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IN THE DISTRICT COURT OF THE UNITED STATES  
DISTRICT OF SOUTH CAROLINA  
CHARLESTON DIVISION

IN RE: LIPITOR 2:14-MN-2502

TRANSCRIPT OF TELEPHONE CONFERENCE  
THURSDAY, JANUARY 22, 2016  
BEFORE THE HONORABLE RICHARD M. GERGEL,  
UNITED STATES DISTRICT JUDGE

APPEARED FOR PLAINTIFFS:

Blair Hahn, Esquire  
Mark Tanenbaum, Esquire

APPEARED FOR DEFENDANTS:

Mark Cheffo, Esquire  
Michael Cole, Esquire

Court Reporter: Amy C. Diaz, RPR, CRR  
P.O. Box 835  
Charleston, SC 29402

Proceedings recorded by mechanical shorthand,  
Transcript produced by computer-aided transcription.

1 THE COURT: Judge, this is Blair Hahn and Mark  
2 Tanenbaum.

3 THE COURT: Mr. Cheffo, are you there?

4 MR. CHEFFO: We are. I'm here with Mike Cole.

5 THE COURT: I was about to declare the plaintiffs  
6 the winner because you weren't there.

7 Okay. Folks, this is obviously in the MDL, and In  
8 Re: Lipitor, 2:14-2502.

9 Could counsel identify themselves for the record,  
10 beginning with plaintiffs' counsel?

11 MR. HAHN: Blair Hahn for the plaintiffs.

12 MR. TANENBAUM: Mark Tanenbaum.

13 THE COURT: Defense counsel?

14 MR. CHEFFO: It's Mark Cheffo.

15 THE COURT: Yes.

16 MR. COLE: Mike Cole.

17 THE COURT: Folks, I have obviously received the  
18 correspondence of counsel regarding the 80-milligram cases.  
19 And let me just start, Mr. Hahn, with you, so I can  
20 understand exactly what your wording means.

21 Have you reviewed the full inventory of all pending  
22 MDL cases, identified those with 80 milligrams and then  
23 evaluated whether they meet the standards of the Waters and  
24 the SPARCL study?

25 MR. HAHN: Yes, sir.

1 THE COURT: So you have -- and --

2 MR. HAHN: Based on the fact sheets, we identified  
3 the 80-milligram cases and then went further, as necessary,  
4 until they were disqualified from the SPARCL analysis.

5 THE COURT: And the 80 -- and I know you had done a  
6 rough estimate when we started this process that you thought  
7 it was about 10 percent of your total cases. Did that vary  
8 once you actually got into the plaintiff fact sheets?

9 MR. HAHN: It's hard -- I don't know -- I don't  
10 think so, Judge, but that's just very rough, because we had  
11 paralegals that were pulling the fact sheets and then making  
12 the determinations originally because there were a lot of  
13 fact sheets and it was very obvious whether or not they met  
14 the criteria or not. So those were knocked off quickly and  
15 didn't make it.

16 THE COURT: Mr. Cheffo, have you made any  
17 independent review of the fact sheets from the defense end to  
18 confirm this?

19 MR. CHEFFO: We haven't done -- the quick answer is  
20 yes, we have done some, Your Honor. We didn't go through the  
21 entire inventory. We did some spot checking. I think we  
22 started to look a little bit at the Hanly Conroy because we  
23 thought, you know, based on our discussions that might make  
24 some sense. So we basically looked at Blair's and Hanly  
25 Conroy. And beyond that, I think -- I think that the rough

1 numbers that we had was 8 or 9 percent of the total  
2 inventory, based on certain fact sheet information, was  
3 80 milligrams. But as I think we have learned, and Blair,  
4 sometimes people split the 80, so it's probably less than  
5 that.

6 THE COURT: I got you. I re-read the Waters  
7 article today. And I will tell you, I think plaintiffs make  
8 a valid point that, you know, about the SPARCL criteria.

9 And let me explain my reasoning about this. There  
10 are three studies that Waters -- as everybody knows, there  
11 are three studies that that article addresses: TNT, SPARCL  
12 and IDEAL. TNT and IDEAL deal with people with a history of  
13 cardiac disease. And when you look at all the four sort of  
14 metabolic-related risk factors, IDEAL and TNT, there is some  
15 increased risk with Lipitor, but neither are statistically  
16 significant for increased risk and none of them have a hazard  
17 ratio in excess of 2.

18 SPARCL, which has both statistical significance,  
19 that is the bottom of the range is more than 1, and the --  
20 has a hazard ratio of more than 2, clearly exempts people who  
21 have a prior history of cardiac disease, so -- coronary  
22 artery disease. So I don't think we all know, and they  
23 don't -- this article doesn't presume to tell us why there  
24 might be a difference between TNT, IDEAL and then SPARCL.  
25 But it nonetheless is present.

1           And I think -- though I didn't consider that,  
2 frankly -- and I think, Mr. Cheffo, you are right about  
3 that -- that I think -- but I think the plaintiffs make a  
4 point that they don't really fall within the criteria.

5           So what you are telling me, Mr. Hahn, is the best of  
6 your knowledge, you don't have a plaintiff that meets the  
7 profile of a SPARCL subject for 80 milligrams?

8           MR. HAHN: That's correct, Your Honor.

9           THE COURT: And Mr. Cheffo, you don't have for me  
10 any evidence -- you can't identify any plaintiff who might  
11 fit that profile?

12           MR. CHEFFO: Here is what I would say on that one,  
13 Your Honor. I would think probably we think we do. And we  
14 don't have complete information, and obviously we are in  
15 discovery, Your Honor knows that. What I would say is if  
16 you will recall the plaintiffs identified Brown, Stefano and  
17 Rocco. We've looked at those, you know, quite carefully, as  
18 I'm sure the plaintiffs have, and based on our information,  
19 we actually think the Brown case, again, based on what we  
20 know now, would fit within the criteria. Brown and Stefano,  
21 they basically -- I'm sorry -- Stefano and Rocco, I think the  
22 plaintiffs' concern was that those folks had, you know,  
23 coronary artery disease before, and that seems consistent  
24 with what our information shows, but Brown does not; and in  
25 fact, has some inclusion criteria, including this kind of

1 ocular issue, amaurosis fugax, which is kind of a transient  
2 ischemic attack, which is consistent with the SPARCL  
3 inclusion criteria.

4 So again, with the caveat that we haven't deposed  
5 them, we haven't done anything. But if you look at the  
6 information, and digging right now, Brown would actually seem  
7 to fit within what we understand the SPARCL criteria to be.

8 THE COURT: Okay. And Mr. Hahn, can you tell me  
9 why you don't think Brown fits?

10 MR. HAHN: Ms. Brown was diagnosed with CHD the day  
11 that she was placed on 80 milligrams. So she -- she clearly  
12 had CHD before she was put on 80 milligrams. But for  
13 purposes of SPARCL, she had -- when she was put on  
14 80 milligrams, she was diagnosed with heart disease.

15 THE COURT: So literally she -- she is at an  
16 appointment, she's diagnosed with coronary artery disease and  
17 she's then placed on the drug?

18 MR. HAHN: Yes, sir.

19 MR. CHEFFO: I would just say this, you know, not  
20 to split hairs, but these are relatively -- I think precision  
21 is important with the criteria. My understanding of the  
22 records is she actually had heart failure, and, you know,  
23 again with -- heart failure is actually not an exclusionary  
24 SPARCL criteria, it's not coronary artery disease. So  
25 again, I get it, you know, these are close contests, but

1 based on what we know of the records, heart failure, unless  
2 there is something I haven't seen or am missing, would not  
3 actually be an exclusionary factor, and that's not what led  
4 her to be diagnosed the next day.

5 THE COURT: Well --

6 MR. HAHN: We are pulling the medical record. I  
7 was reading off a summary, Judge. This woman also has  
8 Multiple Sclerosis.

9 THE COURT: Which is a really confounding thing,  
10 frankly, all by itself.

11 MR. CHEFFO: We've looked at that, too. And, you  
12 know, again, unless there is studies or, you know, in some  
13 regards -- I don't want to be arguing against my own position  
14 here -- but frankly, we've looked at the literature and  
15 haven't really seen MS in and of itself being kind of a risk  
16 factor for type 2 diabetes.

17 THE COURT: You know, I'm looking here at Waters and  
18 I need to go back and read SPARCL, but when it's  
19 describing -- when Waters is describing the SPARCL criteria,  
20 it says no known coronary disease. I mean, you are telling  
21 me that heart failure is not coronary disease?

22 MR. CHEFFO: Well, you know, that's -- yeah, I'm  
23 saying that that would be -- here is what I have -- and I  
24 also have a summary -- it says first of all in 2011 after the  
25 endocardiogram, her internist reported diagnosed with

1 unspecified systolic heart failure. The diagnosis does not  
2 carry forward, doesn't show up, it's not further discussed in  
3 the record. There is no one else who she says she had heart  
4 failure and it's not carried forward.

5 And as I understand it, and in asking kind of the  
6 experts and the folks who probably know more than I do, if --  
7 based on that presentation, if she appeared towards SPARCL,  
8 she would not be excluded based on that.

9 MR. HAHN: I could also add that since our letter  
10 to the Court we have received from Ms. Brown -- because we  
11 have been in contact with her about, you know, her inclusion  
12 as a bellwether -- we have received from her an order from  
13 her doctor telling her that she's not to -- that he doesn't  
14 think it's in her best interests to participate in trial  
15 because of her Multiple Sclerosis. So she has asked us to  
16 dismiss the case anyway.

17 THE COURT: Listen, I might need -- if I was going  
18 to think further about this -- I'm now looking, you know, in  
19 realtime at the SPARCL article in the *New England Journal of*  
20 *Medicine* and it says: "In patients with recent stroke or TIA  
21 and without known coronary heart disease." I just can't  
22 believe heart failure, it doesn't fall into coronary heart  
23 disease. It just -- I mean, that just doesn't make any  
24 sense to me. I'm glad to read this more carefully. But it  
25 certainly is in conflict.

1 I'm also -- I mean, the moment I heard -- I didn't  
2 remember her name was Brown -- that there was a Multiple  
3 Sclerosis, it's just another sort of -- you know, it's not  
4 typical in any way. And, you know, listen, I have been -- I  
5 was expecting we would have dozens of Water -- people meeting  
6 the SPARCL criteria and we are down to one and we are  
7 splitting hairs over whether heart failure is coronary  
8 disease. I don't know. I'm fairly -- I will look again at  
9 that issue and read more carefully the article on SPARCL, but  
10 I'm fairly -- count me a sceptic right now.

11 MR. CHEFFO: Fair enough, Judge.

12 THE COURT: Let's talk for just a minute about where  
13 that leaves us. That's the -- you know, assuming we don't  
14 have a case in the 80 milligrams, you know, I think the --  
15 let me ask this first from the plaintiff: Is there any  
16 reason to believe that if we picked a 20- or 40-milligram  
17 case to try as a bellwether that you would have any class of  
18 cases or factual presentation or new theory that might  
19 survive specific causation, assuming the correctness of the  
20 Murphy order? Mr. Hahn?

21 MR. HAHN: The short answer is no, sir, Your Honor,  
22 we don't. Given the Murphy order and the Court's reading of  
23 the medicine, we are not going to be able to get a  
24 differential diagnosis that's going to survive.

25 THE COURT: Well, it's not a differential diagnosis,

1 you've got to show specific causation more likely than not.  
2 And you have an opinion to that. And what I -- you know,  
3 received from, you know, what I've seen from your specific  
4 causation experts, we've just got two of them here, are  
5 really that it's a risk factor, but none of it is, you know,  
6 as a matter more likely than not. You can't statistically  
7 demonstrate that. You haven't shown that you can eliminate  
8 these other factors. You know, to me, I mean, we don't need  
9 to reargue that.

10 But if we assume for a minute that the critical  
11 question then is whether the Court is correct regarding the  
12 standard, if you are telling me, Mr. Hahn, that if I'm  
13 correct, then you are not going to have a case that survives  
14 summary judgment?

15 MR. HAHN: Yes, sir.

16 THE COURT: Well, let's talk about what's -- you  
17 know, I have several options here. One option is I could  
18 issue my orders in this case and send the cases back to the  
19 districts from which they came. I am very mindful that if I  
20 do that, that is going to impose an enormous financial burden  
21 on plaintiffs and defendants, mainly plaintiffs' and  
22 defendant's counsel, and tremendous cost.

23 Is there a desire, notwithstanding that, that  
24 either party wants me to do that?

25 MR. CHEFFO: I mean, if you would like, I have a

1 proposal along those lines.

2 THE COURT: Okay.

3 MR. CHEFFO: I don't want to cut you off, Judge.

4 THE COURT: Go right ahead, Mark.

5 MR. CHEFFO: Thank you. You know, this is -- I  
6 think I'm taking a little bit out of kind of column A and  
7 column B from some other litigations that we have all been  
8 involved in when we've had similar-type issues. And  
9 basically, you know, what Blair is saying is -- it's kind of  
10 not a surprise, I think he said it in his letter, right? And  
11 I'm not in no way being pejorative. I think that the  
12 plaintiffs' view, as I understood it, is look, you know, we  
13 understand Your Honor's ruling, we kind of disagree with it,  
14 we think ultimately if it stands we are not going to be able  
15 to satisfy that type standard, right?

16 So I think what is most efficient for this  
17 litigation -- and ultimately that case and their -- you know,  
18 is to have that ultimately reviewed, right? And I think that  
19 what other courts in similar situations have done is they  
20 have basically said, just issue an order to show cause and  
21 said, look, you know, if anybody thinks that they are  
22 differently situated or has some kind of different argument  
23 or something else, they can come forward; if not, what we are  
24 going to do is we are going to grant judgment on that.

25 And to the extent obviously you package it, if you

1 will -- my term, not yours, Your Honor -- but you issue your  
2 other rulings, and to the extent that there were any other  
3 independent bases for some or all of those cases to be  
4 granted summary judgment, they would then, you know,  
5 presumably get appealed to the Fourth Circuit and the Circuit  
6 Court would do what it's going to do. And I think that's  
7 the appropriate, you know, remedy in an MDL.

8 And obviously, if the Circuit Court affirms, then  
9 it's efficient and everyone hasn't spent a lot of time and  
10 effort and money on cases that are not viable. And if some  
11 or all of them were to, you know, if the Court were to have a  
12 different view, then obviously we will all be guided by that.  
13 And I think that is very customary in an MDL and typically  
14 the way courts have handled it. Because, you know, basically  
15 have your ruling and then kind of, you know, send it back,  
16 you know, where other courts are not bound by a District  
17 Court ruling, and then without appellate review, I think  
18 would be the most inefficient way.

19 So I guess the long way of saying, if the point is  
20 that there is a fundamental legal dispute about this, you  
21 know, we obviously think you are right and the plaintiffs  
22 think that maybe you are not, the most efficient way is to  
23 expeditiously grant summary judgment for all the cases on  
24 that ground, and anything else, get to the Fourth Circuit and  
25 have the Court review it.

1 THE COURT: Mr. Hahn, what are your thoughts?

2 MR. HAHN: Judge, I -- I believe that Mark was  
3 cheating and reading off of my notepad. We basically agree.

4 He said one thing that gave me a little pause, which  
5 was that your *Daubert* rulings would not be binding on  
6 transferee courts. That it was my understanding that your  
7 general causation *Daubert* rulings would all be binding on  
8 transferee courts. And so that would be the only thing that  
9 we would have available to us would be go to the Fourth  
10 Circuit.

11 MR. CHEFFO: I'm sorry, Blair, I agree with you. I  
12 was talking more about like the Murphy or Handshoe, if they  
13 were, you know, if they were specific to Murphy, but the  
14 principles would be -- but we actually agree completely on  
15 that.

16 THE COURT: Yeah. You know, I have -- I mean, I  
17 think we need to -- we've got a fair amount of work to do  
18 here, a whole laundry list of orders that my chambers needs  
19 to get out and which we are actively working on. And I think  
20 the idea of -- let me just sort of formalize what I just  
21 asked Mr. Hahn in this hearing, which is, you know, is there  
22 any reason to believe that any plaintiff case would survive  
23 summary judgment if the standards set forth in that order  
24 were upheld and the answer is no, then I think we are -- I  
25 think that may make a lot of sense.

1 I just -- what I don't want to do is, you know,  
2 there is a huge burden on my colleagues all around the  
3 country to get these cases and try to put their arms around  
4 it, there is a huge burden on the plaintiff trying to manage  
5 these cases, and there is a huge burden on the defendant  
6 defending these cases. And I share the view of, apparently  
7 of all counsel, that that's really, you know, a really  
8 inefficient way to get to the end game here. Because what we  
9 need to know is whether the Court's specific causation  
10 analysis is correct, right? I mean, and to the extent  
11 that's -- I mean, we are going to reach general causation.  
12 We are going to deal with dosage and all of that. So, you  
13 know, we'll have all of those issues addressed. We'll deal  
14 with efficacy and Fleming and Abramson and all of those,  
15 we'll do all of those issues.

16 But in the end game, you know, in the end of this,  
17 we are -- you know, I think making definitive rulings that  
18 are applicable to all the pending cases and then letting the  
19 plaintiff just tee it up as a clean attack on the Court's  
20 conclusions would -- and let the Fourth Circuit sort of  
21 likely have the final word there, I think that's -- that kind  
22 of makes sense to me.

23 MR. HAHN: The only thing I would say, Judge, is  
24 it's not an attack on your ruling.

25 THE COURT: I don't take anything anybody does

1 personally, okay? But, you know, obviously the -- you need  
2 not say that the Court was casual in reaching the decision.  
3 It was very carefully reasoned and thought through, but, you  
4 know, I have no delusions of perfection. And I think there  
5 is a reason we have appellate review is just for cases like  
6 this, and it deserves as quickly as possible a review. And  
7 it also has the benefit that in the event the Fourth Circuit  
8 did not agree with me, we would still have the MDL in place  
9 to address further issues as might be needed. And I might  
10 say if at any point the parties thought better of trying to  
11 find some resolution of this thing, I'm glad to do what I can  
12 to help bring that about, as well.

13 So are there other matters that we need to address  
14 right now?

15 MR. HAHN: Do we still need to have a status  
16 conference next week?

17 THE COURT: That was on my mind, as well. I mean,  
18 obviously I was planning to address these 80-milligram cases  
19 and all of that.

20 Mr. Cole, what do you think?

21 MR. COLE: I don't really see that we need to do  
22 anything because of where we are right now. We have a plan  
23 to go forward. And at least from our side we have a handle  
24 on all of our folks as to kind of where we are going, we can  
25 explain and we can work with Your Honor and Blair and Mark to

1 just sort of move this along. So it seems to me we probably  
2 don't need one, but I'm here and I don't mind doing it.

3 THE COURT: Well, I think one of the things I've  
4 never been crazy about is wasted effort, you know? I've  
5 always -- Mr. Hahn, do you have any reason we would need to  
6 get together next week?

7 MR. HAHN: No, sir, Your Honor. I think what we  
8 have right now is a Scheduling Order that is in place that  
9 brings us to you ultimately to rule on all of the outstanding  
10 issues with all of the experts, whether it be pending dose  
11 issues or Dr. Handshoe's opinion has yet to be ruled on.

12 THE COURT: Correct.

13 MR. HAHN: So my expectation would be that the  
14 Court would rule on all of those pending expert issues --

15 THE COURT: Mr. Hahn, every issue. We intend to  
16 rule on every *Daubert* motion.

17 MR. HAHN: Yes, sir. And at that point then  
18 perhaps we could sit down and figure out the cleanest way for  
19 us to then have an appeal to the Fourth Circuit.

20 THE COURT: Okay. Well, we are going to -- rather  
21 than be spending time getting ready for our meeting next  
22 week, we are going to continue working on our orders because  
23 we get it that everybody is waiting and time is money. So,  
24 you know, we are plugging along here and we will continue  
25 those efforts.

1 MR. CHEFFO: Could I raise just one case management  
2 issue off the record, if that's acceptable?

3 THE COURT: You want to do it off the record?  
4 Let's see if we've got anything else. Anything further we  
5 need to address? Okay. The hearing is now to a close and  
6 I'm directing my court reporter who is no longer on the  
7 record.

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10 I certify that the foregoing is a correct transcript from the  
11 record of proceedings in the above-titled matter.

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17 Amy C. Diaz, RPR, CRR January 22, 2016  
18 S/ Amy Diaz  
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