition. Now. to the fact that the defendants want to 14 15 take additional depositions now, that is a problem, Your Honor, 16 there's no doubt about it, but that's not before Your Honor. 17 We are happy to have them tell you, tell us, why they should be 18 entitled to depositions at this point, especially one of their 19 own former company employees, at this late stage in the game, but that's not before you, Your Honor. 20 21 If they want to bring those arguments later, 22 they think discovery should be reopened, okay, fine, but 23 discovery is closed except for those issues that are either 24 before Magistrate Judge North or by agreement have been moved. 25 So the thrust of their argument, Your Honor, at

09.57

least it was in their papers, is that Your Honor needs more
 time, this Court needs to have thoughtful analysis of these
 issues -- as if you wouldn't -- and they are concerned,

issues -- as if you wouldn't -- and they are concerned, presumably, that you're not going to have the time and, I guess, the ability to thoroughly analyze things in the time that you have.

7 I think since they have even filed their motion 8 for a continuance you have disproved that. That assumption is 9 iust false. You issued a preemption opinion. You just gave us 10 opinions in chambers, Your Honor. I think that fails. I think 11 the prejudice to the plaintiffs is very obvious not only for 12 the time frame, but the type of diagnosis these women have, 13 some of them who have passed away already.

14 Quite frankly, Your Honor, we have all known the 15 rules of this Court for preparing for this trial for a long 16 time. We negotiated heavily on this schedule. We have gone 17 over and above to prepare experts for the date of September 16. 18 It would be definitively prejudicial to the plaintiffs if we 19 have to move this, especially in light of the larger lens we 20 are looking through with the MDL and the experts that we have 21 set up.

Thank you, Your Honor.
THE COURT: Thank you.
MR. MOORE: One minute, Your Honor.
Our work in defending a case begins when we get

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the pretrial rulings. What I think I just heard Mr. Coffin say 1 2 from the stand is that you should permit Dr. Kessler to render 3 an opinion that he did not express in the section of his report 4 where he says, "My opinions are as follows," and his suggested 5 remedy for that is that we get to cross him in front of the jury on the fact that it wasn't in his report. An opinion 6 7 that's not in the report, an opinion that's not stated as an 8 opinion, that we are not put on notice of, is not one that 9 should be presented in front of the jury. If they are going to 10 present a new failure to warn case, as I said, we need time to 11 defend ourselves.

12 The last observation I would make, Judge, stems 13 around this idea of prejudice. This is the first of five 14 bellwether trials. We are not moving any of the other 15 bellwether trials. The second one is not until March. There 16 is literally no difference in anyone's world for this MDL if 17 this case is tried on September 16 or November 4 or December 1. 18 There really isn't. We have plenty of time to get ready for 19 the second trial. It just gives us more time to get through 20 the work that we have to do before the first one. That's all. 21 Thank you, Your Honor. 22 **THE COURT:** We are going to try our case in 23 September. We are going to try this case in September. Ι

24 think Mr. Strongman heard that yesterday.

I will tell you, because we are sitting on the

10:00

cusp of significant decisions, that I need to let you know what 1 2 my thoughts are. I am not inclined to grant an interlocutory appeal, and let me tell you. I do think it requires some 3 4 factual determinations for the appellate court. The circuit cautions us all the time, "Don't send us things piecemeal," and 5 so I think we need to try this case. We may have to look at 6 7 these issues. Let's see where this trial takes us, and that's 8 as much as I will say today.

9 I know you need a decision, but you probably are
10 going to get a paragraph this afternoon. We are going to
11 proceed with trial in September. I'm going to deny the
12 interlocutory appeal at this juncture. We will see what
13 happens after the course of our first trial because it may be
14 that we will be sending up a complete case for the
15 Fifth Circuit to review. That's my ruling.

16 I know you need something written addressing 17 those three factors that I have not just now other than that. 18 Now that you know, that's really going to go on the bottom of 19 the list.

MS. EISENSTEIN: Can I ask Your Honor if you might consider at least reserving decision on interlocutory appeal of the *Mills* case, which I think is not necessarily hinging on the *Earnest* decision and whether or not you --

24 THE COURT: What I said and what I'm comfortable25 saying is, at this juncture, no. I think we need to get

10:03

through this first trial and perhaps send up a complete case to the Fifth Circuit. MR. COFFIN: Thank you, Your Honor. MR. MOORE: Thank you, Your Honor. 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. <u>/s/ Toni Doyle Tusa</u> Toni Doyle Tusa, CCR, FCRR Official Court Reporter 

10:06