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

IN RE: LIPITOR : 2:14 MN 2502

Status Conference in the above-captioned matter held Friday, September 19, 2014, commencing at 10:08 a.m., before the Honorable Richard M. Gergel, in Courtroom III, United States Courthouse, 83 Meeting Street, Charleston, South Carolina, 29401.

REPORTED BY DEBRA LEE POTOCKI, RMR, RDR, CRR
Official Reporter for the U.S. District Court
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A P P E A R A N C E S

APPEARED FOR PLAINTIFFS:

- Jayne Conroy, Esquire
- Mitchell M. Breit, Esquire
- Ramon R. Lopez, Esquire
- Mark C. Tanenbaum, Esquire
- Mia Maness, Esquire
- Ann Estelle Rice Ervin, Esquire
- Joseph F. Rice, Esquire
- Blair H. Hahn, Esquire
- Christiaan Marcum, Esquire
- David F. Miceli, Esquire
- Michael Heaviside, Esquire
- Joshua M. Mankoff, Esquire

APPEARED FOR DEFENDANTS:

- Michael T. Cole, Esquire
- Mark S. Cheffo, Esquire
- Sheila Birnbaum, Esquire
- Rachel B. Passaretti-Wu, Esquire
- Michael Parini, Esquire
- Sheila Brodbeck, Esquire
- Lyn Pruitt, Esquire
- Mark Jones, Esquire
- Habib Nasrullah, Esquire

1 THE COURT: We are here in the matter of the Lipitor
2 MDL, 2:14-2502.

3 Could counsel who will be speaking today identify
4 themselves for the record, beginning with plaintiffs' counsel.

5 MR. HAHN: Blair Hahn for the plaintiffs, Your Honor.

6 MR. CHEFFO: Mark Cheffo for defendants, Your Honor.

7 THE COURT: Very good, thank you. Because there are
8 obviously folks both on the telephone and in this courtroom
9 who weren't sitting in my chambers yesterday when I had the
10 opportunity to meet with lead counsel for the plaintiff and
11 the defendant, I think we ought to probably, on the record,
12 address some of these issues, so that there will be a fuller
13 understanding of what you're seeking and the Court's response.

14 Mr. Cheffo, do you want to start?

15 MR. CHEFFO: Yes, Your Honor, thank you. I've been
16 tasked, Your Honor, to speak really, I think, jointly on
17 behalf of the defendant and certainly the plaintiffs with
18 respect to this request.

19 You know, we've been before Your Honor monthly, you know
20 that really both sides have been working hard, we've heard you
21 from day one that we need to be doing that. And I think in
22 fairness, there's some speed bumps, but for the most part
23 there's really been a herculean effort in terms of the
24 depositions, the amount of production, the millions of pages.

25 So I think the schedule you've put in place has really

1 benefited both sides in getting us to where we are, and this
2 is not a speech about slowing down. But I think what we've
3 come to realize, and I think the request is for a modest
4 extension of our period of time. And it's really based on the
5 phasing of where we are, Your Honor. And it focuses mostly on
6 the fact that we've now produced lots of documents, and we
7 have depositions --

8 THE COURT: When you say lots of documents, give me
9 an idea, because that lots may be different from --

10 MR. CHEFFO: Yes, Your Honor. Almost 10 million
11 pages, in a very short period of time, comparatively. We will
12 have produced 30 plus custodial files. And many of these are
13 just enormous in kind of the scope of years and volume. So
14 the production really crosses all phases of, you know, what
15 you would expect a pharma company to have in this type of
16 litigation, from pharmacovigilance to marketing to sales to
17 safety to medical. And that process is ongoing as well with
18 respect to a few of them.

19 But I think where we are, Your Honor, is a point that
20 having three months will allow us to really not even take --
21 to take a deep breath, but will allow us to internalize these
22 documents, prepare witnesses in a way that Your Honor would
23 expect us to do it, have the plaintiffs have an opportunity to
24 review the documents in a way that they probably need to do
25 it. And then have expert reports that are produced, and

1 experts who are, you know, facile with the information.
2 Because I know you've said, and we agree, that this should
3 really be done once and it should be done the right way. And
4 kind of following that admonition, you know, we think that
5 this relatively modest request will allow us to do that, Your
6 Honor.

7 THE COURT: Now, obviously I'm not a stranger to this
8 discussion, because I was part of it yesterday.

9 MR. CHEFFO: You were, Your Honor.

10 THE COURT: And I asked you and Mr. Hahn to try to
11 sit down and figure out, if you were given three more months,
12 90 additional days, where in that schedule you would put it,
13 because what we're talking about, instead of a trial on or
14 about July 1, would be on or about October 1. And have y'all
15 had a chance to talk about that?

16 MR. CHEFFO: We have talked informally, and I think
17 our plan is this, again, with Your Honor's, you know, kind of
18 indulgence. What we'd like to do is we're going to, over the
19 weekend, prepare a proposal. And I think, you know, the
20 starting point will be the schedule we have, but as you might
21 imagine, we've all learned a little bit, we might tweak a week
22 here or two weeks, and work with them. So we're going send
23 them something on Monday, they're going to review it. I'm
24 hopeful, like most things we've done in this area, we'll come
25 to agreement in probably mid to late week next week, we'll

1 have a proposed joint schedule. And if there's a little tweak
2 we need to do, you know, plaintiff, defendant, we'll do that
3 for Your Honor.

4 THE COURT: You know, several times we've had
5 schedule issues come up, some of them just having trouble
6 meeting them, and other cases, one side complained you haven't
7 produced something in which the schedule hasn't come up yet,
8 right? I think you may remember a few of those.

9 MR. CHEFFO: I do, Your Honor.

10 THE COURT: And the answer to all of those has been,
11 well, you guys came up with the schedule, right? And I want
12 you to do that, because you've got to live with it.

13 But I do think there is great benefit in moving this thing
14 along. I must confess, I did not anticipate that the
15 plaintiffs' hunger for documents, which they probably deeply
16 regret at this moment, would come to 10 million. And that
17 presents, I'm sure, its own organizational challenges, which
18 these guys seem very much up to, but which will be challenging
19 nonetheless.

20 So, you know, let me hear from Mr. Hahn so it will be on
21 the record, weigh in on this as well.

22 MR. CHEFFO: Yes, Your Honor.

23 THE COURT: Thank you, Mr. Cheffo.

24 MR. HAHN: Thank you, Your Honor. I agree with what
25 Mr. Cheffo has said. I think everybody has made best efforts

1 to comply with the schedule. This is a very large
2 undertaking, as we talked about yesterday. This is, on one
3 hand, a very simple failure to warn case; on the other hand
4 it's a search for the knowledge of Pfizer, which is one of the
5 largest corporations in the world. So there's just a lot of
6 people and a lot of documents to look for.

7 Of the 10 million pages that they have produced to date,
8 7 million of them have been produced to us since the 1st of
9 August. We are in the process of looking through those.

10 THE COURT: You're at about three and a half million
11 yourself.

12 MR. HAHN: Yes, sir. And we've got five more
13 custodial files that we expect we will be receiving in the
14 coming weeks. So we agree, this is the first time I've ever
15 asked the Court for an extension on a trial date, but we agree
16 that we can put three months to good use, and create the best
17 product possible for this MDL, and meet our obligations to all
18 of the litigants within the MDL.

19 What we did talk about generally, and I think we're going
20 to work this out this week, is expanding the schedule for
21 general causation. And so what is currently on the schedule
22 is now until the middle of January, we would make from now
23 until April, and that's where we'll use the time. We're not
24 talking about expanding the time on any of the specific
25 causation issues; we think we can handle those without

1 incident.

2 So that's where plaintiffs --

3 THE COURT: Let me just say that I don't think I'm
4 telling you any secret when I tell you I'm not particularly a
5 softy on extensions. I remember we had a roster meeting one
6 time and a fellow stood up and said, Your Honor, I need an
7 extension because my wife is giving her sister a kidney. I
8 said, God bless her. Next guy stood up. I said, is your wife
9 donating a kidney? Tough standard.

10 But I think it's -- I think y'all both make a good case
11 for it. But it's like I tell my prisoners, you get one chance
12 to mess up, and then after that, you know, I'm not nearly so
13 reasonable. So y'all need to live with this, study it
14 carefully, be methodical about what you're doing. Because
15 come October, we're going to try this case. I mean, I think
16 y'all have made the case you need a little bit more time and
17 I'm going to give it to you. But we're going to live with
18 that schedule.

19 MR. HAHN: Yes, sir.

20 THE COURT: Fair enough?

21 MR. CHEFFO: Yes, Your Honor, thank you.

22 THE COURT: Okay. I was asked to consider a
23 fairly -- what I consider fairly elaborate protocols for
24 discovery by the defendant, which I thought was fraught with
25 potential complications and controversy, and that the Federal

1 Rules we're accustomed to operating under generally work fine.
2 But I did think some issues were sort of raised that I want to
3 sort of see if we don't have -- we can come to some common
4 understanding.

5 Listen, folks, we're going to have issues that arise in
6 the midst of depositions, we're going to have issues that
7 arise that we don't even think about right now. And part of
8 my management of this is I'm going to do everything I can to
9 be available to promptly address these issues. So all we're
10 trying to do is anticipate the more obvious issues that may
11 arise.

12 But one of them is this issue about access to treating
13 physicians of plaintiffs. And I've read the case law out
14 there on this issue, and this has been a somewhat perplexing
15 problem for courts and for litigants in these things. But I
16 wanted to tell you that after thinking about it and studying
17 it, and I will say I'm somewhat influenced by our own practice
18 here in South Carolina, it is an unethical act for a defense
19 lawyer in, say even a malpractice case, to meet with the
20 plaintiff's treating physician ex parte. It's just considered
21 an unethical act. On the part of the physician, not the
22 lawyer, on the part of the physician. And I think there are
23 other states have some -- adopt that view. Some say if it's a
24 medical malpractice case, that that is waived. There are all
25 variations of this. We've got cases from 46 states. And I've

1 got to basically have a rule here for us. And I think the
2 best rule is that, A, the plaintiff, of course, can meet with
3 their clients' treaters, because they're their treaters. And
4 they don't need to have anyone else present. But if they show
5 them documents outside the documents that would be the
6 treatment records, you need to provide them to the defendants.
7 Just if you show them anything else, you need to show it to
8 them.

9 Defense witnesses, unless they have the permission of
10 plaintiffs' counsel, cannot meet ex parte, and must do it by
11 deposition. And if there are problems in that, I'm glad to
12 hear it. I know Judge Fallon went down a different route one
13 time and wanted to have joint meetings, and there was just an
14 organizational disaster and he eventually reversed himself.

15 And I do get the logic and concerns about this. It's not
16 a perfect situation, but I think under the circumstances, it
17 is the one that is most manageable.

18 There was also raised a question about the production of
19 documents that are going to be shown to witnesses in
20 depositions. And, you know, South Carolina has a rule, I dare
21 say I have lawyers here from other states, if they've ever
22 seen anything like this, that we provide that if you show --
23 our local rule -- that if you show a document to a witness
24 that has not previously been provided, that witness can then
25 leave the deposition with the lawyer. It's a very peculiar --

1 even when I practiced, I found it an odd rule. But it's
2 rarely actually used, but there it is, it is in our local
3 rule.

4 But I do think that because of the sheer volume of
5 depositions y'all are undertaking, I think it is better that
6 to the extent it is practicable, y'all share the documents
7 you're going to show the witnesses. There are going to be
8 situations where a deposition is truly discovery, the witness
9 is going to say something you didn't anticipate was going to
10 take you down a certain path. That's the nature of discovery.
11 And it may well be that you didn't anticipate giving them the
12 documents, because you didn't know that issue was coming up.
13 So I say as is practicable, so I don't want people, you know,
14 knowingly ambushing somebody, but on the other hand -- sort of
15 "gotcha" justice -- but on the other hand, there are going to
16 be circumstances where people of good faith just didn't
17 anticipate it.

18 I'm available. I'll try to make myself available, to the
19 extent some controversy arises in a deposition itself. I want
20 you to be guided by the principle that at least five days
21 prior, you should provide the other side a listing of the
22 documents you intend to share. And it's a mutual thing. I
23 think it will make all of this more manageable and help you
24 prepare your witnesses in an orderly way. Because I think
25 we're talking about, I don't know, what, 150 depositions, Mr.

1 Cheffo, getting ready to undertake? Something like that?

2 MR. CHEFFO: That's correct, Your Honor.

3 THE COURT: I just think organizationally it will
4 be -- it will make the whole experience more manageable. And
5 to the extent those rules present a problem, I'm glad to hear
6 from you.

7 Does anybody have any heartburn about it right this
8 moment, of following that rule? Mr. Cheffo?

9 MR. CHEFFO: No, I think the way you've articulated,
10 the rule of reason applies, and we're, you know, flexible if
11 something comes up. But I do think with the sheer volume on
12 both sides, it's actually very helpful.

13 THE COURT: Mr. Hahn?

14 MR. HAHN: No, Your Honor, we agree.

15 THE COURT: Okay. And again, if we, by going through
16 experience teaches us that we need to make any revision, let's
17 talk about it.

18 There was some suggestion about giving 30-day notice of
19 depositions. The answer is no. We don't have enough time for
20 that.

21 There was an issue raised about that there was a concern
22 in our last roster meeting that plaintiffs -- the 14
23 designated plaintiffs had -- some of them had given very
24 limited production. And there was a concern. And I said I
25 want all the plaintiffs' lawyers to go back to their

1 individual clients, inquire again, and to provide a written
2 response about what they did in producing anything additional.

3 Mr. Cheffo, did you get written responses from all 14?

4 MR. CHEFFO: We did not, Your Honor, I think -- We
5 got very limited responses.

6 THE COURT: I'm going to direct the plaintiffs, by
7 the 26th, September 26th, to provide a written response on
8 what was done on each one of those clients, detailing what you
9 did and what you learned, and obviously producing anything new
10 that you obtained. Okay?

11 MR. CHEFFO: Yes, Your Honor.

12 THE COURT: I know there were issues raised about
13 certain things were -- when you had 32 or 37 custodial files,
14 there was some clarification on some of the clinical data, and
15 I think three additional months will give y'all some space
16 there. But I want y'all to work those things out, because
17 obviously the clinical data information is very important to
18 plaintiffs' experts, and they need to be able to have access
19 to them and manipulate that data, that they can reach and form
20 opinions.

21 I think we had some issue about scheduling corporate
22 witnesses, which I think can now be largely resolved with a
23 little bit more time.

24 Let's talk a minute about these adverse event source files
25 and where we are on that.

1 Mr. Hahn, let me hear from you, sir, about your perception
2 of where we are on that.

3 MR. HAHN: I'll start by saying the reason we need
4 the adverse event source files, Your Honor, is because this is
5 a warnings case, and --

6 THE COURT: You don't have to explain that to me, I
7 get it, okay? I mean, I wondered some about some of the stuff
8 you've been chasing. Adverse event files, I do not wonder
9 about.

10 MR. HAHN: Well, the source files, 25 of them were
11 produced. Of those 25, 20 percent of them we saw very clear
12 evidence where the actual source file would note diabetes
13 diagnosis, and what was then put into the adverse event
14 reports that were submitted to FDA was something less than
15 diabetes.

16 THE COURT: Well, which is fine. You know, we did
17 the 25 as sort of starting point to see what, A, would more
18 be helpful, worth the burden, and secondly, when we went
19 looking, were there discrete types of documents that tended to
20 provide the relevant information, so that it wouldn't be
21 necessary to produce necessarily voluminous irrelevant
22 information.

23 MR. HAHN: Yes, sir.

24 THE COURT: Now, are you able now, having seen the 25
25 source files, gotten some idea about how to more narrowly

1 define what you're looking for?

2 MR. HAHN: Yes and no, Your Honor. The reason that I
3 say that is, yes, as it relates to documents that are stored
4 electronically. No, as it relates to documents that are
5 stored in paper form. The AERs we're looking for, the source
6 files we're looking for, primarily are pre-2004. And so --

7 THE COURT: They're not going to likely be digital,
8 right?

9 MR. HAHN: A lot of that is not going to be
10 electronic. I've spoken with Mr. Cheffo today and last night
11 about this issue. And we are going to be setting up a
12 conference with his IT person that understands these issues,
13 this coming week, to further define the issue. And from
14 there, we hope that we will have negotiated a plan to move
15 forward. If not --

16 THE COURT: I'm hoping we can come up with a sampling
17 situation, as opposed to trying to chase every adverse event
18 file. I know we're in the thousands, are we not?

19 MR. HAHN: We are. And we have no desire to create
20 more paper to look at, Judge. So we are very interested in a
21 sampling that we think is fair and --

22 THE COURT: What I don't want is to have a sampling
23 that then the defendant comes in and challenges the sampling
24 as being unrepresentative or something. I mean, if we're
25 going to get into that, then I'm going to make them produce

1 everything. But perhaps we can agree on something that would
2 be representative. You know, people don't -- Gallop doesn't
3 do a poll where they go to everybody's house. There is some
4 value in sampling. And, you know, 25 is probably not enough,
5 but at some point you're going to start seeing the same
6 pattern, I would suspect, whatever that pattern is, I don't
7 know what it is. And how meaningful it is.

8 But you made the point, I thought it was a worthy pursuit,
9 that what was reported to the FDA may underreport the elevated
10 glucose issue, and that you wanted other opportunities; that
11 seemed reasonable. But I would imagine a lot in those files
12 is like completely not relevant. And I really want y'all to
13 work on a way, if you can, using your IT people, et cetera, to
14 try to narrow, to lessen the burden on all the parties here,
15 both in gathering it and in reviewing it.

16 MR. HAHN: In prior litigations we've used a similar
17 type of procedure on call notes, to not get all the call
18 notes, get a representative sample of them, and so that's what
19 we're going to be proposing.

20 THE COURT: But I want an understanding, once y'all
21 come to that, that we're not going to use the fact that it's a
22 sample as suggesting that it's not reliable information. I
23 think, Mr. Cheffo, that's an important issue here.

24 MR. CHEFFO: I understand. And I do agree with what
25 Mr. Hahn said. I think part of the issue is, Your Honor,

1 we've heard you now and before, that there's some element that
2 you'd like us to look, but I want to understand, and it's
3 really just a matter of timing, is what they think is
4 different in the source files versus what they have, and then
5 talk about kind of a candid discussion about the limitations
6 about, you know, do we have to go over the ocean here or not,
7 and then see if we can come to some accommodation. Because I
8 think we've agreed that if there's something that's kind of
9 within our reasonable ability in this sample, that I'm hoping
10 we can have an agreement. So I think we can do that next
11 week, you know, we'll know pretty quickly.

12 THE COURT: And, you know, to the extent that y'all
13 are finding a discrepancy in between the underlying data and
14 the report, don't play hide the ball with Mr. Cheffo, show it
15 to him. So, you know, you don't look like you're just, you
16 know, off on a lark of your own, that you've got some
17 reasonable basis for this. You're going to show to it him
18 eventually anyway, just go ahead and show it to him. And it's
19 not a -- it probably is a situation that doesn't exactly shock
20 him. But, you know, the significance of it, he's not going to
21 argue about it later.

22 But I think it's, you know, unlike a lot of the discovery,
23 which I think falls within broadly the ambit of discovery, but
24 which weren't as directly relevant to the failure to warn,
25 these adverse event reports get right to, I think, the

1 plaintiffs' claim. And whether there's anything to it, we'll
2 know later. But I think it's the type of thing that we, you
3 know, probably should -- when I'm making that sort of burden
4 analysis, I tip towards benefit on something as direct as
5 that, that issue. Okay?

6 MR. HAHN: Thank you, Judge.

7 THE COURT: Yes. Okay. I'm glad to hear from
8 counsel here about issues or concerns. First let me hear from
9 you, Mr. Hahn, anything you need to bring to my attention?

10 MR. HAHN: The only other issue, Judge, that we
11 talked about yesterday, was the issue of who would go first in
12 depositions. I understood you to say the defendants would go
13 first in discovery depositions, but that we would not be
14 precluded, for the trial cases, to notice a second trial
15 deposition.

16 THE COURT: That is correct. This is -- you can use,
17 y'all could ultimately use a deposition as a de bene esse
18 deposition, but if you wanted to use a discovery, and then
19 come back and do a trial, then the issue of who goes first
20 becomes a lot less of concern. Traditionally, if it's your
21 treater, the defendant would go first, I mean, that seems to
22 me the ordinary course, makes sense here. But, on the other
23 hand, if he's your witness at trial, and you can't get him
24 here, go video him, you know, state your name for the record
25 and do like a normal direct and normal cross. And that way I

1 think we solve that problem, but we keep the, you know, we
2 keep an ordinary course of discovery going. So yes.

3 MR. HAHN: Thank you, Judge. If I could have just
4 one minute.

5 THE COURT: Yes.

6 MR. HAHN: Thank you, Judge, I think that's
7 everything.

8 THE COURT: Mr. Cheffo?

9 MR. CHEFFO: Nothing for us, Your Honor, thank you
10 for helping us work through these things today.

11 THE COURT: You know, we had talked about our next
12 meeting. We're going to move it to the 24th rather than the
13 17th. I have a trial that week before, and I'd rather not
14 break up a trial to do this. So we'll do it Friday the 24th,
15 and we're going to start at 9:00 o'clock. I have some other
16 things that day I need to take care of, but we'll start at
17 9:00 on that morning.

18 And I have been asked by counsel to consider moving to
19 Thursdays thereafter, and I'm fine with that, because of
20 travel and so forth may be easier to do if we do it on
21 Thursdays. And we'll set off a new schedule, we'll put it in
22 an order or something, we'll let you know about that.

23 Okay. Are there other matters, folks in the courtroom,
24 anyone in the courtroom wishes to address?

25 Okay. How about anyone on the telephone, any issues

1 anyone else wishes to address for the Court at this time?

2 (No response.)

3 THE COURT: Okay. Without more, we'll see you next
4 month. Thank you.

5

6 (Court adjourned at 10:33 a.m.)

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REPORTER'S CERTIFICATION

I, Debra L. Potocki, RMR, RDR, CRR, Official Court Reporter for the United States District Court for the District of South Carolina, hereby certify that the foregoing is a true and correct transcript of the stenographically recorded above proceedings.

S/Debra L. Potocki

Debra L. Potocki, RMR, RDR, CRR