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

IN RE: LIPITOR	:	2:14 MN 2502
	:	2:14 CV 1400
	:	2:14 CV 1879

Status Conference in the above-captioned matter held on Thursday, December 3, 2015, commencing at 10:06 a.m., before the Honorable Richard M. Gergel, in Courtroom I, United States Courthouse, 83 Meeting Street, Charleston, South Carolina, 29401.

REPORTED BY DEBRA LEE POTOCKI, RMR, RDR, CRR
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A P P E A R A N C E S

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Michael T. Cole, Esquire
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Melissa Whitney, Esquire
Loren Brown, Esquire
Matt Holian, Esquire
Michael Hogue, Esquire

THE COURT: We're on the telephone here?

THE CLERK: Yes, sir.

THE COURT: Very good.

Okay. We are here in the matter of these specific causation expert Daubert motions in the Hempstead case.

Who will be arguing for plaintiff?

MR. TANENBAUM: Beth Middleton Burke will be arguing for the plaintiff.

I may say something else?

THE COURT: We're glad to hear from you always.

MR. TANENBAUM: And Mr. Marcum as well.

THE COURT: Good. Let me clarify a couple matters first. I understand that y'all wish to stand on your briefs as to Dr. Handshoe's specific causation, is that correct?

MR. TANENBAUM: Yes.

THE COURT: Very good. I received a motion about Dr. Robinson's report, and let me just -- we're not deciding it now, but I just wanted to say that I don't want -- I mean, I want the deposition to take place before she goes to Europe or wherever she's going. I will review all of this in due course. To the extent the plaintiff wishes to modify the report in response to this motion, I have offered no opinion about that. I want it done at least ten days before the deposition, so that we don't have a new report the hour before they walk in there. So ten days before. To the extent -- I'm

not saying you need to, but you certainly are given a little forecast of what they claim the deficiencies are -- to the extent you want to respond, you have every right to do it. But I offer no opinion about it. I will read all of it later, and I'm not ready to make a decision now, I don't have enough information to make that decision. Okay?

MR. TANENBAUM: Thank you very much, Your Honor.

THE COURT: We noticed, as we were looking at the record here, there is a reference that the defendant makes, it's really a question to Dr. Murphy about it represents that the plaintiff, Miss Hempstead, had acknowledged a 60-pound weight gain as an adult. And it apparently was in her deposition, but that portion of the deposition's not in the record. So I would simply ask defendant that, to the extent you wish the Court to consider that, that we not have just the representation of counsel that that's what it says. I need to see that portion of the deposition.

MR. CHEFFO: Of course, Your Honor, we will. Thank you.

THE COURT: You understand what I'm talking about, Mr. Tanenbaum?

MR. TANENBAUM: That's the first I've heard about that. I know their papers --

THE COURT: There's a question --

MS. BURKE: I understand it.

THE COURT: Good. The real lawyer is here. And, you know, I just, as I'm sure no lawyer would intentionally misrepresent something, but I want to actually see what the plaintiff said, okay? And what she allegedly acknowledged.

There was an issue raised about wanting to meet with me by counsel. Of course I'm always willing to do that, but I really thought it would be not right to do it without Mr. Hahn, and I know he's ill right now. And I'd like to do it in December. And I'm looking at my calendar. It looks like other than December 9th and 10th, I could pretty much move things around to accommodate y'all. I know that some may have to travel for this, but it really -- whether you want to do it on the record, off the record, it's fine, but I want to talk to y'all, and I want to do it with Mr. Hahn present.

MR. TANENBAUM: Sure.

THE COURT: So, Mr. Cheffo, I know you have to travel, so --

MR. CHEFFO: That's fine. We were talking, we're going to, with Your Honor's permission, we'll kind of caucus amongst ourselves. If we could do it next week, that will be great. We'll check in with Mr. Hahn.

THE COURT: I think we can probably work it out. I think the 9th and 10th are next Thursday, but probably Friday, if you wanted to do it, but we have to get Mr. Hahn well too, so let's make sure we can do it at a time that works for

everybody, okay?

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

THE COURT: Okay. Mr. Cheffo, who's going to argue for the defense?

MR. CHEFFO: Yes, Your Honor. So I was going to argue the Handshoe motion, and maybe, you know, I know they're going to rest on the papers, and I --

THE COURT: I don't need to hear any more.

MR. CHEFFO: Then we're done.

THE COURT: I already voiced my own opinions about that particular expert previously.

MR. CHEFFO: Absolutely, Your Honor.

THE COURT: I don't think you need to buy it back.

MR. CHEFFO: No intention of doing that. Mr. Brown, Loren Brown, will be arguing with respect to Dr. Murphy.

THE COURT: So let me hear, since it's your motion, let me hear from the defendant on the motion to -- to disqual -- not to allow the testimony, under Daubert, of Dr. Murphy.

MR. CHEFFO: I was going to say, Your Honor, as kind of a lead in, I think Mr. Brown will handle kind of the details. But I guess what we would just say, the way we've kind of approached this, and I think, as I said, Loren will handle the specifics, is, you know, we spent a lot of time on the 22nd with respect to Handshoe, we're not going to cover

that today. But I think in our view, Your Honor, we've taken an approach that not all experts are the same, we tried not to have a scatter shot approach, and kind of understanding different qualifications. I think you'll hear that our issues and concerns with respect to Dr. Murphy are, in some material respects, different than Dr. Handshoe. But what I would say is this, is that at their core, at their core, there are certain things about Dr. Murphy that are really similar, and analytically almost identical, we believe, to Dr. Handshoe. So again, we understand the differences, you'll hear them.

THE COURT: And Mr. Brown can raise those issues, to the extent he wishes to, or you want to add when he finishes, about the similarity. But, you know, I didn't just read y'all's briefs, I read each deposition twice, I read the underlying -- to the extent it was in the record -- the underlying studies that were referenced by both parties, and I read the case law. So --

MR. CHEFFO: As we expected you would.

THE COURT: So I'm sort of -- I know what you're talking about. And I think we would both agree that whatever the conclusions are about Dr. Murphy's particular methodology or whether her reliance on -- whether she applied it properly, or whether there was sufficient data, she is a more serious expert, she has a more serious claim to offer opinions than the first expert.

MR. CHEFFO: I think we would stipulate to that, Your Honor, with the caveat --

THE COURT: And I understand why the plaintiffs often want to focus on that, and I think they're entitled to do it that way, and they don't wish to argue the thing. It sort of speaks sort of volumes myself, my own view of that. I've read the Handshoe deposition carefully.

And, you know, it's sort of interesting to me that Handshoe's deposition, they've done, I think the next day, right, they actually take a somewhat different approach, as they got wiped out the first day, they tried to, you know, re-coach him. And he didn't do any better the second day, but he took a different approach, a somewhat different approach, and a different approach from Dr. Murphy, in some ways, basically arguing that he ruled out everything, which Dr. Murphy makes no pretense to do, and which she is not required to do.

I mean, you know, we'll talk about this, about differential diagnosis. You know, differential diagnosis means, I think, something different to lawyers and judges than it means to doctors, okay? The traditional differential diagnosis in medicine is that a doctor evaluates a patient sitting in his or her office, clinical evaluation, case history, review of laboratory studies. And differential diagnosis is a sort of process of diagnosis by exclusion. You

just go through until you eventually -- a combination of what evidence it has of a particular factor, and ruling out other factors, that the kind of diagnosis kind of announces itself.

This is a little bit different. I think the case law kind of broadly refers to differential diagnosis and differential etiology, without really noting that this is, in some ways, different. It is similar, I mean, it's a doctor, and the doctor is trying to wrestle with multiple potential explanations for a disease. I mean, that -- it is similar.

But the doctor has no obligation to rule everything else out, because it can be multiple causes, as long as the drug here is allegedly a substantial contributing factor. Right? They don't have to exclude others. Now, obviously, to the extent there are other powerful factors, then you have to explain why is it not enough, but you don't have to exclude it. And in some ways I think this is, you know, almost contrary to differential diagnosis. Some of this data suggests the more risk factors, the more the risk of Lipitor causing it. Certainly that's -- Mr. Marcum put up that chart last time which sort of demonstrated.

So it's not a perfect fit to call it differential diagnosis, at least in the way I think about it and the way medicine thinks about it. But in the end, we're just a 702 analysis, right? We've got to show there's a reliable methodology, we have to show it was reliably applied and

there's data to support it. And whatever we call it is sort of academic to me.

The doctor doesn't get a pass by having an MD after her name. But, you know, there are parts of differential diagnosis that she applies that are, you know, at least consistent with the process. But in the end, you've got to have the data, right? You've got to have it. And my inquiry here is sort of how do we know it's Lipitor, right? I mean, I'm really kind of interested in hearing what everybody has to say about that. How do we know that?

And I mean, Dr. Murphy doesn't literally make any bones about it that there are other factors present. I mean, she doesn't go to this artificial explanation to say they don't exist; she acknowledges they exist. The question is, is what is our evidence, when we get to the end of the day, that Lipitor caused Mrs. Hempstead's diabetes. That's really the question here. And do we have a method for doing that, have we applied that method in a reasonable way, and is there data to support that conclusion.

I mean, it's a complicated issue, but when you get down, it's not that complicated when you really kind of put it down to those issues. And I am hoping, by helping to try to focus where this argument is, is that everybody gets a fair shot at addressing that issue.

And, you know, I fussed a little bit with the plaintiffs

about Dr. Handshoe in the other one, and I was aware, I'd already read Dr. Murphy's material, I knew she was a more serious expert. And the question is, okay, you've got a really credentialed person who practices in this field, but still the question is, can she get the -- can she walk across the desert, right? Can she deliver an opinion that is reliable that gets by Daubert. That's the question here.

So I think this ought to be useful today, and I want to give everyone, I'm trying to focus you where I'm going here, is I'm really looking at what evidence do we have that Lipitor caused it. Because we don't have the duty to strike everything else out. I mean, we just don't have an obligation to do it, the plaintiff does -- it's not the plaintiff's burden to eliminate everything else, it's just to say why is it -- you know, why is it Lipitor? Why is it a substantial contributing factor?

Okay, Mr. Brown.

MR. BROWN: Thank you, Your Honor. As you know, I'm Loren Brown, I've been working with Mark and the rest of the team on this case. And as you probably observed, I took Dr. Murphy's deposition. I also helped on the briefing, and as a result of that, I get the opportunity to argue this motion.

THE COURT: I noticed that Cheffo had you do the harder one and he did the easy one. I just wanted to note

that was the case.

MR. BROWN: We've been joking about that for a few days. I said, Mark, you've got a lay up today, and I have a three pointer half court shot, depending how Judge Gergel looks at it.

So, Your Honor, I have slides today, but the goal here is not to do a Power Point show, I can promise you that. The goal here is to answer the questions that you have on your mind, and I'm ready to do that right away, if there are particular questions that you would like me to address.

THE COURT: Well, you know, I'm just sort of -- and let me -- I'm kind of giving plaintiffs' counsel kind of a lead here of where I'm going here. There are different ways to analyze the data. We could take Dr. Murphy's take on it, which is it has -- there's a hazard ratio of 1.60, that's her -- If you quantify that, of a pool of people who would take Lipitor and get diabetes, about 63 percent of them would have gotten it regardless, taking the placebo group and all that. That's the experience. And 37 percent would have gotten it, a substantial contributing factor would have been Lipitor.

Another way to look at it is look at the SPARCL data, it's somewhat similar, it's about 69 percent would have gotten it anyway. And then another sort of data point is the BMI more than 22. But 90 percent it attributes to weight. So what we're dealing with on all those different data points, and all

of them are sort of estimates, they're not precisely the number, the question is, what makes us think that Mrs. Hempstead is among the minority in which Lipitor would cause it versus those other known present factors. So what is it exactly about her medical history?

Because I think, you know, when you have a hazard ratio between one and two, statistically significant between one and two, there's sort of a general causation, you know, you're there on general causation, but then you've got the question, how about the specific individual. If it's over two, then the plaintiff's expert can reasonably assert more likely than not it was caused. Doesn't mean that ends the analysis between one and two, right? I mean, you then have to look to the evidence. What is it -- because there are some, under this hypothesis, there is some minority group, not one or two people, who are affected. So how do we know or not know, what is the evidence that Mrs. Hempstead is in that minority group.

MR. BROWN: Right.

THE COURT: Does that define it?

MR. BROWN: It does, Your Honor, very well. A couple things I would say up front. When you look at the cases, and you see risk -- courts addressing risk ratios above 2.0, and you assume that that risk ratio is valid, okay, that it is an accurate risk ratio and that it actually applies to the plaintiff that you're talking about, that plaintiff fits into

the population, 2.0, in many courts a differential diagnosis methodology, if you want to call it that -- we can call it a ruling out process, because I think Your Honor is saying the same thing -- often you just rely on statistical probabilities. The plaintiffs, in a lot of those cases where the risk ratio is actually above 2.0, they don't even need a diabetologist or something like that, sometimes they'll just put up a statistician and say as a matter of mere probability it's more likely --

THE COURT: It's a plausible hypothesis, to the extent those numbers are valid.

MR. BROWN: And some courts, some courts have allowed it based on just a probability analysis.

THE COURT: Right. But you might then come and demonstrate why this particular plaintiff doesn't fit into that number. And so -- or that the numbers used are confounding or for whatever reason are not valid. Right. But it's a pretty good position for a plaintiff to be in, to be over two. It's not at the end of the day if it's between one and two.

MR. BROWN: Yes.

THE COURT: But it's harder, right?

MR. BROWN: Correct.

THE COURT: And you've got to then look to what tells us that for Mrs. Hempstead -- I mean, Dr. Murphy says but for,

but for the Lipitor, she would not have gotten diabetes. And what's our evidence?

MR. BROWN: So I will say very quickly up front, that their only evidence is temporality. That's their only evidence. And as Your Honor knows from the case law, temporality is not enough.

THE COURT: Let me say, is all temporality equal?

MR. BROWN: No.

THE COURT: That is, Westberry is like dramatic, right?

MR. BROWN: Yes.

THE COURT: I mean, the guy is covered with talcum powder, he immediately has symptoms instantaneously. He doesn't show up for work and it goes away. I mean, you know, only a moron would say that that's not -- I hope none of y'all were the defense counsel in that case -- would say that temporality -- but temporality is not the only factor there. They had an established evidence that talc was bad, that it was toxic at high levels, though no one can measure it. The guy was covered in it, everybody conceded it was a high dose exposure, and no one seemed to quarrel that his symptoms were inconsistent with the known toxicity of this particular substance.

So, but temporality was a huge issue in Westberry, and I think appropriately so.

MR. BROWN: Yes.

THE COURT: But, you know, I think about temporality myself, about -- and Adair keeps correcting me -- it's proximate temporality we're talking about, something that's immediate. And that's not the only type of temporality, it can be temporality, but it's not immediate, right?

MR. BROWN: Yes.

THE COURT: But it's less compelling than the immediate response, right?

MR. BROWN: I think you've nailed it, Your Honor. Westberry is a case where you don't have a disease process that backs up years before you actually have a reaction, or in that case, the sinus infection. You had exposure to these rubber gaskets, which were talc at high doses, as Your Honor said. You had a very tight connection between that exposure and a sinus reaction. And then very importantly, in that case, you see evidence that the sinus infection subsides when you take the exposure away.

THE COURT: Right, it's almost the dose response.

MR. BROWN: The other thing in that case is you see the defense putting forward alternative explanations that are far different from this case. Pointing to things like the fact that the plaintiff was waterskiing months before the sinus infection, or pointing to things that the plaintiff had a cold months before the sinus infection, which are far

different than the kind of risk factors that -- well established risk factors that you see in this case.

THE COURT: But I guess my point to you was, temporality is -- there's not one thing to temporality.

MR. BROWN: Right.

THE COURT: It's a nuanced concept.

MR. BROWN: Yes.

THE COURT: And you can't say temporality is like well established -- I mean, I would agree there's a majority of cases that say just cause and effect is not enough. That's the majority. But there are unusual sets of facts in which the facts themselves kind of announce the conclusion.

MR. BROWN: Yes.

THE COURT: And this is not a Westberry case, right?

MR. BROWN: I agree with you.

THE COURT: We're talking three years. I mean, they have a theory about that, and I understand it, but it's basically that no diabetes-Lipitor-diabetes causation.

MR. BROWN: Correct. And, you know, this is -- if you get outside of Westberry and you look at cases -- because I would be the first one to acknowledge that that could be powerful evidence in certain kinds of cases -- when you step away from that and you say there are, you know, drug manufacturers have to deal with severe skin reactions sometimes in relation to a drug, and what you see is an

exposure to a drug, a severe skin reaction, you take the drug away, and the skin reaction subsides. If you have that kind of proof in a given case --

THE COURT: But it's not the only kind of proof, right?

MR. BROWN: It is not the only kind of proof at all.

THE COURT: There could be temporality. Their hypothesis is that it's a cumulative effect.

MR. BROWN: Correct.

THE COURT: But it's just less potent than the one -- but it doesn't eliminate it.

MR. BROWN: And here, Your Honor, and you know this already, you've read the record very carefully, and I'm certainly not here today to debate factually all these risk factors. What --

THE COURT: Well, I want to focus on this. You know, there's sort of two parts of your argument, as I read the brief. One of them is she doesn't -- Dr. Murphy does not really tell us why, other than temporality, that Lipitor caused it. And then she doesn't -- secondly, she doesn't really adequately address the other factors.

Let me stay for a minute, on this issue of what evidence there is that other than the fact that three years after she started it, she got diabetes, what other evidence do we have?

MR. BROWN: So I asked that exact question, Your

Honor. This is slide 21. And we'll certainly provide these slides to the Court and to plaintiffs' counsel as well.

THE COURT: What page of the depositions is that?

MR. BROWN: This is page 187.

THE COURT: I actually remember this. Actually something also like 124 and 125 also address this very same issue, which is her basic evidence is the temporal -- when you strip everything else away.

MR. BROWN: Correct.

THE COURT: And there's this question she asks, how would -- Pfizer can't tell us which people's lives were saved by Lipitor, who didn't have a heart attack, right? She's right, you can't tell us that. Doesn't mean it's not valid, you just can't identify the person. And I think she said -- I think this is what I'm thinking about at 124-125 of the deposition, where she says you can't do any better than I can. Well, of course, that's not your burden here, right? She's got to demonstrate it.

MR. BROWN: Right.

THE COURT: But it's kind of, to me, a telling point that she makes about that.

MR. BROWN: There is nothing here other than a temporal argument. And she admits that. So she admits that the temporal relationship and the increased glucose, which is the same thing, she's just saying that the last rise in

glucose that put Miss Hempstead past the diagnostic threshold, is her evidence of causation. And Your Honor also saw, at the same time, I pressed her a little bit on, well, if a mere temporal relationship is all the evidence you have, wouldn't Lipitor be a contributing factor, in your opinion, in every single case?

THE COURT: Right. She said yes.

MR. BROWN: Yes.

THE COURT: But it can't be, because -- this is my beginning point here -- if it's only a minority of the people are affected, then it can't be 100 percent. That's contrary to her own hazard ratio of 1.6, which is a minority.

MR. BROWN: Correct.

THE COURT: It can't be.

MR. BROWN: Correct.

THE COURT: The quote I was referencing is about the absence of a fingerprint, on page 152 of the deposition, where Dr. Murphy says, "I don't know how you can -- I don't -- I don't know how you can do that sort of thing, same thing with how you can identify which patient Lipitor prevented an MI in, you can't, you just can't do that."

MR. BROWN: Right.

THE COURT: Well, this highlights the challenge we have here. Because to the extent there's a hazard ratio of greater than one, you've got statistical significance to --

whatever that pool is that we rely on, you've got statistical significance for general causation. But then you have specific causation. And Dr. Murphy is a specific causation expert. I thought at times that she was kind of confusing her role. That she said if there is a -- if the patient took the drug, and the patient got diabetes, cause.

MR. BROWN: That's exactly what she said, many different ways.

THE COURT: I'll give you a citation, was it 187 you referred to?

MR. BROWN: Yeah, 187, line 12, Your Honor.

THE COURT: She says, "Other than the temporal relationship -- the answer at line 19 -- the temporal relationship and the increased glucose and the fact that she was taking it."

MR. BROWN: Correct.

THE COURT: Then at 124, which is what I actually was re-reading this morning, was, "If a patient was taking the patient -- 124, line seven -- if the patient was taking Lipitor and they developed the diabetes while on it, and again, I can't speak to other cases I haven't reviewed to know if there's something or things that I haven't thought of that wouldn't change my mind, but I think I would think that it would be a contributing factor, yes."

MR. BROWN: That's the same testimony I have here,

Your Honor.

THE COURT: Yeah. And then she gave two exceptions why it wouldn't apply.

MR. BROWN: And both of those exceptions were instances where you wouldn't have a temporal relationship.

THE COURT: Existing diabetes and you didn't take the medicine.

MR. BROWN: Exactly.

THE COURT: So I mean, I am using you a little bit as a straight man, for my able plaintiff's counsel to be able to address this issue, is that -- I mean, I know you also criticize Dr. Murphy, we'll talk about in a second, about not eliminating other causes. But I think y'all overstate that a bit, because she doesn't have to. Okay? To the extent -- I mean, I do think there's an issue about weight and how weight was dealt with, okay? And I believe she left it but one paragraph, and she makes the correct point that the patient's not obese, which would be a higher risk factor, but really fails to address BMI above 22 and what that means, right?

MR. BROWN: Right.

THE COURT: Between that and obesity, what that means. And she admits it, she said I never considered the BMI, she didn't consider the risk factor, which I think was five, wasn't that right? Five point five? And then there was a -- the ten pounds -- ten-kilogram weight gain and what that

meant, and then the 60-pound weight gain over all those --

MR. BROWN: That's correct.

THE COURT: -- are part of the -- that's the nurses study, isn't it?

MR. BROWN: Sixty-pound weight gain, you're talking about the plaintiff or --

THE COURT: Yeah, the plaintiff's 60-pound weight gain and the -- and that that had a 12 factor increase?

MR. BROWN: Yeah, I mean, we have it as approximately 11-fold increase.

THE COURT: And I'm saying is that the nurses study where that comes from?

MR. BROWN: I have the references here. I believe you're right, it is the nurses study, you're right, Your Honor.

THE COURT: I mean, I recognize that chart.

MR. BROWN: Correct.

THE COURT: And she doesn't really quarrel, she says I'm not saying 100 percent about the nurses study. She cited the nurses study herself, didn't she?

MR. BROWN: Yes.

THE COURT: And she said I'm not saying they're lying, right?

MR. BROWN: Right.

THE COURT: I'm not saying they're lying, but it is

the most powerful predictive factor.

MR. BROWN: Right.

THE COURT: And I guess what your point is, is she didn't really consider the full dimension of this weight, did she?

MR. BROWN: Well, we probably overstated it, but Your Honor has already gotten to the issue that I think matters most. Once you acknowledge -- put aside, if we could just go back to the beginning.

THE COURT: By the way, I messed everybody up on their power points because I come in, and nobody --

MR. BROWN: I'm not here to give a Power Point today, Your Honor.

So what I tried to do is bucket these risk factors. And again, without getting into debating each of these, because I agree with you, a number of them could easily go to weight and raise factual issues. But once you acknowledge that there are very powerful risk factors here that did play a role, once you do that, BMI --

THE COURT: You then have an explanation. You don't have the classic differential diagnosis, which is the diagnosis of exclusion is the only thing left.

MR. BROWN: I agree with you.

THE COURT: That is not the case here. And to her credit, she doesn't try to claim that.

MR. BROWN: That's correct.

THE COURT: She, you know -- you know, you may criticize she didn't fully address the weight thing and all that, and I think there's probably some validity to it, but she was -- compared to Dr. Handshoe, she was a picture of clarity and candor, okay?

MR. BROWN: Yes.

THE COURT: And she readily acknowledged there are things you couldn't eliminate. And there's nothing wrong with saying that Lipitor is a substantial contributing factor, even though you have BMI, even though you have family history, even though you have age and a history of hypertension. All of those does not eliminate the fact that Lipitor could be a substantial contributing cause.

MR. BROWN: If you have a method to actually show that.

THE COURT: And you have a method of showing that. And I'll go back to the chart that Mr. Marcum put up the last time, which is completely counter intuitive to traditional differential diagnosis, right? That you do this process of elimination. And, in fact, the data suggests the more risk factors you have, the greater the risk of Lipitor -- I mean, it's, to me, a little counterintuitive; maybe it makes sense to other people, but it's not traditionally what I would think would have been the answer.

MR. BROWN: Right. But again, that principally comes from data at 80 milligrams.

THE COURT: Eighty milligrams. Mr. Hahn called it the horse dose. And people with all these, you know, really potent risk factors for diabetes.

But, you know, there's a premise the plaintiffs have -- this is move general causation -- that Lipitor, at some level, has this effect on diabetes. And, you know, I think -- I mean, the FDA wasn't willy-nilly in making the amendment. There was something going on there. And obviously the SPARCL study contributed to that perception, just like the Jupiter study, I think did, that there is something at very high doses that may be going on here. But then we get to the next point, exactly where does it leave us in an individual case.

MR. BROWN: And maybe I'm putting the cart before the horse, Your Honor, but you're going to reach the 20-milligram question, because there's still a big question in this case whether --

THE COURT: Let me just say here, my plan had been to do general causation and then specific causation. But because I thought dose was an important issue, I wanted to give everybody an opportunity to go back and address that issue, and I didn't want to stop the case in the meantime. And I think -- I'll be honest, I think at some level the plaintiff is going to have general causation. We'll figure out at what

level that is. And so I didn't think I was wasting my time. Okay? So in exactly where we fall on dose levels, I think is going to be important.

I'll say to the plaintiffs' counsel, you probably ought to do better than what I suggest Dr. Robinson did, okay? I mean, you need to address, as I asked y'all to, the specific evidence at specific dose levels. I do think that's an important thing to do. And it's going to be -- you know, I know that's not what either party, frankly, wanted me to do. Defense wants me to throw the whole case out, plaintiff wants me to say at all levels there's merit. And it may well be one of those surprising situations where the truth lies somewhere in the middle, okay?

So but the answer is, yes, I recognize that to the extent I were to conclude that 20 milligrams dosage, there's not evidence, then this case would go away on that basis. Correct? And but we've got -- this is just a bellwether case, we've got lots of cases, we have lots of issues, and I'm trying to provide guidance both in the general causation and on specific causation. Because I recognize that if we don't find a path to resolve this case, these cases are going to go back to jurisdictions all over the United States, and I want my colleagues not to have all the brain injury I've had to go through to figure all this out. So I'm trying to write the orders in a manner that is clear, and informs them, without

having to do all the struggle, frankly, I've had to do, to come to understand this area.

MR. BROWN: You've gotten it pretty well, Your Honor. So you know these issues and you've already put your finger on the weight gain issue. I can certainly talk more about that and why I think the ones that I've circled present the most significant method --

THE COURT: I've heard a lot about the -- perhaps she did have metabolic, I didn't really consider it, she had clinical reasons why it's not important to her, I get that. But, you know, all that is kind of gilding the lily a little bit. Because once she admits BMI is important, and there are variations on that BMI that she doesn't really dispute, then Mrs. Hempstead has a plausible explanation of why she got diabetes, but it doesn't tell us that the Lipitor was not a substantial contributing cause. So we're sort of back where the question is, you know, what's our evidence.

MR. BROWN: Right. And the only thing I would add on that, I would even say that the evidence is at odds with the theory. Because if you go to the point in time when Miss Hempstead stopped taking Lipitor for a period of three weeks --

THE COURT: Didn't she have like a really sudden rise in her --

MR. BROWN: No, her blood sugar actually dropped.

THE COURT: Dropped. When she went off it.

MR. BROWN: Excuse me. Her blood sugar went up to its highest point in 2003 when she was off the medication for three weeks.

THE COURT: Of course, don't make the same mistake you're claiming the plaintiff makes of "this is complicated," okay?

MR. BROWN: It's very complicated.

THE COURT: You shouldn't be guilty of the same thing, which is to make sort of shortcut conclusions.

MR. BROWN: The only reason I brought that up is because the plaintiff's expert, Dr. Singh, actually believes that if it goes up in relation to the drug, comes back down when you come off the drug, and goes back up when you go on the drug, that's evidence of causation. And I --

THE COURT: Dose response, basically. Form of dose response.

MR. BROWN: And I asked, "In a case where a patient stops taking Lipitor and the diabetes does not subside, it would be fair to infer that the diabetes was driven by other factors, correct? Witness: Would be fair to infer that we can not distinguish whether the diabetes is driven by Lipitor or other factors."

And I emphasized that also because when Your Honor looks at the plaintiff's opposition brief on the dose question, they

again make reference to this Singh methodology. So the fact that blood glucose goes up to its highest point when she comes off, at a minimum, is not consistent with the theory.

THE COURT: Yeah, I'm just saying it's so medically complicated, it's just hard to say just because there's temporal relationship, there's causation. That's the same rap I would have is that this is -- that her multiple problems here are very complicated.

MR. BROWN: So, Your Honor, what I could do is just reserve, wait and see how the plaintiffs go. I would like to give you the page cite for the 60-pound weight gain from Miss Hempstead's deposition transcript. The --

THE COURT: Is it in the record? Because we just couldn't find it. It was a huge record, so we could have missed it.

MR. BROWN: My guess is that Miss Hempstead's transcript is somewhere in the record, but we're going to make sure you have that transcript no matter what. And the page cite is 186, lines seven to 12.

THE COURT: I'm sorry.

MR. BROWN: 186 in Miss Hempstead's deposition transcript, pages seven to 12.

THE COURT: If y'all would file that just to let me -- so we've been on the Easter egg hunt and we haven't found the egg yet.

Let me hear from plaintiffs.

MR. BROWN: Thank you, Your Honor.

THE COURT: Then we'll give you a chance to respond.

MR. BROWN: Thank you, Your Honor.

MS. BURKE: Good morning, Judge Gergel.

THE COURT: Good morning.

MS. BURKE: I know Mark introduced me, but I'm Beth Middleton Burke, and this is the first time I've had the opportunity to argue in the Lipitor MDL.

I do think that Dr. Murphy is probably the easiest of the arguments so far, so I can take comfort in that, because as you pointed out, and Pfizer has pointed out, she is eminently qualified to give an opinion in this case.

THE COURT: I read all her credentials and aware of that. It doesn't, of course, substitute for the issue, Miss Middleton, which is, what's the evidence that we have beyond the fact that the diabetes followed the drug by three years, what evidence do we have of medical causation of diabetes being caused by the statin. That's the question I have.

MS. BURKE: Let me ask you, Judge, how do you want me to start with this?

THE COURT: I mean, that's my question. I was trying preliminarily, I know that your able opposing counsel has a whole Power Point which he quickly dispensed with, recognizing that I sort of knew the record. And I'm not doing this

argument to entertain the lawyers or give them the experience, I'm trying to figure this out myself. I mean, this is, I think we're down to sort of the meat of the case right here. And at least as to specific causation. And if the answer is all she's got is that one follow the other, just say it. I mean, I've got to deal with that. If there's more, I've scoured that record looking for it. My clerks have scoured the record. And I'm asking you now, if you've got something else, and I'm not asking you to lapse into what these other factors, why they're not so important. We'll get to that. My point is, what is it about the Lipitor that tells us that Lipitor was a substantial contributing factor.

MS. BURKE: What I would like to do very quickly is dispense with Pfizer's argument that it's nothing but a temporal relationship, because that's absolutely not the case. And here is an excerpt from Dr. Murphy's transcript where she explains that you have to have a temporal relationship, we all know that. So it's an important and necessary step --

THE COURT: Absolutely. If you didn't have it, it wouldn't be -- I mean gotten the diabetes before, there's no case.

MS. BURKE: Absolutely.

THE COURT: So that's an obvious given. But the point is, because we have these other powerful potential predictive factors, taking really Dr. Murphy's words herself,

the question is, what makes us think that Lipitor -- you know, I framed this thing, here we are, by her own data, it's a minority among the people who are taking Lipitor and develop diabetes. Doesn't mean Mrs. Hempstead's not among them, but how do we know she is? Because most probably she is not. Do you understand what I'm saying?

MS. BURKE: I do. I understand. Don't agree, but I understand.

So let's take a look at a few of the studies and reports that Dr. Murphy referenced in her report and included in her reliance list and discussed at her deposition. And the first one is the women's health initiative, which I know you're familiar with. When you look at the hazard ratio for Lipitor, when it suggested for age and race and ethnicity, the hazard ratio is almost two. It's 1.99. So when you get that hazard ratio, you've controlled for these other powerful risk factors. And that shows that even in a person whose age puts them at an increased risk, their race and ethnicity puts them at an increased risk, the Lipitor doubles, almost doubles their chances of developing new onset diabetes.

THE COURT: I thought Dr. Murphy eliminated race, she said it was not a factor.

MS. BURKE: She eliminated it as a substantial contributing factor, even a significant contributing factor. It's one of the big four that she considered. She considers

weight, family history and ethnicity she lumps together, because she feels like ethnicity contributes very little to what family history doesn't always account for. So you're correct in that.

THE COURT: But she also made a point that family history wasn't important because -- it wasn't particularly important because the -- was only a single parent, no siblings, father older age, I get all that.

MS. BURKE: Absolutely. So you want to focus on BMI.

THE COURT: What I really want to say, I know you want to look at these other factors. Okay, that's fine. I'm going to get to that. I promise you we're going to get to the other factors. My question is, if the answer is, there's just not -- is there anything that tells us that Lipitor caused it. Caused the diabetes. We'll get to whether these other factors did or did not and how important they were and that, I'll get to that. But if there's anything in the record you can point to me, other than the fact that the diabetes followed by three years the ingestion of Lipitor, I need to know about it, because it's important to me.

MS. BURKE: If you're asking me if there is a biomarker or fingerprint --

THE COURT: Or any evidence of any type whatsoever that tells me Lipitor's the one, you know. You know, Diet Coke, Coke's is the one, is there anything that tells us that

Lipitor's the one?

MS. BURKE: Well, as you noted several times today already, Lipitor doesn't have to be the only one; there are others.

THE COURT: I was obviously using the Coke thing, was a substantial factor. Other than the fact that it followed three years after ingestion, do we have any other evidence that tells us that Lipitor was a substantial contributing factor. And the answer is, if that's it, that's fine, but if there's more, I'd like to know about it.

MS. BURKE: I do think there's more, and you have to look specifically at Miss Hempstead in combination with the observational studies and the meta-analysis that --

THE COURT: Specifically what about her tells us it was the Lipitor?

MS. BURKE: When you look at Miss Hempstead's glucose reading from 1994 to 2005, and there's actually a glucose reading from 1992 that's not on this chart that's 88. So if we start at '92 at 88, her next reading, two years later, is 115 at an ER visit, GI infection, not a fasting blood glucose.

THE COURT: I'm familiar, I remember all this.

MS. BURKE: So then for the next -- Miss Hempstead is a good patient. She sees her doctor at least annually for physicals, and then she gets regular checkups, because she has hypertension that is treated. So we have a 101 in 1995, which

is one point over normal. But then we have a series of normal blood glucoses leading up to when she starts Lipitor. We have 90, 90, 74. And then when she starts Lipitor in June of 1999, her blood glucose is 97. She stays on Lipitor for about six months, and then restarts it in July of 2000. Her next blood glucose reading, that 103 is in October of 2000. So at that point she's been on Lipitor for several months, and she has her highest fasting blood glucose reading.

THE COURT: I think she goes down to 95. You know, what that chart does not note is that meanwhile, she's having a steady weight gain during this period of time. The same period, '94 to 2004, she's experiencing a ten-kilogram weight gain. And it puts her at a point which increases her risk.

So yes, you're absolutely right, I mean, if they didn't have this, if we said she already had diabetes, we wouldn't be talking about it, right? So we know that 100 percent of the people who are studied in these various studies, placebo group, we know that a certain percentage of them get it, though they don't have diabetes ahead of time, right?

MS. BURKE: Right, exactly.

THE COURT: And they didn't take Lipitor, right?

MS. BURKE: Yes, sir.

THE COURT: And they got it. And then we take the group that took the Lipitor, and the Cederberg study is slightly higher, it is higher, no question about it,

statistically significantly higher. But it's still a minority of those people. Most of those people would have gotten it anyway. So I don't know about her. Now you're looking to me and you're saying, okay, she got -- you know, her blood sugar went up after she was on Lipitor. That's going to be true on everybody who did not have diabetes, before they took the Lipitor and then got diabetes, that's going to fit the profile of everybody.

So it's just another marker for not having diabetes before you started. Every one of these people in these studies are going to fit that profile to some degree. The question is, is it the weight gain, is it the age, is it family history, is it Lipitor. Or some -- I mean, those are kind of factors you've got to ask. So I'm trying to tease out, and it might well be that y'all are ahead of the science, okay? Your assertion is ahead of the science. But I'm looking for the science, because I have to have some data here to support a claim. The claim is her diabetes was caused by her Lipitor. And I'm looking for something, because she has multiple risk factors, she is not static, that is, her weight is growing during this period of time you've just pointed out to me. And so we're looking for what does it tell us that it was the Lipitor that is the culprit. And it could be both. That is, I mean, it could be both weight and Lipitor. But it is the science tells us it's completely consistent with the weight gain alone. So

the question is, how do we know the Lipitor is a substantial contributing factor? And frankly, if the answer is because there's no signature or no marker, that's the best we can do, maybe that's the answer. I know that's not the answer you want to give me, and you want to point to these other things that -- and we'll get to, I promise you I'm going to get to, you know, weight and these ethnicity and all these other things that she argues help inform her.

But I think the crux of this case is that you need to have evidence more than temporality, in this setting, to show causation. And the fact that her blood sugar went up afterwards, that's 100 percent of the people who would be in this pool, a majority of which it would be unrelated to Lipitor. That's the problem.

MS. BURKE: Well, it is true that Lipitor-induced diabetes presents similarly, if not identically, to any other case of diabetes, Type II diabetes specifically. And that's why I think this is important to note, that after she's been on Lipitor for approximately almost three, four years, 2002 you see the 114, 122 in 2003, 214 in 2004, and then we get to the diagnosis of 613, you definitely see the trend upward in Lipitor beginning after she's been on Lipitor for a number of years. And this trend is born out in the Cederberg article.

THE COURT: Right, but it also corresponds, if you put another chart up with weight, it would follow, it would be

a scale going up as well, correct?

MS. BURKE: Well, that may be true, it depends on the patient.

THE COURT: I'm only talking about -- I'm not smart enough, I have to do one patient at a time. This is a specific causation question. For Mrs. Hempstead, it would be a steadily rising weight, and the data supports that that can produce the very results you're talking about. And you're telling me, oh, no, I think it's the Lipitor. And we know that the weight has a factor, substantially higher risk than just the Lipitor. So I am just -- I'm looking for something that maybe is -- doesn't exist. I don't know. But I'm -- I agree with you that there is a temporal -- that the blood sugar rises after taking Lipitor, as it does -- gradually, gradually -- as it does, I would -- my hunch is, well, it's got to rise in every case in which someone didn't have diabetes and then developed diabetes. And so I don't know why she's different, why she's not in that 63 percent group using that data that Dr. Murphy used, the 1.6 hazard ratio, why is she not in the 63 percent versus the 37 percent.

MS. BURKE: When you say the 1.61 hazard ratio, are you talking about the Atorvastatin adjusted has a ratio in the Women's Health Initiative?

THE COURT: She used that herself.

MS. BURKE: Yes. And this --

THE COURT: I'm using her data.

MS. BURKE: And that hazard ratio adjusts for BMI. So you include women in there with higher BMI.

THE COURT: I'm using her numbers. She used that as a hazard ratio. She was asked by Mr. Brown about the 1.4 something of the -- I believe it was the Cederberg study, and she said that's in the realm. So it's not a precise -- I don't want to hold her to something, I'm just taking that's the most friendly number I can give to her position. Okay? If I go to another number, the percentage of the chance of it being caused by something other than the Lipitor, only goes up. So I'm using her most friendly number, I'm taking her number, I'm saying okay, she says that 63 percent of the people who get Lipitor, who -- I mean, if you just apply the math, 63 percent are going to be unrelated to the Lipitor, and not substantially caused by the Lipitor, and we have 37 percent. And I'm struggling to say just because you're in the minority, Miss Hempstead's in the minority, arguably doesn't mean she wasn't among them. Somebody is going to be in that 37 percent.

The question I ask is how do we know which group she falls into? And all I'm hearing, and I've asked you, and I don't think you're trying to not respond to me, is that you have nothing but temporality. I mean, that's basically what you have. And it's dressed up in different ways, but sure, she

had an increased glucose, that's another way of saying she got diabetes after taking the drug, and 63 percent of the people will have that same response without taking the -- have the same effect without taking the drug.

MS. BURKE: Your Honor, I apologize for not being clear about how Dr. Murphy looked at BMI and looked at Miss Hempstead's adult weight gain. She absolutely acknowledges the fact that Miss Hempstead had a slow and steady weight gain as an adult. She acknowledges that on page 15 of her report. She acknowledges that increased BMI is a powerful risk factor for diabetes.

THE COURT: The strongest.

MS. BURKE: It's the strongest. Particularly if you're obese. Miss Hempstead is never obese. Never obese.

THE COURT: That's true. And it would be, I think, 24 times the factor if she were obese. But it doesn't eliminate the fact that when you have -- and this is the nurses study's point -- you've got a BMI over 22, your risk factors go up. It's relative, that is -- So yes, she is not obese. Does she have a risk factor? It's, I believe, 5.5 in her weight category. And that's one way to look at it. And that's, you know, substantially higher than 1.6. Okay? Doesn't mean they can't be related or whatever, but that's a reality. And then they asked her, well, how about the weight gain in the last decade. That chart you had, basically

tracking that chart with weight. And she said, I didn't think about that. I didn't consider that. And they said, well, let's look at the data. And she didn't quarrel with the data that it was -- I think was it -- I can't remember what the percentage was, there was some risk, increased risk, I think two point something. And then they asked her, well, how about the 60-pound weight gain over her adult life? And she said, again, I mean, I really thought Dr. Murphy was a pretty candid person. She said, I didn't consider it. I just didn't consider that. Well, let's look at that data. And it was 12 times, the 60-pound weight.

And it just -- you know, my -- I don't want to make more of the other factors, because I think it ignores the reality that you could have all those factors and still have Lipitor as a substantial contributing factor. In fact the chart Mr. Marcum put up suggests that to be the more likely place you would find it.

So I think it's sort of wrong headed to fuss too much about the other factors being present, because it's perfectly fine for them to be present. But then you're back to this issue of what role Lipitor had. Because the odds are, it didn't cause it, but in some cases it did; how do we know that. I mean, how do we know in our specific causation analysis, she's one of the minority, not in the majority.

MS. BURKE: Well, Judge, again, it goes back to the

studies that Dr. Murphy looked at that controlled for BMI. And I know you say she didn't consider the adult weight gain, but she did. She considered it in her report.

THE COURT: I'm just taking what she said herself. I'm just taking what she said herself.

MS. BURKE: And she ultimately said at her deposition that she felt like the Culver paper was only one paper on that topic, and that it ultimately supported what she said about BMI being the strongest indicator of diabetes.

THE COURT: We agree. And they asked her, they tried to nail her down about the 90 percent, and she said, you know, that's -- I'm not saying they're lying, I'm not going to get locked into -- I think it was a reasonable response. It's big number. She said it supports my conclusion.

So let's just for purposes, let's go to 80 percent, not 90. Let's be most generous to her. So in 80 percent of the cases, say hypothetically, it would be attributed to weight, and in 20 percent of the cases it wouldn't. What makes us think that Mrs. Hempstead's in the 20 percent group? I'm saying that's another way to look at it. But I think more precisely, it tells us weight's a really big deal here. And it could explain this all by itself, with nothing else needed. It could also be Lipitor. What makes us think it's Lipitor, other than the fact that she got the diabetes three years after taking the drug?

MS. BURKE: Judge, you did nail it again, I mean, increasing in weight and high BMI are very strong predictors of diabetes. And yes, people who are overweight as an adult and who gain weight as an adult, and particularly have a BMI over 30, are at an increased risk of diabetes. And it happens in people with higher weight, in the absence of Lipitor. But at this point this is where I think Dr. Murphy's experience and knowledge and expertise as an endocrinologist who has been practicing for 20 years, who formed the opinion that Lipitor caused diabetes, before she ever got involved in this case, and testified to that at her deposition. Further testified that her review of the literature, after she got involved in this case, further strengthened her opinion on that point. When she looks at the studies, when she looks at the meta-analysis, when she looks at the randomized -- I'm sorry -- the observational studies and the meta-analysis, because as you know, we don't have a randomized controlled trial with diabetes as a prespecified end point, when those studies control for BMI, those individuals, particularly the women, still are at an increased risk of getting diabetes because of Lipitor, over and above what their risk was when they --

THE COURT: Don't we know that --

MS. BURKE: -- with just the high BMI.

THE COURT: We know that, okay? We know, in a

variety of different data we get, I mean, just take the placebo group in SPARCL, right? It's like six percent of the placebo group got diabetes in the course of the study. And like 8.7 in the Lipitor group. So we know that among some people there is going to be some association -- this is 80 milligrams, SPARCL's the 80 milligram stroke victim -- we know at least there's something going on there, we think, with Lipitor.

But who among those -- and that would be like 67 percent would not be related in the SPARCL study -- who among those, we ask, are in which group? And what I think I see the plaintiff's problem here is, notwithstanding this whole general causation issue, which we're going to sort out hopefully very soon about where it falls, in specific causation we're having trouble finding a way to demonstrate that Lipitor, in a particular case, caused the diabetes. And if all we're left with at the end of the day is temporality, we're not going to get there.

MS. BURKE: Well, Your Honor, because we don't have a biomarker or fingerprint, that's exactly why we have to have the differential diagnosis.

THE COURT: Here's what you're trying to do. You're trying to use what you call differential diagnosis, to say we're just going to rely on her gut feeling from her experience. Remember, this is, you know, a lady who spends a

lot of time dealing with diabetics, this is a huge part of her practice. She's never met a person, never diagnosed a person with statin-induced diabetes, never met such a person, can not -- has never evaluated or treated such a person. None of your experts have ever seen such an animal. And so we can't rely much on -- experience only takes us so far in this. Okay? And so she is saying, you know, she wants -- and I think this is the lesson in a lot of these cases. They say, listen, just because you have an MD after your name and you call it differential diagnosis, you've got to have a reliable method, you've got to have it -- you've got to use it, apply it in a reasonable way, and you've got to have data to support it. You can't just say, I am a doctor, I get to say this.

And so in the end of the day, that's what you're telling me, temporality, and it's her impression that she's -- that this is a patient who has this statin-induced diabetes, even though in her own personal experience -- and she is, I mean, I don't know what percentage of her time dealing with diabetics, I think it's nearly a hundred percent of her practice -- she's never seen this. One of the most renowned persons in the country has never seen, never diagnosed, never treated a person that fell into that category. It's just troubling me to call upon that person's experience to guide us, when the data just is to the contrary. The odds are she's wrong, okay?

Now, it might be, if she could point to me something to

say this is why the Lipitor mattered here, I wouldn't be hard to persuade. But I have pored over this record, as have my clerks, looking. I sent them back to the record, find me something in this record more than it took she got it three years later. I've come up empty.

MS. BURKE: Judge, you raise about five points that I probably need to address.

THE COURT: I'm sorry.

MS. BURKE: I want to start with, first of all, Dr. Murphy's testimony on why she has never had the opportunity to diagnose anyone with statin- or Lipitor-induced diabetes. And it's because of by virtue of the fact she is a specialist in endocrinology, it's very rare she actually diagnoses diabetes first.

THE COURT: But she hasn't treated anyone. She's never treated anybody with that phenomenon. I'm just saying to you, to say -- you know, if somebody -- I mean, one of the things that doctors will often say is, you know, I've been at the bedside, I've treated this condition, I recognize it, I know what it looks like, and I have my hands on the patient, I know what I'm talking about. And that carries some weight in the traditional differential diagnosis, particularly when it's your patient and you know the history and you're monitoring and all that, that's fine. But she's really doing something very different. This is something she has no -- you're

telling me she doesn't even diagnose diabetes, but she's here diagnosing Mrs. Hempstead's cause of her diabetes.

I share your view that she is, you know, more knowledgeable than the average person. She has outstanding credentials. I give you all of that. But we haven't even talked about her methodology. She doesn't -- I mean, she has this five-part test that she mistakenly calls four-part, okay? And she has two number twos, which demonstrates that she doesn't really use this, okay? It's like a made up, and she admitted it, she'd never seen it anywhere, never used anywhere. At step three, which she numbers the second step two, she says, you know, the diabetes followed the Lipitor. And then in step four and five, where she's supposed to talk about relative risk, when Mr. Brown asked her about it in the deposition, she said, I can't talk about relative risk, there's not enough data. But what she never gets to is in that methodology she said that she's never used herself and no one else has ever used, she never gets to the point to tell us why Lipitor's the one, or a substantial contributing -- why is it a substantial contributing factor more than temporality? And frankly, I think she gave the answer in her deposition, she says, that's all I got. I mean -- I mean, that's enough. And the point was being made, well, you know, most of the time it isn't. She said, well, that's enough for me, if it is. And I think she's giving us her own understanding of

causation, which I think more reflects general causation than specific causation.

MS. BURKE: Well, Your Honor, I don't know what to say other than I disagree with your reading of her deposition. I think she qualifies and quantifies the importance of the temporal relationship very clearly, and that it is one step in her process. She starts with a review of the literature, and establishes what she thinks --

THE COURT: Take me after step three. After she says -- re-numbered step three, I'll call it step three -- where she says temporality, and then steps four and five in her report are where she is supposed to deal with the relative risk of these other factors, and she is supposed to talk about how likely is it that Lipitor caused new onset diabetes in this individual at this time. And I think that calls upon relative risk. But when she was asked about, okay, rank these risks, and she gave us some numbers, she gave us 2.3 for family history, then tried to back off that. She gave us hypertension about 1.76 or something. And at one point she said, oh, asking something about the BMI, I don't think that's as much as another risk factor. And Mr. Brown asked her, oh, what are the other risk factors? Oh, I can't quantify it. She doesn't actually do it.

And again, I don't want to make too much of these other things, because I think they can be in conjunction with her

Lipitor. That is, you could have BMI of this, you could have all these other factors, and Lipitor could be a substantial contributing factor. So I think in some ways we're chasing our tail in all this. But then you're back to the question, which she doesn't even have in her methodology, how do we know when, in the end of the day, other than temporality, how do we know that it's Lipitor? And it's not even in her method to address that issue.

MS. BURKE: Judge, I do think it is her method to address that issue, and she does address it.

And getting back to this issue of ranking or quantifying, the two experts, case specific experts for Pfizer that I deposed in this case, they were unwilling and unable to rank or quantify risk factors for Miss Hempstead either.

THE COURT: Well, you know, you're the one that has a Daubert motion.

MS. BURKE: I understand.

THE COURT: I'll address one at a time. If they have inadequate testimony, you can make motions on them. I'm only dealing with one witness at a time. And my witness here, I mean, there's several parts of this equation. One of them is, is there an adequate alternative explanation for the diabetes other than the Lipitor. You know, it's kind of like what is it, the Cooper case with the pedicle screw in the Fourth Circuit, and that case noted the defendants had this whole

thing about smoking as a potential alternative cause and all that, and you had to sort of sort all that out. And, you know, it just puts an obligation, when -- so it's important to know there are alternative theories and alternative cause, potential alternative cause. But that doesn't end the analysis. You've then got to get to why we think it's the Lipitor, or in Cooper, why we think it's the pedicle screw. Just having it as an hypothesis and a possible explanation is not enough. And we have it as -- I agree with you, it's a possible explanation. Possible. Not probable, possible. And how do we take it from possible to probable, other than -- because temporal alone won't get us there.

MS. BURKE: And, Your Honor, I just want to clarify the reason I raised the point about Pfizer's experts not ranking or quantifying the risk factors that Miss Hempstead had for diabetes, in addition to Lipitor, is to show that their methodologies are very similar. And although Dr. Murphy can't name her methodology and can't say that it's been published anywhere, what she did was very sound. And she relied on the Bradford Hill criteria for steps one, two and three, then she undertook a differential diagnosis --

THE COURT: Answer me this. Here's the questions. How likely is it that Lipitor caused new onset diabetes? Where does she answer that question? How likely is it? What is the probability?

MS. BURKE: I mean, she says that it is her opinion to a reasonable degree --

THE COURT: I'm not going to have --

MS. BURKE: -- contributing factor, and she understands that that's greater than 51 percent.

THE COURT: What's the underlying data to support that? What is her underlying basis? We don't give the doctors a pass on providing us appropriate data. Okay? We've got to have the underlying data. Other than temporality, she offers us none. How likely is it that Lipitor caused, in this individual patient, at this time. I mean, she can tell us why some of the other risk factors may or may not be important, as important as it might have been, that's fine, I agree with that. But then she doesn't tell us, other than temporality, why we think it's Lipitor.

MS. BURKE: Well, as far as the underlying data, it's all set out in her report and in her reliance list.

THE COURT: Okay.

MS. BURKE: She claims --

THE COURT: Here's your time to point it out to me. I mean, I've read it and re-read it, and I can't find it. I mean, it's, you know, you get right up -- you know, you think, wow, this woman has really interesting credentials, impressive background, actual experience treating -- she says this is the kind of expert we need in the case. And then we get to her

methodology, and she stops at step three, basically. If it's temporality, it's over. That's what she says in her deposition. If you have temporality, that's enough. She stops, in her own method, at step three. That's the concern I have. And it just doesn't go from there.

And, you know, maybe we ought to just stop at that, by saying okay, that's her testimony. And I've got to decide if temporality is enough. And on these facts, it doesn't look like enough to me.

MS. BURKE: Well, Your Honor, we believe that her differential diagnosis is textbook, it's complete. She acknowledges the --

THE COURT: Okay. Textbook is --

MS. BURKE: -- and then rules them out --

THE COURT: Let me ask you about this. Textbook. You're talking to somebody who probably cross-examined 400 doctors. Okay?

MS. BURKE: I understand.

THE COURT: So you're talking to somebody who knows differential diagnosis. And classic differential diagnosis is you take the possible causes, you rule them out until you have a final determinative diagnosis. Sometimes it's a diagnosis literally by exclusion. Sometimes you have lab data to support it, and you can make the diagnosis based on the full record.

There's nothing about this that really looks like differential diagnosis. And frankly, I think it imposes on her a burden she should not have to carry. That is, she doesn't have to rule out the other factors. She just doesn't. And in that way, I think that part of the traditional classic differential diagnosis doesn't fit here. And it's not fair to ask her to do that, because -- But it doesn't, in the end of the day, and I keep going back to this, you've just got -- Cooper says about the pedicle screw, it just says you've got to put the medical evidence, the doctor's got to put the medical evidence up that tells us the basis that this thing caused the injury. And the fact, just like in Cooper, just because the screw failed after the surgery, doesn't mean the screw was defective. Right? I mean, you need more evidence.

MS. BURKE: Your Honor -- I'm sorry.

THE COURT: You go right ahead. I don't mean to cut you off.

MS. BURKE: I think I've said just about all I have to say, but I do just want to point to page 16 of her report in her summary. And again, it says, "Studies, which either adjust for known risk factors such as age and BMI, or are adequately randomized for them, show an increased risk of new onset diabetes from Lipitor exposure. For example, as discussed previously, in a multivariate adjustment accounting for age, race/ethnicity, education, cigarette smoking, BMI,

physical activity, alcohol intake, energy intake, family history of DM, and hormone therapy used in women, the relative risk of new onset diabetes was 1.61."

THE COURT: Let me say, I'm with you. Listen.

MS. BURKE: She has to rely on these studies, because we don't have --

THE COURT: I'm with her to this point. Yes, general causation, statistical significance, she's there. Now, what makes us think that Miss Hempstead is in the minority that Lipitor caused it, according to her own hazard ratio, or is it easily argued that it's not. And frankly, Miss Middleton, that's where I think the thing falls apart for her. She never seems to understand the difference between general causation and specific causation.

I remember reading that part of the deposition. You know, let me tell you where I read this whole thing. I went down to the MDL conference at Breakers. And they don't work at the level I work, they do about three hours and they play golf. So I spent the rest of my time reading and re-reading Dr. Murphy and Dr. Handshoe's depositions. I read it without reading any of y'all's briefs. I didn't want anybody to taint my view of this, I wanted just to read it, I read the reports and I read the depositions. That's all I did. And I focused on it, and I came back, and I did a memo before I ever read anybody's view of it. Because I didn't want to be tainted, I

wanted to see my own take on this. And I remember reading right when you were talking, I said, now she's going to get there. She is going to show me why, in this minority, she's -- and she just -- it just stops. She does a general causation. She'd have been a fine general causation expert for y'all; she just doesn't get there on specific causation. That's the problem.

MS. BURKE: Well, Your Honor, unless these gentlemen that are with me have anything to add -- It doesn't look like they do.

THE COURT: Mr. Marcum is never bashful, I'm waiting for him to leap to his feet here at any moment.

MS. BURKE: Just in conclusion, Your Honor, I would just like to say, once again, I believe that her differential diagnosis, her methodology is exactly similar to the case specific experts that Pfizer has put forward. They look at the same medical records, they look at the same literature, they just reach a completely different conclusion, and it's the classic battle of the experts. And when Dr. Murphy is on the witness stand in Charleston, they can cross-examine her on why she doesn't think that her adult weight gain is more substantial than Lipitor, as long as you will allow them to do it. And I think --

THE COURT: And if I didn't have any obligations under Daubert, that would be a fine thing to say. But I have

been imposed the responsibility to be a gatekeeper, to show that the evidence has to be reliable. And I have really a low bar. You can look back at my record, I rarely keep an expert out. But you do have to have a situation where you have a reliable methodology, a reliable application of that methodology, and data to support it. And it's a low bar. Just doesn't look like she's getting there.

Mr. Tanenbaum?

MR. TANENBAUM: I can't join this conversation very well, Your Honor, but --

THE COURT: It never stopped you before.

MR. TANENBAUM: You're right. And I'll keep going.

I don't know exactly what the schedule is for dose specific causation briefing, but I would just ask Your Honor to reserve the final order on this matter until we finish that. Because I think that -- if I could finish -- I think, Your Honor, that there is significant, and I've said this before and you keep asking for it and it's being worked up, I think there is significant evidence that some of the scientists, that 20 and 40 milligrams, not ten, but -- ten also -- but 20 and 40 milligrams is considered a high dose. I saw it yesterday in some studies that we pulled up.

THE COURT: I've seen some studies that say that, yes, I've seen that.

MR. TANENBAUM: And that the -- and I don't want -- I

get a little confused about this stuff. But if there's no significant difference in the causal relationship, risk relationship, between the ten and the 80, and I know we've got that e-mail out there, I know with this e-mail exchange, and I know Your Honor's hesitant to consider that. But I think some of the journals, some of the studies that I saw yesterday that we were talking about yesterday, do -- Okay. That's the cue for him to stand up and tell --

MR. MARCUM: He's seen some things like Cederberg that tie not just the dose, but also the duration together.

THE COURT: Right. Let me just say, I think general causation and specific causation are really somewhat different analyses. And the -- you know, this case started, the defendant said y'all had no basis scientifically for either general or specific. I think there is, at some level, some evidence on general. And how far we go with that, we'll have to figure out. I think it's important to address that, but I think there's something to it.

But, you know, the challenge here is when you're -- and we're thinking a lot about this, about, you know, when you have these risk ratios, if it's one or below, nothing to it, right? One to two, there's some relationship, but it's a minority. Over two, it gets easier in terms of analysis for the plaintiff. And we're in this, you know, one to two. And in some cases, that's solvable, because there's some lab tests

or signature marker or something that tells us the challenged drug or toxic substance is the one. We just don't have it here. And, you know, it's a problem.

And so I'm not going to wait to do the -- I see the analysis is different. Frankly, I was ready to write the general causation before, and I thought with all the effort everybody has put in this case, I thought they needed to -- I think the plaintiff needed to address dosage, I thought it was important to do, because the answer may be it's not everything but it's partial, and you deserve the right to try to prove that, and not have everything go out, even claims that may be meritorious.

But then you're going to be back to this issue, which frankly I don't think y'all figured a path out yet, which is how do I take this small slight increase in risk, whatever it is, and how do I sort it out and identify a particular patient who's the victim. And I think it's a challenge. I have to tell you, I would have put my money that Dr. Murphy could have done it, and it doesn't look like to me she did. It's as simple as that.

So, Mr. Tanenbaum, I understand your desire to do that, for me to delay, but I'm not going to. I'm in the middle of working on these orders now. I'm going to be informed by the argument here.

I do want copies of everybody's slide show in full, I

would like those. You know, the reason I really like them is y'all's best arguments are sometimes made in contemplation of the slide show.

MR. MARCUM: Nine o'clock last night is when you think of them.

THE COURT: I really find them, and you know, because it's kind of like these are the best documents, this is the best argument. And what I tend to do is go back to them and re-read them. That's why on this 60-pound weight thing, and I want to read what she actually said. It may not be fair -- the lawyer's characterization of it to the expert may not be fair, and I want to make sure that it's an accurate representation.

MR. MARCUM: All that I'd add, Your Honor, if I could --

THE COURT: Yes.

MR. MARCUM: -- to what Miss Middleton said, she's done a great job, just in specific causation, the starting point of all of these cases in terms of the data you're asking for, is the data that has been marshaled by the general causation experts. And I think if you look at Dr. Murphy's report, if you look at our Power Point, depositions, et cetera, that's the data that she relied upon.

THE COURT: Mr. Marcum, let me tell you something. I have great respect to you, and I have gone to that chart many

times you showed me, and studied it, I have it right up here.

MR. MARCUM: The SPARCL chart.

THE COURT: The SPARCL chart. I've used it. I think it's a really fine point to make. But your general causation experts, to the last person, said, I wouldn't know how to identify the individual patient. To the last person they said that.

MR. MARCUM: I think we have some slides addressing that particular point.

MS. BURKE: We can, if you would like to see, I mean, at the end of this presentation, and I added this testimony from Dr. Roberts at the last minute last night, because you raised that point at the last Daubert hearing, that I think your exact quote was our general --

THE COURT: Let me take away "everybody." Just about everybody asked the question. I hate to say everybody about a record that's 10,000 pages or something. Virtually all, if not all of your experts, have said, when asked, and I'm particularly thinking, you know, Dr. Singh, who I considered the most serious of y'all's general causation experts, he said, I wouldn't know how to do it. I just wouldn't know. Again, I put him in the category with Dr. Murphy, he's a serious guy, okay, that's a serious expert. But when asked the question, he said, beats me, I wouldn't know how to do it.

Other people, other experts, I can't get them off the top

of my head, were asked the same question, gave the same answer. And, you know, they were being hired, I asked y'all, I said, Mr. Hahn, why did y'all get different general and specific causation experts, and he explained to me the reasoning in class action --

MR. MARCUM: Do it that way in every case.

THE COURT: -- mass tort, you need to do it that way. I understand it.

So the fact that these folks weren't ready to tell you how you would do it, doesn't end the case. But the fact that, you know, we now have gotten to this stage, and frankly, I don't think Dr. Murphy has any better answer than these other folks did, kind of brings us to a problem about specific causation. I mean, that's sort of where I see it.

MR. MARCUM: We understand that's where you see it.

THE COURT: I don't expect y'all to say, well, thank you, Judge, we now agree with you, you made that great point. Yes.

MS. BURKE: One quick final point?

THE COURT: Yes, ma'am. You can make more than one, if you wish.

MS. BURKE: Since you like Dr. Singh so much, I want you to know Dr. Murphy really likes Dr. Singh, too, and just want to remind the Court that she does cite his meta-analysis that gives us an odds ratio of 2.04, which is a 104 increased

risk of diabetes in women.

THE COURT: Was that the one with the Chen study and the --

MS. BURKE: Chen and Culver.

THE COURT: And it's only the Chen study that has the significance. And Chen has more problems than Wrigley's has Chiclets. I didn't find that a particularly persuasive part of his studies, but I did think a lot of what he did was helpful.

Okay. Folks, I want to work out, y'all confer, when Mr. Hahn is well, give him a chance to get well, and I want to meet with counsel.

Thank you very much.

(Court adjourned at 11:36 a.m.)

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
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Debra L. Potocki, RMR, RDR, CRR