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

IN RE: LIPITOR : 2:14 MN 2502

Motion Hearing in the above-captioned matter held on Thursday, October 22, 2015, commencing at 10:08 a.m., before the Honorable Richard M. Gergel, in Courtroom I, United States Courthouse, 83 Meeting Street, Charleston, South Carolina, 29401.

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A P P E A R A N C E S

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THE COURT: We have our folks on the phone?

THE CLERK: Yes, sir.

THE COURT: Good. Okay. We're in the matter of the In Re: Lipitor, 2:14-2502.

Those attorneys who will be arguing today, could you state your name for the record, beginning with plaintiffs' counsel.

MR. HAHN: Morning, Your Honor, Blair Hahn for the plaintiffs. And we have at counsel table the folks that know the most about the case, Judge, so --

THE COURT: You have Mr. Tanenbaum standing up.

MR. MARCUM: I'm not sure that's accurate.

MR. TANENBAUM: And Miss Bierstein will be arguing for us, as well as Christiaan Marcum.

THE COURT: Very good. Mr. Cheffo?

MR. CHEFFO: Morning, Your Honor, Mark Cheffo.

THE COURT: You're going to be the only one arguing?

MR. CHEFFO: Unless I need to buy a vowel again, I think so, Your Honor.

THE COURT: You have a talented crew, as you both do here.

Okay. Folks, we're going to deal with two different issues. First let's address the dosage issue, and then we will go and we'll maybe take a break and then we'll do the -- depending how long that takes -- then we'll go on to specific causation.

And, folks, I wanted to explain to you, you know, originally the specific causation had me doing both Daniels and Hempstead at the same time. And I found it confusing when you had two cases, frankly. I found myself not knowing which one did what. And I didn't think it was fair, frankly, to Mrs. Hempstead, that I was confusing Miss Daniels. I mean it was just confusing to me. And I thought it was better, so we're going to reschedule the Hempstead specific causation. I kind of got it in my mind, I have a really busy trial schedule, but we're going to reschedule it, and I think the specific causation is important, it's important to each of these individual plaintiffs, and I think they deserve to have individual consideration.

Okay. I'm going to have the defendant go first on --

Yes, Mr. Hahn?

MR. HAHN: Judge, as to Miss Hempstead, the parties sent, last week, a joint proposed scheduling order that we haven't heard from the Court on. There are a lot of deadlines that are making all of us a little bit antsy. So if we could get some feedback. On Daniels? I'm sorry, on Daniels.

THE COURT: Yeah, we have some issues. Let's sort out today some issues, and then we'll -- that wasn't an accident, you know, I might have missed it, but Miss Boroughs did not, okay?

Mr. Cheffo.

MR. CHEFFO: Thank you, Your Honor. And thanks again for the opportunity.

Your Honor has, from both sides, we've given you and your staff a mountain of paper probably literally -- two motions. We have had, you know, a long time to argue, more than I think most courts would have given both sides, and we appreciate that.

So, you know, Your Honor issued an order, and as you are kind of wont to do, is was very specific and we kind of took it seriously. And, you know, our understanding, this is what you said, is that "An issue has arisen whether plaintiffs' experts have offered sufficient evidence to support their opinions that Lipitor causes diabetes in female patients at a dosage level less than 80 milligrams. The parties are directed to file briefs that address the issue and to provide supporting record evidence."

So again, for purposes of today, and I think our briefing, Your Honor, we took the Court at its word, and we assumed and presumed that, you know, there's been a lot of information, Your Honor's asked a lot of questions, you've gone through all the information. And, you know, you didn't really want to hear a lot of lawyer backfill and kind of Easter egg hunt of all kinds of information that the experts didn't rely on; you wanted to focus on the specific question. So that's where, you know, in the 25 or so minutes that I think this

presentation will have, I have tried to focus, in addition to trying to respond to what we understand fairly, or I think fairly characterized are some of the plaintiffs' points that they've raised both in their argument and in their submission.

So starting with that, you know, the first real point here is does dose matter for general causation? And we think the answer is, you know, absolutely yes, and we'll talk about both the case law that addresses that, as well as really just the scientific principles, as well as the experts on both sides, which certainly have considered and evaluated the issues of dose at the general causation level.

So to start with, you know, where there is no disagreement is the plaintiffs admit and have admitted in their papers that their causation experts do not specify at which -- the dose at which causation occurs. This is from their briefing. None of his opinions are dose specific, with respect to Dr. Gale. Quon, same thing; Dr. Singh, he didn't separately consider whether the causal effect exists at all doses. And Dr. Roberts does not quantify the dose-response relationship.

Now, the plaintiffs, again, I think fairly, raise at least two issues. They say, well, first is really you shouldn't be looking at that or you shouldn't be considering that because that may not be or isn't a -- this dose concept isn't something that you should be considering at this stage of the case for general causation. And when they say that, you know,

they apparently claim -- this was most surprising to me, frankly, that they had no reason to expect that they would be required to prove dose in connection with general causation.

I think the record is pretty clear that there's been a huge amount of information all throughout, that that didn't just kind of pop up. Where we're mindful and have been throughout this litigation of kind of the goose/gander, and we don't think that this litigation or any litigation that's as important as this, should be kind of gotcha. But I think as we'll look at the record and what actually happened, none of that, in fact, happened here.

So I think the best place to start, from our perspective, Your Honor, is with Bextra/Celebrex. And I think as you'll see, the Bextra/Celebrex case is squarely on point, I think it's incredibly instructive, it deals with very similar issues that the Court has before it, but it certainly also, as you'll see, it's not anomalous, it's not on an island.

THE COURT: It was described as an outlier by the plaintiffs.

MR. CHEFFO: Yeah, it was, like Judge Breyer just all of a sudden woke up one day and said I'm going to have dose be part of general causation with no support. Of course, that's just, you know, simply not the case. Particularly from, you know, any Federal District Court Judge, but certainly, you know, Judge Breyer, one of the more kind of, I think,

respected and thoughtful judges on the bench, frankly.

So this is in connection with the Bextra/Celebrex MDL. Pfizer happened to be defendant there as well. And the issue came up.

THE COURT: Were you the lawyer?

MR. CHEFFO: I was not. I was not. Actually one of the lawyers was involved in it, and I suspect there's probably some of the good lawyers on the plaintiffs' side who were involved either directly or indirectly. And this is, if you do kind of what we all do, Your Honor, you know, everybody knows about these decisions, right? There's not that many like this, but certainly if you practice in mass torts or products liability, you know, this is a big deal and we followed it.

THE COURT: There's also Westlaw, right?

MR. CHEFFO: There is Westlaw, and probably Lexis, although I don't believe I've used either one of those in a long time, Your Honor.

THE COURT: I'm not quite sure how you do that, Mr. Cheffo. I live on those.

MR. CHEFFO: Ask the people that sit next to me, that's how I do it.

So basically, what did the Court say? A threshold question raised by Pfizer's motion is whether a particular dose of Celebrex is relevant to the what? The general

causation inquiry. The Court finds that, yes, dose matters, must analyze plaintiffs' experts as to causation at the doses at issue. The court went on, the general causation inquiry is whether exposure to the challenged substance at the level of exposure alleged by the plaintiffs is capable of causing the injuries.

And there again, looking at these kind of differences in dose, what did Judge Breyer do? In 2007 he excluded expert testimony at the 200 milligram dose, while allowing it at others, because the analytical gap, which is what we've argued all along, between the data and these experts' conclusions, was simply too great to make the opinion admissible.

So again, we think that's on all fours here, particularly when you look at the four dosage ranges with Lipitor, you look at the differentiation, at least as Your Honor has asked to us address today, between 80, and then ten, 20 and 40.

And again, was Judge Breyer on kind of an island? I don't think so. In fact, two years before his decision in McClain, the Eleventh Circuit looked at this issue specifically, and they said that failure to analyze dose signals a methodology problem at, again, at the general causation stage. Scientific knowledge of the harmful exposure -- harmful level of exposure to a chemical is among the minimal facts, minimal facts necessary to sustain the plaintiffs' burden. And the Court went on then to say that dose is the single most important

factor to consider in evaluating whether an alleged exposure causes a specific adverse effect.

And I think there's two kind of, in addition to those points, important points here, one is, you know, obviously the Court, the McClain court is taking this information from the case law, but presumably also from the science. And also, the Court has, in this case and some of the others, they haven't drawn a distinction between environmental exposure, toxic or pharma. Because when you're looking at the general causation concepts, all of the same principles apply. And we see the Fourth Circuit does the same thing, Your Honor.

But before we get there, we have Chapman, which is another case, not an outlier, Eleventh Circuit case. This is in connection with an appeal, as I understand it, from the Dentu-Creme MDL, right? It got up to the Eleventh Circuit, and in dealing with the general causation element, the Court kind of ratified what McClain had said, in the first box, then it said knowledge of dose response is an indispensable methodological factor to establish general causation.

So clearly no surprise if, as you said, you kind of did a Westlaw search. And then you wouldn't have to look any farther than the Fourth Circuit to also find these same principles in both Zellers and Westberry, to carry the burden of proving a plaintiff's injury was caused by exposure to a specified substance, the plaintiff must demonstrate the levels

of exposure that are hazardous to human beings generally. And, of course, Westberry says scientific knowledge of the harmful level of exposure to a chemical is among the minimal facts -- probably relying on some of the Eleventh Circuit thinking -- necessary to sustain the plaintiff's burden in a toxic tort case.

So there are really just a huge number of cases that are both in this circuit, from the Fourth Circuit, and outside, and you don't really have to look very hard to find dose as part of a general causation element in --

THE COURT: You know, Mr. Cheffo, recognizing those cases, there's also data suggesting at certain levels there's not an adverse effect.

MR. CHEFFO: Exactly.

THE COURT: I mean, which -- I mean, the experts here rely on dose. I mean, they, in the Bradford Hill factors, they note there's a dose response. And seems like there's a plausible explanation for that. There's data to support their argument there to some degree.

And so the sort of issue is, how important is it that there is, in fact, data available? I mean, in some of these cases cited by the plaintiff there's like a dearth of data. And it doesn't seem so much they're not requiring dosage, they're just saying you don't have to have a placebo, clinical random study, if -- you know, the defendant doesn't win just

because it doesn't exist. When there's a dearth of data, you might look for other data that then may give you -- that may give you a reliable result.

But here, we've got a random clinical study, randomized clinical study that show at ten milligrams doesn't have an effect. And to simply extrapolate, because other studies show at a higher dose it does, down to ten, it doesn't seem to me to be -- doesn't seem to make a lot of sense.

I mean, so even if you didn't want to go as far as you're going here, this particular scenario is sort of like the Celebrex case where they actually had data at one level and not at another. And, you know, it seems that at that point you've got to say, well, we just can't extrapolate from dosage at a higher level that necessarily there is causation at another level, when we know the studies don't show that. Right? I mean --

MR. CHEFFO: I think that's right, Your Honor. I mean --

THE COURT: You see, that's even narrower than your argument. And I read all these cases, but -- on both sides, and there are interesting points on all those cases. I think the Seroquel case is actually very interesting, and -- in which, you know, in that case the expert does not -- says at lower doses I can not offer an opinion. It's not the data. I mean, so you're dealing with a -- this is not a situation, at

least at the extremes, where there's a lack of data. There is data.

MR. CHEFFO: Exactly.

THE COURT: And the question is what do you do. And but I've got to tell you something, I mean, I don't want to interrupt your presentation, I find it very interesting. But let's say I buy your argument, let's hypothetically assume that for a second. Is it your argument that since the plaintiff did not ask the question, and their experts did not address it, that they should be excluded? That's just the consequence, even though if they were asked, they might have an opinion today?

MR. CHEFFO: No.

THE COURT: No, they can't be asked. It's your argument, no, they can't be asked, they get excluded, that's it, summary judgment, and all the cases go away because the plaintiffs made the strategic call not to ask him to look at that issue.

MR. CHEFFO: Not at all, Your Honor.

THE COURT: So what's the answer?

MR. CHEFFO: Well, the answer -- And let me answer you directly. The answer first of all is, you know, I wanted to make sure that dose was at issue, we've talked about that, whether it's as broad --

THE COURT: Let me -- I think dose is an issue.

MR. CHEFFO: The answer -- so this is absolutely not a situation of gotcha, right? This is not where they weren't asked. And I think as you'll see in the presentation, what we tried to do is a few things. And the quick answer is, they, in fact, did look, right, and they were asked at their depositions about this, and the fact remains is we've gone a step farther. We've said, you know, yes, they didn't look at it, but let's be clear here. The reason why they didn't kind of analyze it, Your Honor, with Dr. Jewell, is because, as you said, there's really nothing there. If you look at clinical trial data, right, you have ASCOT, which is squarely contrary. Then you have, you know, the SPARCL data, which Your Honor has kind of, you know, I think formed a view as. But beyond that, there's no data. I mean, there is the law lags science, right? And I think you've kind of alluded to this before, which is, this is not a situation that, you know, don't look over there, there's the elephant in the room, there's this giant amount of data, and we're trying to say, well, no one asked them, and let's just slice this onion really thin.

THE COURT: Let me ask you this. I don't even have an opinion at 80 milligrams that it -- because they haven't addressed dose at all. I mean, theoretically, to survive Daubert, they would have to answer even at 80 milligrams that they -- it's statistically significant, in applying the Bradford Hill factors, there's causation. They have not done

that yet. And the question is, is that the end. Is that just the end of the case because -- I mean, maybe I agree with you they should have done it, and maybe they had their own strategic reasons, ill advised, not to do it. But I have been very mindful that I have in my hands the claims of thousands of people. And I have been flexible with both of y'all on some of these deadlines, because the consequences are so harsh to impose the rule, and that it seems out of proportion to what we're trying to do, which is to have a system of justice.

So even if I'm where you're at, are we not going to allow the experts already designated at least to try to answer the question? Because I don't have enough evidence to allow any of them to testify, if dosage is important.

MR. CHEFFO: I would say this, Your Honor. I say this absolutely -- and I think, you know, look, Your Honor knows full well that you appointed some excellent lawyers, right, who have huge amount of resources, have spent a ton of time. And the answer is, is no. I mean, at some point, these issues --

THE COURT: Your theory is the door is closed.

MR. CHEFFO: But at some point --

THE COURT: I agree, at some point the door has to close and there have to be limits. I'm just -- I mean, I think they should have addressed it, okay? I think they should have. But I think -- and I don't know this because I

haven't had -- at least on some of the claims they may indeed survive, they could have answered something that could survive Daubert. Now whether they could prevail at trial, whether they can do specific causation, all this, the jury's out on that stuff. But at least as to that issue, I literally have nobody has offered an opinion at any dose.

MR. CHEFFO: But here's the thing, Your Honor. The reason why you haven't seen evidence that passes Daubert, right, and that's been our position all along, but that's different than suggesting that this concept of dose has been formed. Remember I think we had a slide that showed Dr. Gale and said he has done a dose-specific analysis, right? And what I'll show you in a few minutes is, you know, they basically did say, well, we don't have clinical trial data, and it's what they said in their most recent submission. But, Judge -- because your question was, tell me what you have at dose, and what your experts relied on. And they didn't say, Judge, we have nothing, it's a one page, you know. They said here's a 50-, 60-page, whatever they put in, and they said, well, you should look at observational studies, you should look at Japanese label --

THE COURT: That's lawyer talk.

MR. CHEFFO: I agree.

THE COURT: At some point you have to have experts opine as to causation. Okay?

MR. CHEFFO: That's right.

THE COURT: And we don't have causation. And the question -- I mean, this is the sort of central question in my mind, is if I go where you're going, I basically -- because they made a strategic call -- and I can not understand why they did it. I mean, you're sitting there representing thousands of people who have dosage at all these different levels. Are you going to go over and just throw part of them over the side of the boat? When you have an individual claim, individual client, you aren't confronted with that problem. And they may -- you know, I'm reading that they may have made what I think is not a great judgment, but is the death penalty a consequence of that infraction, or should I try to fashion some way to afford them an opportunity to specifically answer the question you think they should have addressed with their experts. They may or may not survive Daubert. But I mean, I think -- you and I both think if they actually applied it, certainly at 80 milligrams, they probably could get to a jury on that question. Right now, if I take your approach, no, they haven't offered an opinion, they lose.

MR. CHEFFO: I give them -- maybe I'm giving them more credit than the Court. I think that these, again, this is not a surprise, right? And to come in and basically say we didn't ask the question, we didn't answer it, and now we should get an opportunity, I think that's the wrong -- from my

perspective -- I think, again, if you really look, this was -- you know, we make strategic decisions as lawyers, but we make strategic decisions based on the evidence and based on the data, right? So it's not --

THE COURT: Let me ask you, I asked the question about 80 milligrams, anything less than 80, because you argued in your brief less than 80. You said there's no evidence less than 80.

MR. CHEFFO: Two points. We said we don't think there's any there, but we recognize the SPARCL study.

THE COURT: But the truth is, and the more I thought about it, they haven't even offered and opinion at 80.

MR. CHEFFO: I agree.

THE COURT: And that seems to me a very harsh result. And if you get lower than 80, there's some data out there; I don't know what to make of it. Is it enough to survive Daubert? Beats me; I'm not an epidemiologist, I'm not a cardiologist. But it might. I mean, I can't ignore these various studies that are out there that I -- I mean, I know from their argument they would argue -- whether the experts buy it -- as much as I like Mr. Hahn, he is not a cardiologist, he can not offer an opinion.

And so, you know, I -- I mean, that's the difficult question I'm confronting. If I buy your argument, it seems to me an incredibly harsh result. And I'm going to be honest

with you, if I was sitting up on an Appellate Court and a District Judge did that, I'd send it back, to say you should afford them a chance to answer the question.

MR. CHEFFO: See, here's the thing. Look at this slate of experts, right? They didn't just have somebody who is kind of a run-of-the-mill kind of doctor. They had people they presented as kind of world class folks, right? And they had epidemiologists. Right? They --

THE COURT: They told them not to answer this question.

MR. CHEFFO: I don't think that's true.

THE COURT: Well, let me say this. You don't think question is answerable. Maybe it isn't, okay? And if then you're right, you get that result, maybe they can't offer an opinion. But I think they were worried -- this is me surmising, I don't know, I don't expect them to acknowledge this -- that they recognize if they did that, that at ten milligrams, all their ten-milligram cases would go away.

MR. CHEFFO: This happens every day. This is what happened in Bextra/Celebrex. After the judge said, okay, the next day, right, summary judgment. Accutane recently a decision, if you don't meet it --

So I think the answer --

THE COURT: And I think if the evidence is sort of -- I mean, I've read all of this stuff, I spent like three hours

rereading over Cederberg last night, just over and over, trying to make sure I understood the data. It's an observational study, it's not the strongest evidence, but it's some evidence. It's something to argue about. Am I not going to give them a chance to ask the question? It may not survive. But I don't -- I've said to you a couple times when you push me to what you thought was the -- was sort of the making the end game come faster than I thought it was appropriate, I would say, slow down, Mr. Cheffo, one day you may be happy I gave them the opportunity to do this.

I think it would be a mistake not to allow them an opportunity to address this issue. I think they should have done it. I'm with you. I think -- I agree with you it's necessary under these facts. These particular cases where you have discrete evidence that at some level it does not produce the adverse effect claimed with diabetes.

But then I'm struggling with what I should do as a consequence of that. And I'd say to you, candidly, I think your proposed solution, which is I grant Daubert motions on all of them because of the failure to do it, and I then grant summary judgment, seems like a very unnecessarily harsh result, in light of what I actually have in the record here.

MR. CHEFFO: Well, look, again, at the end of the day, Your Honor, you're the one that has to make this decision. All we can do is tell you what --

THE COURT: Tell me what's wrong with my reasoning on that. Do you hear where I'm coming --

MR. CHEFFO: There's no question. And that's the problem with mass torts, right? You advertise and you wind up with maybe a nonviable claim.

THE COURT: What percentage of these cases, if you know this and have a rough idea, are patients who had ten milligrams, they were on ten milligram doses.

MR. CHEFFO: I don't know the specifics. I would tell you this, and I know generally that ten is the most common --

THE COURT: I'm aware of that as well.

MR. CHEFFO: -- dose, right? So -- and we could probably try and figure that out.

THE COURT: You've got the fact sheets, so you probably have access to the data. I was just wondering.

MR. CHEFFO: But look, to go to your point, I would say -- because on this one I want to just be clear, again, Your Honor is going to do what you do, but I fully believe that after this incredible amount of just not money, time, effort, experts, you know, that dose is important. I know it is somewhat of a harsh consequence, but it would be just as harsh to the other side if you denied all of our motions and we had a few thousand cases that we thought were not viable. So that's --

THE COURT: I don't want to do that either. What I'm trying to do is -- I think the question of dose needs to be answered. And it hasn't been asked by the plaintiffs to their own experts. And the answer is that they may say, A, I can't offer an opinion, I don't have enough data, or it may be at some dose level it is -- I can give that opinion, but not at others, like Seroquel, like Celebrex.

MR. CHEFFO: I understand that, Your Honor. I would just say this. Again, look, I would look -- you're differentiating here, right? At least as to ten, there should be no question. Because, in fact, the --

THE COURT: And that would be a test. I mean, frankly, I would be pretty skeptical, in light of the -- unless there's other evidence. And let me just go ahead so we don't have any mystery. Jewell is gone on NDA and ASCOT. That's gone, okay? So we're not having that. And we're going to issue an order soon on that.

So the question then is, we have data that shows that at 80 milligrams there's -- I can see where the plaintiffs make their argument. There is some data, maybe not as strong because it's not a randomized study at lower levels. Whether that cuts the muster or not, I don't know. I really think it's up to the experts to offer those opinions, not the lawyers. And that's another problem I have with the plaintiffs' argument, is that they're making the argument that

their expert, they need to -- that doesn't replace the testimony of experts.

So the question is, do I give them a chance to do that, and in a way that doesn't reshuffle the deck and start the case over. I am not going to allow that.

MR. CHEFFO: I'm not sure it can be done in a way, because, again, Your Honor is going to do what obviously you feel is appropriate and the right thing, but I would tell you that from my perspective I have -- I don't, you know, I don't believe that this would be an unfair result. And I don't believe it because I believe that if you look at the data, not just my slides and the briefs, they have scoured the universe, right, for things that the experts didn't even think about or rely on. And when you look at all of that information, and when you look at everything and put it together, the reason why they don't talk about dose is because they've taken a shotgun kitchen sink approach, and there is no -- They didn't even recognize ASCOT as being --

THE COURT: Okay. I agree with all that. We have a lay of the land here, they tried -- I mean, it's so obvious to me why they brought Jewell in to massage the facts, because ASCOT eliminates the ten-milligram cases, right? It's obvious. It didn't work. Okay? And a number of these experts rely on Jewell data, which is like kind of a problem, right? I mean, if it goes away, then what happens to those

opinions.

But more importantly, they really do need to address -- I mean, I think -- I don't know how I could plausibly throw the 80 milligram cases out. Maybe very few of them. I don't know what percentage of people take 80 milligrams, probably not a large number. But how can I do that when we've got randomized clinical studies that show, at least under some circumstances, that there is a statistically significant impact. Recent data -- nobody has commented on Cederberg, because nobody knew about it, I take it?

MR. CHEFFO: Two things, Your Honor. Let me talk -- I think to the extent that the Court is focused, and I think has been the questions, and I'm comforted to hear Your Honor is still kind of an open issue on that. But to say, look, that's something where I think I've seen enough, right, there's this SPARCL, but you haven't kind of gone, you haven't carried the football I cross the end zone and --

THE COURT: Haven't asked the question. Haven't asked the question.

MR. CHEFFO: But then it would be, seems to me, more efficient in terms of kind of getting moving the ball from a litigation perspective, ask that question as to 80. Say okay, I have these issues, but I think there's there. But as to, you know, ten, 20 and 40, there's no there there. There's no SPARCL data, there's nothing like that.

THE COURT: This is where the plaintiffs, some of the plaintiffs' cited cases don't help you. Because what they say is okay, we've got these situations where we don't have the gold standard, but we have some data. And our goal is to have -- they use reliable methodology, whether there is sufficient data to support it. And I have trouble imagining at ten they could get there. I mean, just what I have read, I have some trouble imagining that, but it's possible; we'll have to see what they have to say.

At 20 and 40, I'll be honest with you, I just don't know. I don't have enough -- you know, I'm not an epidemiologist. I'm not able to go through, and you aren't either, and neither is the plaintiffs' counsel. The experts need to opine, and they may or may not opine, or if they opine, they may not meet the standards for Daubert. But I am hesitant about just saying -- if none of this was in the record, I could say okay, you know, it's not even -- there's nothing -- literally no there there. There is something, we just don't know what to make of it, because it's their expertise that needs to be applied to the data to tell us. And in the end, I'm not determining whether they're right or wrong, but whether they're sufficiently reliable to put in front of a jury.

MR. CHEFFO: Sure, Your Honor. And we get that. I guess one area that, you know, if we talk a little bit about it in this presentation, is fundamentally, if this really was

a situation, right, where the question was not asked, they didn't look at it, they had no opportunity, they didn't have the right experts with the right expertise, you know, look, as an advocate, I might be saying you still should --

THE COURT: This was intentional. I agree it was intentional. The question is --

MR. CHEFFO: But look, too, Your Honor, I think they did look. See, that's where I think --

THE COURT: Well, we're going to know the answer pretty quickly, because I mean, I understand, and maybe my surmise here is wrong, but I suspect they didn't want an answer to the question because it eliminated a number, maybe a significant number of their cases.

MR. CHEFFO: I don't think that's what they did. See, I think what they did look -- if they didn't want to really look, right, then they basically wouldn't have talked about all of these other -- I mean, some of this stuff is lawyer backfill in their most recent, you know, things like adverse events that we never even see that, right? So we don't need to spend a whole lot of time. I don't think anyone really seriously believes that a Japanese label is going to get you past causation. But they absolutely, I mean, Dr. Singh, their main expert, right, the expert we spent a fair amount of time, he's a guy who talks about, you know, observational studies. He did a meta-analysis, right, of the

observational studies.

THE COURT: Why couldn't they ask Dr. Singh -- you know, if I'm going to allow anything, and I'm not -- I'm not as inclined as I'm acting like here, but if I, in fact, allowed them another bite at the apple, it would only be with their existing expert. I would not allow them to name new experts. But the question is, in a very narrow and discrete way, knowing Jewell is gone, could they ask their experts, at ten, 20, 40 and 80, do they have an opinion, and if so, what is it, and what is the basis and what is their methodology.

MR. CHEFFO: Here's what I would say. So you asked that question, right, you asked that question of the lawyers, right? Now, I know it's a different question, right, but the point is, so I think the way I would think about this, Your Honor, and you're probably, as usual, a few steps ahead of me, but before we get about whether the experts have actually said anything about it, you know, this was essentially tell me what's out there that they could have said, right? So the --

THE COURT: That was exactly what I was trying to do, is there even a plausible basis to offer that opinion. I knew these guys could not substitute for the expertise that would be required. But I wanted to know what's out there that they could even remotely rely upon.

MR. CHEFFO: Exactly. And I think again, when you kind of go through that, right, so the first question would be

if they came and they said, you know, oh, my gosh, in the reliance materials or in this there's this 14 clinical trials that had we just read them or quoted from them we would have -- but I think when you go through it, right, so now the question is what's out there, so if we give them another chance, the constellation of the universe of things they could draw conclusions on would be what they presented to us.

THE COURT: I agree. I think, believe me, with what they threw at me, I think they've cleaned everything out they could find in the cupboard. They gave me everything they could possibly get. But the question is, what we don't know is, could their experts, taking that data, offer an opinion that could survive Daubert. And I've got to tell you, I don't know the answer to that question.

MR. CHEFFO: And what I would say, Your Honor, to that is, I, again, think they looked, and I think what they have said, and I think this is a very fair characterization, is that if you look, and they said this a few times, you know, nothing in and of itself shows me, but if you look at everything, right, there's enough when you combine everything together that you, Judge Gergel, should basically pass at all doses.

THE COURT: I'm not going to extrapolate from 80 milligrams and SPARCL, that someone at ten milligrams can show it's capable of causing injury. I'm not going to do

that. That is, to me, intellectually dishonest to do that. I'm not going to do it.

And so the question is, where does that leave us. Because I do think, had they not taken the approach that they did, had they asked it, at least at 80, they would have survived, and who knows about lower doses. Because, you know, we're kind of in that range of those cases like they were citing where you had to make a decision whether the less-than-perfect data was powerful enough to allow them to do it. And I don't have the expertise --

MR. CHEFFO: Those are different, as Your Honor said. One was, I think, Zellers, or the other Fourth Circuit case, Westberry, the issue was the person said it was talc, they were shaking their things off. And Zicam was basically there was a study that showed that at a kind of a lower dose, right, and then the minimum dose in Zicam, which was only one, was ten times more, 300 percent more. So it wasn't that dose wasn't important in those cases, but it was kind of a check the box, right? Because if you show over --

THE COURT: But they didn't have perfect data. And what some of those cases stand for, not every one of them, but with less-than-perfect data, that doesn't end the case. Because the defendants in those cases came in and said we won because there's not a randomized clinical study. And the courts, understandably, said whoa, hold on a minute, we'd like

to have that, too, but when we don't have it, that doesn't end the case. We've got to look at whether other evidence --

MR. CHEFFO: We do have Navarese and ASCOT though, which is so different, right, at least at ten milligrams. So here, you know, the idea that --

THE COURT: Listen, if they come in and argue ten milligrams, I'm obviously going to -- I would scrutinize very carefully any expert who would say that, based on what I know right now, unless there's some other data. And believe me, with the empty cupboard they've given me, I feel like there probably isn't, then that would obviously cause me to be pretty skeptical about the methods they used. But in the end, I've got to -- I just sort of feel like I need to let them have an opportunity to ask the question in a very limited way, in a very discrete way, to ask the question, to have you guys be able to respond to it. And then, in the end, I can make a decision that answering the question, which I actually agree with you, should have been asked and wasn't. I mean --

MR. CHEFFO: Your Honor, with that, so I mean --

THE COURT: I'm glad to go through this.

MR. CHEFFO: Again --

THE COURT: No, no, I find it very interesting.

MR. CHEFFO: I understand Your Honor's point, I think they -- I don't want to repeat what I said, take up the Court's time with that. I do think ultimately where I kind of

come out, where I think, you know, respectfully, Your Honor should come out, is -- and we get it, we get that this is a big decision, we really do. But at the end of the day, would this kind of unnecessarily prolong the inevitable? And I think the answer to that is yes. The reason why --

THE COURT: It might. It might actually trim the case down. Might make it more manageable.

MR. CHEFFO: I'm just not sure why they're not going to be faced with the same issue, if you give them a chance to do it, just tell me at any dose, right, isn't that -- there hasn't -- and I'm not faulting. But if the equation was they didn't feel like they could trim this litigation, they didn't feel like they could stop the thousands of people from just filing any lawsuit, how do they then make that determination if you give them another chance?

THE COURT: Let me say this. They may not be able to make the determination for themselves. I'll handle it for them, okay?

MR. CHEFFO: That's why we have judges, I guess.

THE COURT: I'll solve that problem for them.

MR. CHEFFO: Okay, fair enough.

THE COURT: And, you know, but I mean, I think if we were all sort of talking honestly about this, we'd say, hey, it's not likely ten will make it, it's not likely 80 would go away. And we've really got to look hard at 20 and 40. I

mean, we've just got to. And you'll make an argument, they'll make an argument, and then I have to sit and study that and make a determination. And I just sort of feel like, you know, it's an imperfect situation. But I'm not handling one party's claim, I'm handling thousands of people's claims, and that weighs heavily on me. It does. I just think that you ought not dispose a case where there's record evidence that could well support a different conclusion.

MR. CHEFFO: Okay, Your Honor. And I guess to this point, you know, these are just quotes, not in our briefs, this was in our expert reports, right, where each -- not one, not hidden -- but everybody talked about dose in some level. Right? I won't read these all, but I'll give Your Honor a copy --

THE COURT: Are you going to provide me a copy?

MR. CHEFFO: Yes, Your Honor, I will.

THE COURT: And these are all -- these experts, those are all in the record?

MR. CHEFFO: Exactly, these are our experts, Elasy, Fonseca, Hennekens, Miller and Dr. Sacks. And not all of them, but these are the folks that specifically talked about dose. So again, not kind of hidden under a rock somewhere.

And then the -- you know, the plaintiffs' experts, right, the one, this is just the ones they've said are their causation experts, were asked specifically at their

depositions, right before we filed Daubert briefs, with respect to diabetes --

THE COURT: And the answer was, we didn't look at it.

MR. CHEFFO: I don't know, could be different answers for each one. We can, again, provide that for you. They may have in some and, you know, they --

THE COURT: You know, they are using dose. They use dose, right? They say there's a dose response.

MR. CHEFFO: That's their whole point.

THE COURT: And maybe there is. I mean, I think there's some evidence to support that. But there could be several types of dose responses. One of them could be that at every dose it has a harmful effect, causes diabetes. But a greater statistical association, statistically significant at every level, but higher levels is greater. That's one.

Another one is, as appears to be here, no association at lower doses, association at higher doses. Okay? So how do we deal with that? That's the question is how do we deal with that data today, when I have that in the record.

MR. CHEFFO: Let me just ask the hypothetical to Your Honor, right? I mean, what are the chances that if there were clinical trial data at ten and 20 and 40, that was even mildly helpful or really supporting evidence, is it really the fact that they just were like told, don't pay attention at all to dose, irrespective of what the conclusion are? We know the

answer to that, Your Honor. The answer is, right, that they scoured the -- they scoured the earth for information.

THE COURT: You're projecting that their experts will not support them.

MR. CHEFFO: I'm suggesting that they did it already.

THE COURT: Okay. And lied about it?

MR. CHEFFO: No, no, no. No, no, I'm sorry, I didn't mean to suggest that at all. I'm --

THE COURT: Because you asked them, did they do it, and they said no, we were not asked to do it and we did not do it.

MR. CHEFFO: Well, that's what the plaintiffs said in their briefs, right? This is from their brief. None of his opinions are dose specific. So they say that they're not dose specific. Now, I can't tell you in all these -- and I'm certainly not suggesting, Your Honor, that anybody lied, counsel or anything like that. All I'm suggesting is that, of course, they knew, when going into this, that dose was an issue from us, because we questioned them on it. They knew our experts talked about dose. They knew that they had to find anything, if it said Lipitor probably anywhere, they were going to find it somehow. And if it supported the position of 20 -- and that's why, you know, they do talk about observational studies and they do talk about NDA data, they do talk about glucose levels, because what they did was they

said, okay, we got SPARCL, we got ASCOT, how do we -- what else can we have here? Right? So it's not an absence of information or looking, it's an absence of evidence. And that's different --

THE COURT: So you're projecting that had they actually addressed dose, what would have been the answer.

MR. CHEFFO: I think they did address it, and I think the best thing they could say is we recognize that there's contrary, absolutely contrary evidence, that's why we went and asked Jewell to go back and deal with it. One of the main reasons they did that was because of dose.

THE COURT: There's no question, Jewell is -- Why would you go through all those machinations for the sport of it? You did it because ASCOT was a problem.

MR. CHEFFO: On dose. And then they said okay, ten, 20 and 40. Both sides agree there's not as much information on 20 and 40 as there is in ten and 80. They said, well, the answer to that, because they did have a dose kind of response, is we don't have clinical trial, but we're going to use this kind of constellation of evidence, right, we're going to look at observational studies, we're going to look at adverse events, we're going to look at that chart, right, from the NDA data. So the idea that they weren't looking is not the case, just turns out that the read is very very slim.

THE COURT: But if they had done it, you're

projecting that -- Let me ask you this. Are you projecting what their opinions would have been at, say, 80 milligrams?

MR. CHEFFO: Well --

THE COURT: I mean, can I reach a conclusion on -- when they said I haven't considered dose, can I infer from the record that they would have found causation at 80 milligrams?

MR. CHEFFO: I think what you can do, Your Honor, is if you have a question of whether they specifically addressed 80, based on the record, and that is an open question based on -- I think there has to be a two-step process. First find out is there any plausible basis for an expert to have made this conclusion at 80. At that point, right, if you had said, well, I think there is, they just didn't use essentially the magic words, or it wasn't clear enough to me, you know at that point on 80, I think I would say --

THE COURT: I feel that way about -- I mean, they haven't asked the question on any of these. I don't think any of them -- I don't think I should be trying to infer that they would meet epidemiological standards for causation. I don't think I should make that leap for them.

MR. CHEFFO: I agree.

THE COURT: And they have to do that. And the question is, since they didn't do it, do you win. I mean, basically over, game over, checkmate, everybody goes home because they didn't get that specific evidence.

MR. CHEFFO: I think, Your Honor -- so the answer is as to -- I would say as to ten, 20 and 40 at least, the answer is they have had a full opportunity, and the reason why they didn't ask the question is because, as we'll show you, the data doesn't support it. So to go back and --

THE COURT: So you think that if they came in and they said at 40 milligrams there is causation -- Let's game this out for a minute.

MR. CHEFFO: I guarantee if you give them a chance to say at ten, 20, 40, two, 80, a million, their experts will come back and probably say sure, absolutely, that's what I meant.

THE COURT: Okay. They're going to have to ask, I mean, my vision, to answer the specific question. At 40 milligrams, hypothetically, is there causation. What is your method, what is your data. And then you would have the opportunity to say that's hogwash, it doesn't meet the standard.

MR. CHEFFO: Sure.

THE COURT: And you would then try to strike that opinion under Daubert, right?

MR. CHEFFO: Sure.

THE COURT: And then we would be -- have actually a definitive answer to the question of whether they can survive Daubert at certain dose levels.

MR. CHEFFO: That's one way, Your Honor, of doing it. I think the only reason --

THE COURT: I wouldn't expect you to agree with this in a million years, okay? But I'm just saying to you, the reason I asked that initial question was, am I about to engage in something that is a complete waste of time. That is, there's just no data out there. And the answer was, at least there's enough that I probably need to go to the next step, which is to say I think you were wrong not to have done it, but I think you need to do it, so that then we can address whether you can meet Daubert standards at each of those dose levels.

MR. CHEFFO: Well -- and I do understand that very specifically. And I guess the only problem I'm having, Your Honor, is they asked you essentially to allow their experts, right, by proffering these experts, they asked you to say, let us go in and have these folks testify at ten, 20, 40 and 80. And here's our reports, right, that pass Daubert, right, because again, they wouldn't --

THE COURT: They're not going to pass Daubert without dosage here. But --

MR. CHEFFO: That's what they thought they were doing.

THE COURT: Listen, I know what they were trying to do, and I agree with the defendant as to the need to address

it. What I don't agree is that that makes sense that that's the end of the case. It just seems unreasonably harsh to me, result, and not one in which, you know, hundreds of my colleagues sent all these cases to me to address. I just think that's kind of shortcut, it's tempting, gets this thing -- believe me, this is a lot of work, okay? But I don't think that's what I should be doing. I think I need to game this thing out to the end, allow them to address these in the way they should have, you need to have the chance to challenge the opinions under Daubert, and then we need to have a definitive opinion about that as to ten, 20, 40 and 80.

MR. CHEFFO: And I would just say -- I'm sorry.

THE COURT: That's just sort of --

MR. CHEFFO: Look, again, as I've said all along, and whether I say it or not, it's true, you're the judge, you're going to do what you think you need to and make sense under the law here. I would just see if I could perhaps influence your thinking a little bit at least as -- certainly as to ten, and maybe the other doses. Right? And I think the way I would just try and do that is --

THE COURT: Let me say I am a skeptic at ten, believe me, you don't need to do a lot of persuading on that. Even Cederberg says no, this --

MR. CHEFFO: You asked about Cederberg.

THE COURT: Observational study.

MR. CHEFFO: I get all that. But -- and I would say, you know, there's four C studies, you know, who better to talk about C studies than a guy whose last name ends in C, right? And Cederberg though was interesting, because it came out shortly before their papers. So we, in our brief, recognized, not a gotcha, maybe they didn't deal with it. But the thing about Cederberg that's interesting in those observational data is one, nobody relied on it. Two, they didn't rely on it even in their supplemental or in their depositions. Three, it's in all men, right, with metabolic syndrome. And then four, the plaintiffs basically, again, bootstrapping kind of Jewell, say well, it had these results for men, so it must be far worse in women.

THE COURT: And, of course, the study itself says we can not extrapolate.

MR. CHEFFO: Don't know what's going to happen, right? So, you know, and this is really, I think, the core point. They rely on these observational studies. I'm not going to talk about clinical trials, we talked about them. But this, I think, is where the meat is. You asked them what information is in the record. And again, they went beyond what the experts actually relied on. So this really is -- so when you say do they not have a fair chance, they've put forward what their experts should be limited to, right, and should be able to opine on. And each of them beforehand said,

you can't really look at observational studies.

THE COURT: Listen, I noted that testimony, I mean, that they have said it's an apophasis, I mean -- But now they're going to be asked the question, what is your basis at 20 or 40 milligrams, and then your guys are going to go in there and question them, well, did you not say that that wasn't a sufficient basis? And they get to answer it, and then we get to have a Daubert argument about it.

MR. CHEFFO: If that's what we have to do again, Your Honor, certainly you've kind of written the outline of what would happen. I think though that, again, you know, there should be -- it will be hard, I would kind of suggest, it will be very hard to not have this be an entire Daubert do over. And I --

THE COURT: Let me say something. I have given a lot of thought to how to constrain this. And among the things I'm thinking about, if I decide to do it, is to limit them to their existing experts only, no new experts, deadline for naming experts is passed, to give them a very brief window to do it. To allow you to depose them, allow you, if you wish, to have your own experts supplement their reports. I'm talking about a very brief window. And up or down on this issue, after we do it. But to give everybody a chance. So very limited. And I hadn't thought about limiting it to the data they've offered, but you know, that may be a reasonable

addition as well. I don't know. I want to hear from both of you about that.

But I'm trying to keep this within very tight parameters so we don't have a do over, we don't revisit each of these issues. We're certainly not going out on the Easter egg hunt looking for more experts. We're not doing that.

But I do think it's -- I mean, I'm curious what Dr. Singh would say myself. I'd kind of like to see what he has to say and why he says it. I don't know what the answer is. Perhaps they don't know what his answer is either, you know.

MR. CHEFFO: I think I do, but --

THE COURT: We'll find out.

MR. CHEFFO: -- we'll find out maybe. If you overrule me on this point, we'll find out.

THE COURT: And I'm going to be interested what happens when your colleagues cross-examine him, if that's his opinion. And what method, if they opine at ten, you know, what exactly is your method to reaching that conclusion. I mean obviously that would raise some skepticism, unless they've got some reasoning that hasn't occurred to me for which they have not articulated in their prior briefing to me.

MR. CHEFFO: Look, again, in that kind of hierarchy, Your Honor, sure, we would, to the extent that Your Honor is inclined to allow, and I think those would be parameters that would certainly help us not kind of reinvent the wheel here.

There shouldn't be new experts, they should rely on this information, they shouldn't be able to do any kind of new reanalysis or studies. They should look at the information, look at the data, articulate a specific methodology, and talk dose by dose specifically. And be encouraged -- I would also say on the ten milligrams, there should be a threshold there before they even get to that, in showing how they would even, you know, get to ten.

But again, those are --

THE COURT: Listen, they may take the approach that they did in Seroquel and say we're not willing to offer an opinion at ten. And that's the end of that, right? They may well take that. We don't know what their approach is going to be. They have tried to extrapolate.

MR. CHEFFO: I have a sneaking suspicion what it will be.

THE COURT: We'll find out, won't we. We won't be guessing anymore. But they will -- they're not going to be allowed to extrapolate from SPARCL that ten milligrams causes diabetes. I mean, we're not going to allow that.

MR. CHEFFO: Your Honor, I'm going to try and move kind of quickly.

THE COURT: You go right ahead. I mean, I do these because I have things on my mind and I want to hear y'all's response.

MR. CHEFFO: Exactly, and that's why I want to make sure I try and answer Your Honor's questions but not kind of hit you over the head with issues that we've kind of covered here.

So this is just a limitations on observational studies. I think we've all talked about that.

THE COURT: I'm fully cognizant of that.

MR. CHEFFO: And really, the one thing I would just kind of highlight here is that, you know, it's particularly significant here, right, when you're doing observational studies, because of the kind of overlap between these cardiovascular risk factors and diabetes, which makes it really hard to tease these out. I think everybody recognizes it. But again, I would say the reason why Dr. Singh in particular did a meta-analysis and talked about observational studies, is because he was trying to capture all of the doses. Otherwise, it really would be no reason for him to do it, I think.

So here's these, you know -- and they only picked four studies, which is interesting, because there are a lot of them and they go many different ways. But let me talk about the four. So again, to the extent they are allowed to supplement, this --

THE COURT: But this is the kind of argument you're going to make in the Daubert motion. If they come back and

they say we're relying on Cederberg and Culver, Chen and Carter, you're going to go back and say, how about these other studies?

MR. CHEFFO: It is.

THE COURT: And, of course, one of those issues is cherry picking, right?

MR. CHEFFO: Sure.

THE COURT: And one of the questions is going to be is there an explanation why you disregarded studies that went the other way. And that's when Seroquel was one of those issues, they -- the -- I think the expert relied on ten of 20 observational studies, but she had an explanation why she didn't rely on the other ten, that seemed reasonable to the judge.

I just need to go through that analysis.

MR. CHEFFO: And I get that, Your Honor. And I think, again, if we -- if in our view, we probably wouldn't -- I wouldn't have spent more than three seconds arguing -- talking to you about this, except for the fact, again, we think fundamentally they did do this, and I'm just suggesting that maybe --

THE COURT: Maybe they did; I haven't seen it.

MR. CHEFFO: Maybe though, in order to get to that question, to give them a chance, you have to first look at this data and say what could they possibly use. This is the

data. And I guess what I would say to the Court is even if you take everything, these four studies, the Japanese labels, the adverse events, the glucose data, nobody can pass Daubert by coming and saying --

THE COURT: Let me tell you, you're going to get to make that argument. I'm not trying to second guess that, and we're going to have to dig into it and see where we end up on all that. But I'm not going to forecast it, because the threshold issue is whether these experts, one or more experts can actually offer the opinion in the first place, and tell us, using the Hill factors, why that -- if there is statistically significant association, why it establishes causation. And until they do that, we're not even getting anywhere else. And up to -- even up to 80 milligrams, they haven't done that yet. They just offered a -- you know, they've offered at any dose it causes diabetes. And I don't think the data -- that that can be defended.

MR. CHEFFO: Let me say this, Your Honor. So really for the rest of kind of this presentation, you know, look, it's fair to say, as Your Honor said it, that if they're going to get another chance, then this would be kind of my -- these arguments would be why I don't think they meet Daubert and why they fail, right?

THE COURT: I was trying to encourage you to save it.

MR. CHEFFO: Sometimes it takes me a few minutes.

THE COURT: Otherwise, you know --

MR. CHEFFO: I'm not the brightest bulb obviously, Your Honor. So let me sit down and give the plaintiffs a chance.

THE COURT: And I'll give you a chance to respond.

MR. CHEFFO: Thank you.

MR. TANENBAUM: Your Honor, I hate to ask the Court; could we have about ten minutes to regroup before we go forward?

THE COURT: You mean after I throw a punch at you like this you'd like to go to the corner and have your trainer fix the cuts?

MR. TANENBAUM: Yes, sir. Yes, sir. I think it would shorten the day.

THE COURT: I think that's fine. Let's take a break for about ten minutes.

(A recess was held at this time.)

THE COURT: Who is going to argue for plaintiff?

MR. TANENBAUM: May it please the Court. I might argue later, but I don't -- but we understand Your Honor's thoughts and I think decision about the case specific versus general causation issues. We're going to hand up our deck at the end of the day, or this morning.

THE COURT: I'm sorry, I missed --

MR. TANENBAUM: We're going to hand up what our

presentation was going to be on whether that was required at this point. We now understand it's required. So without having that argument, without presenting argument on that, we'll just hand that up. We're prepared to go back to the experts.

The one thing that we would like the opportunity to present on is Dr. Jewell. And --

THE COURT: We're not rearguing Dr. Jewell. We're not doing it. I've done it. I've given y'all more than enough opportunity, and we're not relitigating Dr. Jewell.

MR. TANENBAUM: All right.

THE COURT: I've heard enough.

MR. TANENBAUM: I understand. Then I think we'll sit down.

MR. HAHN: What do you want from us, Your Honor?

THE COURT: Here's sort of what I'm thinking about. Let me hear everybody, whether this is sort of workable. I want to issue an order, which it won't surprise you that I've already drafted, and which sets forth a schedule and certain parameters. And I want to get y'all's reaction to that. That I would find that the plaintiffs must demonstrate with general causation that particular doses of Lipitor is capable of causing diabetes. And I will allow supplemental reports offering opinions to whether Lipitor causes diabetes at doses of ten, 20, 40 and 80 milligrams.

May not retain new experts. They must be the experts you have already identified.

And the purpose is, is not to amend or add justification to their original report or opinions, it's to specifically address the question, ten milligrams, 20 milligrams, 40 milligrams, 80 milligrams. And to each of those opinions, to the extent they offer an opinion that it causes it, to set forth the data on which they rely upon, and to set forth the methodology they utilize to reach that conclusion.

And as I'm going to indicate in the order, do not rely on Dr. Jewell's reanalysis of ASCOT or the analysis in NDA.

Here's the schedule I'm thinking about. That the supplemental general causation reports would be due on November 23rd, 2015, approximately 30 days from now. On that date, when you provide the report, you need to provide the defendants two dates for each expert who may have offered opinions, so that they may, between November 30 and December 11, going to have the defendant depose them.

The defendants will then have the option, if they so desire, to file supplemental reports. And they must be in -- those supplemental reports would be in by -- must be served by December 18th. And they must, if they provide those supplemental reports, must provide two dates between January 4 and January 15th for their experts to be deposed. And then both parties are going to simultaneously file on January 29,

supplemental briefing strictly on that issue.

MR. TANENBAUM: January 29th, Your Honor?

THE COURT: January 29th. And any reply by February 5.

I'll decide at that point whether I need any further argument on this issue. And I will then address the Daubert motions at that point.

Mr. Cheffo recommended to limit it to the data I asked both parties to get, particularly the plaintiff, to give me the data. And I think it's reasonable to say that you've got to limit it to the data you gave me. I don't want new cooked up studies. You know, at some point -- I'm not to going slam the door on you, but we're not starting over again. You've got to take the data you've given me, and your experts need to rely on that data. I presume you consulted with them before you provided us that data. And they've got to offer us opinions at each of those dosage levels.

Saying that, the outline as I've just given to you, are there objections, and if so, specific objections to that timeline and the protocol.

Mr. Cheffo?

MR. CHEFFO: Your Honor, thank you for that. The only thing, and I wrote down quickly, we'll try work with that, obviously, we want to get this done quickly.

I would just say the depositions, depending on how many,

you know, the timing, we may need to work and maybe ask Your Honor -- I know you want to move that and we do, but again, if they give us six reports, could it be quickly, hopefully they'll do something, maybe they can tell us sooner about who they're going to be doing. Because, frankly, it doesn't seem like they need to give us another six or ten, I'm not going to say they need to tell us today, but so we can start to plan for that?

THE COURT: I would urge you both to help each other on that. And if it becomes a scheduling kind of impossibility because of the burden, then let's get on the telephone and talk about that. I'm trying to get to the end here, you know, and I'm very conscious that I'm delaying potentially a trial in the bellwether cases, and I'm not happy about that, but I want to do this part right.

MR. CHEFFO: I just had like following that, certainly not rearguing, just a few -- I think you may have answered -- I just have three quick points. One is it sounds like some of the trial dates will be, if there are any, will be set after Your Honor rules on Daubert.

THE COURT: Correct. Then let me say this. Sequence needs to be I need to rule on Daubert, and you need to then have the opportunity to move for summary judgment. And it may well be that we won't have a dispute about that. But if we do, then I need to be able to have time to address that, so

that we know, you know, what the lay of the land is on both general and specific causation.

MR. CHEFFO: Fair enough. And one issue, and I want to be very kind of specific and careful here, because, as you know, there is some State Court litigation, and we are very mindful, and I'm sure Your Honor is, that State Court judges, it's their courts, they're not bound by rulings from the MDL, they're not required to follow it. But we also know that some smart and resourceful and efficient State Court judges will often kind of look to the MDL for guidance, right? Whether they decide that's the right way to go or not, right? And the question then becomes, you know, we had positioned, I think collectively, this litigation, such that the first, you know, Daubert rulings, the trials, would be by Your Honor.

So I guess what I would at least ask Your Honor to consider is whether we do it jointly with the parties, or perhaps Your Honor reaching out to the State Court judges to do nothing more than explain the schedule --

THE COURT: There's going to be an order written, filed probably this afternoon --

MR. CHEFFO: See, here's the problem.

THE COURT: -- that lays out why I'm doing this and what I'm doing. And, you know, the state judges have to make their own determination, Mr. Cheffo, what to do. I would think they would want me to do this. There's a lot of brain

damage associated with this work, there's a lot of work, and nobody ought to voluntarily want to initiate this. And to the extent we're doing it, I would think they would want to slow their guns down just a little bit to wait for this.

But I'm not going to go call a state judge over this. I'm going file an order which will clearly explain why we're doing it and the schedule we're doing it on. And if I were one of those judges and I had someone else doing all this work, I'd say I'm going to let that guy do it, why should I go. Because it's not going to be any easier for the state judges to do it than I'm finding it myself.

MR. CHEFFO: Fair enough, Your Honor.

THE COURT: And part of this is to create a sufficient record on the general causation issues to -- so that my colleagues when -- if and when these cases are sent back to them, they have something to work with.

So the answer to your question, I'm not inclined to do it, but I think I will give you all the tools you need in the order I'm intending to file.

MR. CHEFFO: Thanks, Your Honor. And the final really quick point is not in the spirit of asking for an advisory ruling, but I think, as you highlighted, we all want to get quickly, we all want, you know, Your Honor certainly to have enough information, we all want to feel like, Your Honor, feel like you've been able to do kind of what you think is

right and just. Having said all that, there's been an enormous amount of effort and time and money and expense from the parties on this. So, you know, we're just suggesting that the hopefully Your Honor will make it clear and the plaintiffs are clear that there really should be consequences if these new reports or things they do are not kind of within the spirit of what, you know, should be the take away here. So again, I'm --

THE COURT: Let me say this. Listen. I'm giving them the opportunity to address the question. I think it's really a quite generous opportunity I'm giving them to do it. And they're going to get one chance to do it. And then I'm going to rule. I'm going to feel like I've got everything I need to rule, I've got -- I know basically the data they've got; I now need to see how their experts apply it and what opinions they offer. And then I'm going to rule on these Daubert motions. That's what I intend to do.

MR. CHEFFO: Great. Thank you, Your Honor.

THE COURT: Thank you.

Mr. Marcum?

MR. MARCUM: Your Honor, with due respect, and in terms of the issue of relying simply on what has been put into the supplemental briefing, I remind the Court that we had two business days in which to assemble that brief. There was a weekend, and I promise you we worked all that weekend. But I

do think that there ought to be some limited flexibility on that particular part of the Court's ruling. And respectfully request that --

THE COURT: I'll tell you what. If you can demonstrate to me that your expert has previously relied on something, and you can show me in a report where they did, and it's already in the record, I'm okay with that. And I will allow that. But what we're not doing is we're not sending Dr. Jewell back to do something new. Okay?

MR. MARCUM: Understood.

THE COURT: We're not reshuffling the deck and starting over again. But I think to the extent there is something in one of those -- they previously relied on, and you didn't mention it, as long as the other side has seen the report and all that data has been previously disclosed, your reliance, I don't really have a problem with that.

MR. MARCUM: And I would hope there would be some -- I believe the Cederberg article came out two days before we put in our expert reports, just in --

THE COURT: When I read the Cederberg report I just wrote, don't I want to hear from both sides about this? I mean, I really -- I mean, it is a dynamic time. I mean, I've said this to you guys privately, I think that in the way this litigation works, y'all got rushed into court before the science caught up. And it may -- sometimes that science helps

you and sometimes it hurts you and sometimes it goes both ways, right? And so it doesn't really surprise me that this report came out. I mean, it just doesn't surprise me. And because this is a very dynamic period. And several years from now, other studies are going to come out, and one -- both of you are going to say I wish I had that, I wish I'd have had that in my case. But that's just the way it is. At some point you guys set the timetable by filing the lawsuit, and at some point we have to shut the door. But I think it's reasonable that Cederberg is addressed as far as it goes, and we don't know how much it goes. I'm going to give y'all a chance to do that.

Does the schedule, Mr. Marcum, sound okay otherwise?

MR. TANENBAUM: I guess that means I'll be in trial in another court in January.

THE COURT: You are, I've already cleared you on that. I already let Judge Duffy know, he knows you're in trial.

MR. MARCUM: We'll work with it.

THE COURT: Good.

MR. MARCUM: And shout if it starts to hurt too much.

THE COURT: Don't expect me to be that receptive. I'm trying to get to the end of this, okay? And so I haven't really -- this is not an approach -- my instinct is to rule and move on, but, you know, there's something more important

than my own preferences about these things.

Okay. So let's move on to the issue, if we might, of specific causation.

MR. CHEFFO: Are you ready for me, Your Honor?

THE COURT: I am ready, Mr. Cheffo.

MR. CHEFFO: Thank you. So we're going to --

MR. MARCUM: Your Honor? We're certainly prepared to go forward on specific, but I wonder if it doesn't make sense for the specific causation experts to get the benefit of the supplemental reports before we do that.

THE COURT: I don't really think that's -- Specific causation is -- I mean, obviously if you didn't survive 20 or 40, Daniels -- I think Daniels is 20, is that right?

MR. MARCUM: Forty.

THE COURT: Forty. Then that would dispose of it anyway. But we're going -- I'm interested on specific causation, even assuming that there is -- you establish general causation, can you demonstrate that Miss Daniels was injured by the Lipitor. And I think that's something that can be addressed now.

MR. MARCUM: Again, we're ready to do it today.

THE COURT: Mr. Cheffo?

MR. CHEFFO: Thank you, Your Honor. So I'm going to be relatively brief. And I think we've gotten a little bit -- since it's getting a little later, we have a little

audio/visual today, so we haven't done that before.

THE COURT: I want you to know Ms. Ravenel always laughs when she hears the parties have a Power Point for me, because she knows I'm historically very impatient with these Power Points. So assumes kind of like I haven't read the thing, you need to tell me again.

MR. CHEFFO: That's why I click very fast, Your Honor.

THE COURT: Yes.

MR. CHEFFO: Not that you're impatient, but I understand the point; I would do the same if I were you.

So plaintiff, Wilma Daniels, is a 67-year-old Colorado resident, she had a history of this family hypercholesterolemia, which is a significant disorder, she had multiple risk factors, brothers and daughter had heart attacks. She took Lipitor for a long time, 40 milligrams. There was a little space in there, but then she took it for most of the time from '97 to 2013. Switched to Crestor, my understanding, for insurance reasons, in 2013, still on statins. And good news for Ms. Daniels is that she hasn't had a heart attack or stroke. And that is actually good and significant news, in light of the fact of her very kind of significant risk factors for both of those things.

And then she has also very significant risk factors on the right-hand side for diabetes. And there's some overlap, as we

talked about, obesity, weight gain, family history, metabolic syndrome, triglycerides and hypertension. So again, I don't think there's much dispute. Probably the only issue of dispute, and I don't think it kind of impacts the Court's analysis, there's a question whether she had prediabetes. The plaintiffs suggest that she got prediabetes a year after using Lipitor. You know, we think in the records there's some indication that she, in fact, had diabetes, or at least prediabetes before. But so we left that off for purposes of today.

THE COURT: Whatever. Whatever.

MR. CHEFFO: It doesn't really matter for purposes of the Court's general -- specific causation analysis.

THE COURT: So plaintiffs have offered one specific causation expert in this case, Dr. Handshoe. He, amongst other things, he's an attending emergency room doc at Trident.

So what's interesting about Dr. Handshoe is kind of more of what he's not. He is a pulmonary critical care and sleep medicine specialist, but he's not a diabetes specialist. He actually hasn't seen a diabetic patient for regular care in two decades, doesn't prescribe statins or treat hyperlipidemia, never published on statins or diabetes, he's never diagnosed what he calls statin-induced diabetes in any patient. In fact, hasn't even laid eyes on a patient who has what he says Miss Daniels has, ever.

But he does have this opinion. The evidence leads him to conclude that Ms. Daniels, otherwise healthy, which is kind of hard to understand that, 50-year-old woman developed statin-induced prediabetes and statin-induced Type II diabetes as a result of her prolonged exposure to Lipitor.

So here's where kind of the audio/visual part comes in. Let me just play this and then I'll see if Your Honor has questions or we need to cover any of the others.

(Video deposition played.)

"Q. Are there any published criteria or diagnostic standards for statin-induced diabetes?

A. No.

Q. Is there any single clinical feature that is different in what you call statin-induced diabetes, than what you find in patients that have nonstatin-induced diabetes?

A. No.

Q. Could you walk into a room of 100 patients with diabetes, and pick out the ones who had what you call statin-induced diabetes versus the nonstatin-induced diabetics?

A. No.

Q. Could you even do that if there were ten people in the room?

A. No.

Q. Could you do it between two people?

A. No.

Q. Is there any validated test or procedure that you could perform that would distinguish what you call statin-induced diabetes from nonstatin-induced diabetes?

A. No."

MR. CHEFFO: Again, he's asked is there anything at all in Miss Daniels' presentation that's inconsistent with someone who never took it.

Roger? Not playing? We'll go to the next one, it's not clicking. Go back. Thank you.

(Brief interruption in proceedings.)

MR. CHEFFO: The good news is we have the script on the right-hand side, I was trying to save you from me saying it as opposed to Dr. Handshoe.

(Brief interruption in proceedings.)

MR. CHEFFO: If those aren't working, we'll just do it without the --

So if you've read this, basically the whole point of here is he's not surprised that this woman would have gotten it anyway, would have gotten -- developed diabetes.

So one of the issues I think we highlighted there was, you know, essentially, and admittedly, this both could be a summary judgment type issue, but I think it's also a fit issue here, he's basically saying is there anything different, can you say that but for taking Lipitor --

THE COURT: He actually takes several different

positions. He says at one point in his deposition he can not establish but for, and then in response, on the examination by plaintiff's counsel, he says he could say but for.

MR. CHEFFO: Right. But I think consistent with everything else, he says there's no way of knowing, there's no test, there's no methodology, and I think he kind of laughs and says, you know, nobody can do that.

THE COURT: He basically says if you're a woman, you have risk factors, the more the merrier, you took Lipitor, and if you are subsequently at some point, not even near the time, but at any time in the future diagnosed with diabetes, it is something called statin-induced diabetes.

MR. CHEFFO: That's what struck me, Your Honor. I mean, you know, we talk about temporal proximity. If I smack my thumb with a hammer and it turns red, okay, that's something you can have temporal proximity. But what essentially --

THE COURT: This is like antitemporal --

MR. CHEFFO: Yeah, this is like, well, if you took it and between one and 25 years you developed diabetes, it must have been --

THE COURT: One precedes the other. That's really a little different from temporal.

MR. CHEFFO: Exactly. But so those -- look, I think we'll kind of cut to the chase, Your Honor. So I think

temporal proximity is essentially what he relies on specifically for --

THE COURT: But what he just basically says is if you took Lipitor and subsequently obtained diabetes, you are a woman and you had risk factors, the more risk factors, the more credible it is, then there's causation. And the question asked, you've got 100 people in a room, and you couldn't pick them out. Well, I started asking myself, well, if you have a hundred people, hypothetical people in a room, you can't pick out how many of them are going to have diabetes anyway. And of course the studies matter, but it's something like 60 to 90 percent, based on the study, are going to be not -- 70 to 90 percent are going to be not the result of Lipitor, even using their premise. And so you can't say most probably it's going to be, because it's most probably not. Then how do you get there? And how do you tease out, you have these other risk factors that have a relative risk far higher, and so --

MR. CHEFFO: Four thousand percent.

THE COURT: With BMI and the weight gain, it's off the chart. And it doesn't mean that Lipitor didn't contribute, because it could have. But the question is, how do you know it? How do you know that? And I've got to say, you know, my frame of reference for this is the classic hospital infection claim, you know, somebody gets an infection in the hospital, they want to sue the hospital. And there are

explanations in which the hospital could be culpable; bad infection control, contaminated instruments, allowed a sick nurse to come in. There are all kinds of potential claims. There also could be that your spouse brought it in, or that no matter how well you run the hospital, there's going to be a certain amount of bugs in the hospital no matter what you do. So how do you prove that that undesired injury was the result of something the hospital did. And most of those claims do not get brought because you just can't prove it. You just simply can't prove it.

So I have looked, you know, what is the methodology Dr. Handshoe uses that once he gets to the list of potential explanations of what could have caused -- and it doesn't need to be one of them, could be multiple ones -- that what is the explanation that Lipitor is among them. And I just couldn't discern any method he had to make that determination.

MR. CHEFFO: And neither could I. I think the only thing that he said is essentially, you know, he says, you know, I used a differential etiology or diagnosis.

THE COURT: That only gets -- Let me say, that gets you only so far.

MR. CHEFFO: Right.

THE COURT: And you're down in a list, and I mean, you're down to some number of risk factors. And then -- and Lipitor is among them, that's fine, I think that's a

reasonable thing. But that doesn't answer the question. The question is, now that you've done that, you've come down to -- you've made a finite list, how then do you tease out that Lipitor played a -- was a substantial factor.

MR. CHEFFO: Exactly.

THE COURT: And the reason I read his deposition was I didn't see an explanation in the plaintiffs' brief, so I went back and read it to see, could he offer us an explanation about how he got there, and it was ipse dixit. Basically if she took it, bingo, and she got diabetes, even though he acknowledges that he couldn't figure out, if she were in a room, that she was actually one of them.

MR. CHEFFO: You hit the nail on the head, Your Honor. He neither rules in nor rules out anything, which are the kind of core kind of guiding principles.

THE COURT: I think differential diagnosis or differential etiology is an imperfect method here. Because that -- those methods assume a single cause. And I don't think the plaintiffs have the burden of showing there's only one cause. There could be multiple contributing factors. It's a kind of imperfect method anyway. But it's okay, it gets you kind of to that list. And that's, I think, a reasonable exercise to say, okay, you know, we got the weight and we have the weight gain and we have the hypertension, we have these factors and we've got Lipitor.

And then the question is, how do we get there? And I've got to say, Mr. Cheffo, the fact that he, A, did not consider relative risk, and B, when he was trying to articulate an explanation on the relative risk, he had his decimal points like off, right? He didn't seem to understand relative risk. I mean, your colleague -- Who took that deposition?

MR. CHEFFO: Actually Mr. Paine right up there.

THE COURT: Outstanding deposition, by the way.

MR. PAINE: Thank you, Your Honor.

THE COURT: I probably deposed 500 doctors in my career, that was a very good deposition. And, you know, there was simply no explanation how we got there. And I reread -- I marked and then went back and to where he, every time he was asked this, how do you get there, how do you know it's Lipitor, he basically says essentially I assume it's Lipitor, if she took Lipitor. Though we know statistically that's not -- I mean, if you had a number over two, right, these are what, 1.37 or 1.25 or 1.09, everybody using these different numbers. None of them are more likely than not. So you have to get some method to help you get to say it's Lipitor. And he didn't offer any. And, you know, I was left kind of confused by that approach.

MR. CHEFFO: Well, I'm just kind of flipping through now, Your Honor, and I guess what I'm going to say is, as I probably might have last time, I don't really think I have

much more to add than I think what Your Honor has articulated, because I think you've covered, frankly, not having seen my slide deck, actually all of them.

I would end by saying this, and then give some time to the plaintiffs. Is that you're right, this is kind of the classic ipse dixit case. It's like at the end he said in my medical judgment. There's case law that says that's not what you can rely on.

And the other thing that just really struck me in addition to this, you know, really having no methodology whatsoever, it's like I kind of feel it, trust me concept, is I had never seen, I kind of pooled my colleagues, a situation where an expert wants to come into Federal Court and say let me try this out. The first time I have ever diagnosed anybody with this or made a conclusion, is in this litigation.

THE COURT: He's never seen it peer reviewed, he's never published it, he's never taught it to anyone else, he's never applied it himself. One thing he said, I applied the Bradford Hill factors because the lawyers told me to do it; that didn't exactly enhance his standing with me.

And, you know, the general causation experts all said, we don't know how you'd get specific causation. We don't have a clue. And it doesn't look like Dr. Handshoe did either.

MR. CHEFFO: Yeah, I think that's right, Your Honor. And unless you have further questions --

THE COURT: No, I don't.

Miss Bierstein, he gave you all the easy ones.

MS. BIERSTEIN: Yes. Before I get to Dr. Handshoe though, Your Honor, I wanted to attend to one other matter, which is that the last time I was here we had long day and a half, and I have to apologize, I let my advocacy run away with my manners in addressing the Court.

THE COURT: You don't need to do that, it was a long tiring day.

MS. BIERSTEIN: Well, I nonetheless do want to apologize, Your Honor, and assure you that will not happen again. I meant no disrespect to the Court.

Can we start with slide 64 on our presentation. I want to talk about Dr. Handshoe a little bit, and respond to the issues that the Court --

(Brief interruption in proceeding.)

MS. BIERSTEIN: So Dr. Handshoe is quadruple board certified, internal medicine, pulmonary diseases, critical care medicine and sleep disorders. So he's --

THE COURT: He's actually quadruple board certified.

MS. BIERSTEIN: Yeah, I thought that's what I said, I meant quadruple board certified. If we move to the next one, you'll see how he divides his time, two weeks in the intensive care unit, two weeks with hospital consultations, office patients the remaining two weeks. My understanding is he's

kind of a diagnostician, people come to him with problem cases in the intensive care unit or in the hospital.

THE COURT: I had actually a lot of interaction with critical care doctors, so I'm pretty familiar with what they do and how they do it. And obviously it's -- they're general medicine, they're among the last people who actually practice sort of very complex general medicine, because they have to manage people literally near death in the ICU. And I understand why you might want him. He -- you know, the question I have, I'll be honest with you, Miss Bierstein, the concern I have about him is that what you're asking him to do is really not in his wheelhouse. That is, you're trying to get him to say that a drug he doesn't prescribe, caused an injury that for all practical purposes he does not regularly treat. He certainly has patients in critical care who have diabetes, but -- and you're asking him to reach a conclusion as to causation, which his practice doesn't really require him to do. And, in fact, he's never done it. He's never -- he's using a method that -- if you call it a method -- that he's never anywhere used himself in his own practice. He wants to use clinical judgment on something he has never done. And there is a lot of knowledge that Dr. Handshoe would have on a lot of issues. And but certainly in that very comprehensive deposition that he gave, he didn't demonstrate a lot of skill on these issues. I mean, his -- you know, when we got down to

here's the list, and I can see differential etiology would get you there, and I think that's a reasonable approach. And I didn't have any quarrel with his list. I mean, he kind of got to -- I mean, after he was questioned, he didn't mention them all in his report straight up, but he acknowledged them, he recognized them. But then from that point to his ultimate opinion, there's nothing there. There's just no method there. And the simple conclusion, that if you had this profile, you were a woman, you took Lipitor, and at some unstated time in the future, with no limitations, the longer the better actually, which is contrary to sort of temporal notion, it was just one precedes the other, then that's causation. And he was asked -- I really did think that question about the 100 people and you couldn't figure it out, you wouldn't know how to -- there would be no lab test to figure it out, there's no clinical study, there's no history, there's nothing that tells you that this is one of those people who got it because of statins versus you got it because of your other risk factors. I mean that, to me, was what I was struggling with.

And if you can articulate to me what method he used, and that that method -- because that's the central part of my analysis here, is what method, did he use a reliable method, and is that peer reviewed or recognized in his profession. It certainly wasn't recognized among any of your causation experts. And he couldn't identify anybody who had ever used

it before. I guess it's possible he has invented something nobody else has ever thought of, and he did it just for us. But I haven't -- I didn't understand what it was. I couldn't understand what he did.

MS. BIERSTEIN: I'm going to try to answer that, Your Honor. I do want to start though with the point you mentioned, that he doesn't do this in his practice. And I want to note, although it's true that he hadn't diagnosed statin-induced diabetes, he does regularly treat patients that he's diagnosed with other drug-induced diabetes. Because steroids is another category of drugs --

THE COURT: I saw that. And I recognize that he is -- I mean, diabetes one of those complications in people under tremendous stress, right? And that's kind of classic in these ICU cases. I mean, I have great admiration for these critical care doctors, that's got to be the most emotionally demanding -- you're 24 hours. The reason he's doing it for two weeks is he physically can't stand on his feet anymore after he's there, he's basically on call 24 hours a day, and every time he's summoned, somebody could be dying. It's an incredible demand on someone who does it. I have great admiration for people who do it. And I recognize -- but saying all those good things about him, where is it that he has any knowledge about the effects of statins?

And he hasn't explained to us why he teases out the

Lipitor. How does he know the Lipitor caused it rather than the 21-pound weight gain or the -- which had a 4000 percent increase in risk, versus the .37 that we take Cederberg. Thirty-seven percent risk. How do we know it? It's not saying -- it can't be so, because I think y'all have shown evidence it does affect some people. But you can't figure out, at least in this case, that it affected Mrs. Daniels. You don't have method to do it.

Now tell me how he got there.

MS. BIERSTEIN: Okay, Your Honor. I think the way he got there, and Your Honor referred to it, but I think the way he got there is the differential diagnosis, although as Your Honor -- technically, differential etiology is the more --

THE COURT: But tell me -- I am with him the way he got the list. Tell me from the time he got the list to the conclusion that it was what he called statin-induced diabetes, how did he get there?

MS. BIERSTEIN: I think the way he got there is by ruling out -- and I'm going to be more specific on that -- that the other factors were sufficient by themselves to explain the diabetes. And I want to go in particular to --

THE COURT: Whoa, whoa, whoa, slow down. He ruled out the BMI and the weight gain?

MS. BIERSTEIN: As sufficiently -- yes, he did, Your Honor. I think based on what her BMI was. Remember, she

started taking Lipitor in '97. By '98, in the first year, she developed the prediabetes. And a lot of the weight gain is after that. And so he, I think, is seeing the Lipitor effect in that first year when she comes in as a woman who doesn't have this huge weight gain, and doesn't have a particular --

THE COURT: Is he blaming the weight gain on the Lipitor?

MS. BIERSTEIN: I don't know that he is; I don't think he addresses that.

THE COURT: We know that is like this huge factor. Now, let me say this. I have read and reread, and I will go back and read it again on this BMI. He did not rule it out. He just did not. And he doesn't really claim to have ruled it out. He simply says I don't -- he thinks more -- the more risk factors. See, this is sort of interesting. This is why I wanted to separate Hempstead. Because your other expert in Hempstead goes the other way. She starts trying to rule out risk factors. He's actually saying the more risk factors, the more credible it is, because -- and I can see he -- calling upon the SPARCL and something about the Jupiter stuff about multiple risk factors. I get that.

So I didn't see him ruling out anything. What I saw him doing was ruling it in, and then that made it more credible. But I didn't see anything in which he ruled out the weight gain to explain away, or that he tried to rule -- I mean, how

can you rule out hypertension, how can you rule out elevated Lipitor. And I wouldn't put it on yourself to do it, because I don't think that you need to do that, I -- I mean, and it almost suggests that unless you can rule out all the risk factors, then you can't prove your case. I don't think that's correct. I think you could have multiple risk factors and still be fine. And if he took that view, he simply said that there were these existing risk factors, he knew them all, he hadn't really considered the relative risk, but if she took that Lipitor, bingo, she got diabetes, diagnosis. I mean, in the end, that's what he says.

MS. BIERSTEIN: Well, Your Honor, I think that's not exactly what he says. Because for one thing, I know you thought he got the temporality a little backwards, but I think the point there that he considered the dose she took, the 40 milligrams, which is the second highest dose, and the amount of time she took it, because the dose times the duration is the total exposure. So he's looking at the fact that she took a lot of Lipitor. The other thing he's looking at, and this is on slide 70, Your Honor, which I think --

THE COURT: You're going to give me this, aren't you?

MS. BIERSTEIN: Yes, we are. In looking at her family history, because what he's trying to figure out is are the other factors by themselves sufficient. Now, to explain it -- or did there need to be something else. This other plus

factor.

THE COURT: Hold on. There are people with this profile who don't take Lipitor who get diabetes. Correct?

MS. BIERSTEIN: Yes, Your Honor.

THE COURT: And, in fact, if you took the total pool of people who present like her, some taking Lipitor and some not, that pool of 100 people is going to be a lot larger, is going to be people who never took Lipitor, right? I mean, the pool of people, if you take the data from these studies that y'all rely on, that would be true, wouldn't it?

MS. BIERSTEIN: I'm not sure, Your Honor, because some of the relative risks for women were over two. And if it's more than two, then more of them are Lipitor induced than not. So the studies we had that are showing relative risk --

THE CLERK: Now you're going back to the argument you're not ruling out, you add it in, right?

MS. BIERSTEIN: Right, but it becomes the extent to which you're adding it in. But I think, Your Honor, if you look at family history, for example, this is something that he considered and ruled out. Because, in fact --

THE COURT: He doesn't rule it out, he just says the risk isn't maybe exactly as high as it can be. The point is, at the end of the day, these risk factors are present, you haven't eliminated them, he doesn't presume to eliminate them, he argues they're present, and that they make her more

vulnerable to Lipitor. I understand his argument about that. So I think arguing -- something he doesn't argue is ridiculous. But here's what I'm struggling with, is at the end of the day, you're not left with just Lipitor, you've got these other risk factors, they're still there. You may argue the degree of them, but the relative risk, they're there, they exist, and the question is, is Lipitor -- can you tease out and say this is one of those situations where Lipitor contributed. And if you reach that conclusion, exactly what is the evidence that it did, other than that she took it.

MR. CHEFFO: Well, again, Your Honor, when you have relative risks two or greater, then even with nothing else, and I think you'll see this in some of the cases that acknowledge it, it's more likely than not that it was the Lipitor.

THE COURT: You haven't shown me any data that would support that. Everything I've seen has numbers, the relative risk, 1.25, 1.37, 1.09, nobody's over two. I haven't seen one study yet that shows that.

MS. BIERSTEIN: Your Honor, that was in mixed populations. If you look in our general causation brief, we cite specifically studies where we're in the 2.6 or 1.9, nudging to two, 2.6. There are some that where you'll see numbers --

THE COURT: Are those clinical studies?

MS. BIERSTEIN: Some of it is observational. Frankly, Your Honor, and this has nothing to do with Dr. Jewell's analysis, on Pfizer's data alone from the NDA, and more important, the updates, for elevated glucose it's way higher than two, way higher than three.

THE COURT: Let me tell you, one of the things that frustrates me, I'm going to forecast this, is you come in and you argue that Lipitor causes diabetes. And now we're talking that Lipitor causes elevated glucose. They may be associated and they may not be. That is, you may not -- they're not the same thing. And, in fact, the label changes, of course, elevated glucose and not diabetes. So you've got to -- it's not going to be enough simply to show it elevates glucose, some to very small degrees; you have to show it causes and it's associated in a statistically significant way to diabetes. That's a very important element here. And I feel like I keep having the goal line moved. And I want y'all to focus, both general and specific, on what the issue is. Just tell me if you don't -- I don't buy that he ruled out the risk factors, I just don't buy that. That's not what he says he did.

Tell me how he knows Lipitor affected -- every piece of evidence he knows that Lipitor affected Mrs. Daniels, that was a substantial contributing factor to Mrs. Daniels' diabetes. What does he know? How does he know that?

MS. BIERSTEIN: Your Honor, I think he knows it, first of all, because he doesn't think her weight, her BMI at the outset was high enough. He --

THE COURT: No, no, no, put aside the other risk factors. How does he know that Lipitor caused it?

MS. BIERSTEIN: Because the other risk factors alone can't explain it, and so Lipitor --

THE COURT: I think this is lawyer reasoning. He does not say that in his deposition. He embraces the other risk factors, he says they prove his point. So tell me, what is it about the Lipitor that tells you affirmatively that it was Lipitor?

MS. BIERSTEIN: Well, again there, Your Honor, I think the amount of Lipitor she took --

THE COURT: Amount.

MS. BIERSTEIN: -- the amount, which is dose times duration.

THE COURT: Okay.

MS. BIERSTEIN: And then I think how quickly she became prediabetic after taking that high dose of Lipitor. So the temporal factor is important, but I don't want to say it's the only thing, because he's looking at the fact that there's not enough family history, there's not enough weight at the outset to explain it. So what could fill in the missing piece? Oh, she's taking this big dose of Lipitor. And, you

know, it's the second highest dose, and after a year of that, boom, something happens that the family history alone wouldn't have explained and the weight gain.

THE COURT: Do you have any data on dose plus duration?

MS. BIERSTEIN: Your Honor, in the Chen study, and the Chen study actually is a cumulative dose study, and in that study there is the suggestion that it looks like this could be a cumulative --

THE COURT: Possible. Possible.

MS. BIERSTEIN: Well, the data showed that. That is, that's how the -- in that study. And then the question is, you know, what does it mean. But the data in the study --

THE COURT: What does the author say?

MR. CHEFFO: -- was done that way.

THE COURT: What does the Chen study, what does the author say it means? Does he say that duration, there's a statistically significant association with dose and duration?

MS. BIERSTEIN: I think they only analyzed it for cumulative doses, they did find significant association on the cumulative dose.

THE COURT: But any particular levels?

MS. BIERSTEIN: They did low, moderate and high, but they were low, moderate and high cumulative, that is, they did not to do ten, 20, 40, 80, because they looked at cumulative

dose, so there was some way they took dose times duration to see how much total exposure.

THE COURT: So you --

MR. CHEFFO: Which is often the case that you look at total exposure.

THE COURT: But what about it -- other than -- so you would inference that she took 40 milligrams, and she took it for a period of time and she got diabetes; what other evidence do we have tying it to Lipitor?

MS. BIERSTEIN: Your Honor, before I answer that, Mr. Marcum has handed to me in the Chen study what the authors write is higher accumulated doses result in a higher risk of nuance of diabetes. That's the sense.

THE COURT: Higher risk. Is there a statistically significant -- Isn't that the study that says at high doses, there's a statistically significant association?

MS. BIERSTEIN: High and moderate, which is significant. But the problem we have translating it to her dose is because they're cumulative, her 40-milligram dose over the course of a year, I don't know where that fits with the Chen study, Your Honor, I have to confess, I can't map her dose onto the Chen study. But they were finding statistically significant associations, as I recall, in the moderate and high cumulative, as opposed to the low cumulative. So I think that's --

THE COURT: And they're different statins and they don't precisely define; do they tell us what is high and what's medium?

MS. BIERSTEIN: Well, they do, but they're cumulative numbers. They do look at atorvastatin. We're looking at the atorvastatin numbers in particular, because they do break it out by statin, Your Honor, so we do have that.

But I think in terms of Dr. Handshoe, I think what's happening is he's looking at the amount of Lipitor she's taking, he's looking at the extent of her weight, he's looking at the extent of her family history, and he's saying -- and he's looking at the time, the time scale, and he's saying the other factors alone are not sufficient, so I think the Lipitor is a substantial factor. And I think he's using his judgment as a clinician and a diagnostician to do that differential etiology.

MR. MARCUM: I would add in, Your Honor, that Dr. Handshoe also specifically cites the Chen study, I believe, which -- in table three of the Chen study, which was Exhibit U to our brief, you'll see the actual hazard ratios for the cumulative doses for atorvastatin.

The other thing that --

THE COURT: Hold on one second.

(Brief interruption in proceedings.)

THE COURT: Miss Boroughs is reminding me when I was

confirming my memory of this, he said there are people who have the risk factors Miss Daniel has, who get diabetes. He said he wouldn't be surprised, even without taking Lipitor, that she got diabetes. And so he isn't saying that he's able to say she was one of those who wouldn't have gotten it, he said just the opposite. And so you're really reading into the deposition something which I think is contrary to what he actually said. That's why we have these depositions, so they actually get locked in, they get questioned and they get locked in. And he just says, you know, if you have a woman, she has these premorbid conditions he's talking about, and they take Lipitor, bingo, that's a statin-induced diabetes. That's his testimony. The more risk factors, the more likely statin induced. He said, page 170, "I do not really rule out the risk factors." Says that page 179 of his deposition.

MS. BIERSTEIN: Your Honor, I'm not sure he always articulated as well. I think the report --

THE COURT: I think you're articulating better, Miss Bierstein, I think that's the problem here is if we just left it to the lawyers, y'all wouldn't have a problem. It's these troubling experts that get in the way, you know? And you pay for them and they still don't listen to you.

But I'm just taking what he actually said. And, you know, he's -- 182, 183, recognize that Lipitor doesn't cause diabetes in some patients, and would get -- some of the

patients would get diabetes anyway if they weren't on Lipitor, but he couldn't tell you which ones, he just couldn't do it. He can't do it.

He says no matter what the risk factors, if she took Lipitor and got diabetes, then that's enough. Two hundred to 201 of his deposition.

MS. BIERSTEIN: I think -- I'm sorry.

THE COURT: No, I'm just saying that doesn't -- Miss Bierstein, that's not what you're telling me. No way to tell the difference between the two.

MS. BIERSTEIN: Your Honor, Mr. Marcum is going to explain, I think, a little bit maybe --

THE COURT: I always listen to Mr. Marcum.

MS. BIERSTEIN: -- what Dr. Handshoe was getting at when he was talking about the other risk factors, but it gets way down into the weeds on the science.

MR. MARCUM: In terms of evidence, Your Honor, I think Dr. Handshoe also relied on the SPARCL paper, the David Waters paper, which analyzed SPARCL, TNT and IDEAL. And this is a figure from that paper. Specific to the SPARCL study, and again, recognizing SPARCL is the 80 milligram dose, not 40. But what this shows you is along the bottom, the number of risk factors of patients in the SPARCL study. And when you get to that last column, you're looking at patients who had the four risk factors identified over here, which are a higher

BMI, high triglycerides, high fasting blood sugar baseline and hypertension. And what that shows you is that in this analysis by Pfizer and David Waters, that the hazard ratio over and above, you know, those risk factors, with the addition of 80 milligrams of Lipitor, was a hazard ratio of 2.439. A significantly increased risk.

And again, the milligram dose I recognize not the 40, it's also smaller numbers of patients who had that many risk factors, but I think it's significant evidence of an a effect over and above any sort of other risk factors for diabetes.

MS. BIERSTEIN: And it's more than doubling of the risk, Your Honor, which means that more than half of the people who would have it, it would have been caused by the Lipitor, so it would be more likely than not in that category that because of that -- it's almost two and half times the risk. So -- and that's something else that Dr. Handshoe was looking at.

THE COURT: Hold just one second.

(Brief interruption in proceedings.)

THE COURT: What's the FBS more than 100?

MR. MARCUM: That's fasting blood sugar at baseline greater than 100. And by the way, in full disclosure, I added those notes over there on that left-hand side.

THE COURT: That's okay.

MR. MARCUM: When you look in the study itself you're

going to see the data, but you're not going to see those things written down over there. But from the study, those were the four predictors, a BMI greater than 30 -- it was actually an incremental increase over 30 at baseline. Triglycerides over 150 at baseline, fasting blood glucose, and again, it's a per increase over 100, which is, of course, the upper limit of normal. At baseline. And then hypertension.

And what they found is that those four risk factors were predictors of diabetes in the study, but what this figure is showing you, it's acknowledged by the authors in the paper that at the highest number of risk factors they found, which was statistically significant at four, there was still an increased risk over and above that with Lipitor. And it's a significant increased risk.

THE COURT: But it's an 80 milligram dosage, and, you know, we know that that's a -- has been, at least in our randomized studies, the only dose level that has actually been demonstrated to have a statistically significant association. Now, again, it seems to me we're going back to trying to extrapolate from an 80 milligram dose, something at 40 milligrams.

MR. MARCUM: A couple things that I add to that, is that this study also, as I said, examined the TNT trial. TNT, of course, was ten milligrams of Lipitor versus 80 milligrams of Lipitor. And what they found with the TNT analysis is that

the hazard ratio between 80 milligrams of Lipitor and ten milligrams was -- I believe it was 1.10, and it was not quite statistically significant.

THE COURT: I remember that.

MR. MARCUM: Indicating that the risk there for new onset diabetes at ten and 80 was actually similar in that study, which was also a five-year study.

THE COURT: They find no statistical significance?

MR. MARCUM: He found it was not quite statistically significant.

THE COURT: But now you're going to back in and say we're going to take that and find then that it was statistically significant at ten; is that what you're arguing now?

MR. MARCUM: I'm not telling you that at all actually.

THE COURT: That was actually argued the other day, that was why I asked.

MR. MARCUM: And I'll show you, again, I think we showed you last time, this was the e-mail from David Waters, the lead author of that paper.

THE COURT: Listen, folks, we're not doing e-mails, I mean, y'all could have deposed him, I mean --

MR. MARCUM: We -- Your Honor, we did. We deposed David DeMicco, who is the recipient of this e-mail.

THE COURT: This is not the way we get expert testimony in these things. It's just a -- y'all have to do better than this.

MR. MARCUM: This was about getting evidence, Your Honor, not expert testimony. And what David Waters said is the risks of ten and 80 here, with respect to the development of diabetes, are similar.

And if you'll do the next slide, the response from David DeMicco is, "As far as the conclusions, I concur with your assessment below. I do think it's important on how we contextualize this."

MS. BIERSTEIN: But now we need to go to the next slide, because Your Honor's concerned about emails. This is the deposition. So this is the Pfizer VP in charge of this, and he says there's no statistically significant difference between Lipitor at 80 milligrams and ten milligrams. That is the Pfizer VP, not in an e-mail, this is his sworn --

THE COURT: He's saying there's no statistical significance in either, is what he's arguing.

MS. BIERSTEIN: No. There's no difference. It's the word difference, Your Honor, in the TNT study.

THE COURT: And but he's also saying neither one shows statistical significance, that's his point.

MR. MARCUM: But we know that's not true, because there was --

THE COURT: So now we're going to say -- okay, I -- we went through the other day. It's kind of a backward way of getting to this point.

MS. BIERSTEIN: Your Honor, I just, in closing, because I think we've taken Dr. Handshoe, I mean, as I said, I think he does the differential etiology, Your Honor's reading it differently, I think he does an adequate differential etiology. I wish he had explained it better at his deposition. I think his report shows him going through the process.

And unless the Court has further questions, I'm going to sit down.

THE COURT: Thank you, Miss Bierstein.

MR. MARCUM: Your Honor, I appreciate you listening to me as always, even if it didn't work.

THE COURT: Mr. Cheffo, anything in reply?

MR. CHEFFO: Your Honor, I don't think I do, unless you have specific questions.

THE COURT: I don't. And I'm going to go back and reread the Handshoe deposition, in light of Miss Bierstein's argument. I've heard it, that's one reason we have oral argument is we hear that perspective. Let me go reread the deposition in light of what she is saying, because frankly, I read it very differently. And I didn't think it was an articulation problem, I thought he was actually fairly

articulate, it was just I frankly thought most of it was a lot of nonsense. And there were some of plaintiffs' experts I was pretty impressed with on general causation, and I just didn't have that impression about Dr. Handshoe. He was just a really different level of quality of expert, and that's not the only measure, but it was pretty noticeable that he was out of his depth. I mean, this discussion about relative risk was sort of embarrassing. I mean, in the midst of the deposition the questioner said exactly, "Did you just say what I think you said?" I mean, it was like amazing. And he just didn't seem -- y'all were asking him to do something he really wasn't qualified to do. That was certainly my impression in reading that deposition. And he didn't measure up to the type of thoughtful, I thought, some like Dr. Singh, pretty thoughtful testimony.

So that's not the only measure of things, I want to go back, I'm going to reread, sit down and reread the deposition in light of what Miss Bierstein has said, read it one more time, take -- go right back through it as if I've never read it, and see if I can see that argument, because I didn't pick it up the first time. And we will rule.

Let me tell you sort of the course of things as we're trying to forecast here. Managing this is a little bit of a bear. We're going to schedule the Hempstead specific causation, I think in early December. I would have done it

earlier, I've just got back-to-back trials, I just can't figure a time to do. I would have preferred to do it two weeks from now or something, I just don't have time on my calendar to do it.

Meanwhile, you folks are going to be doing the -- addressing these questions on dosage. We'll get to that. Hopefully in early February I will have that information, I'll be prepared to rule. If you feel strongly about oral argument, I'll consider it. I feel like I've given y'all a lot here, and I'm not sure how much more is going to be that helpful. But if you feel strongly, y'all let me know about that. Okay?

And I want to hear what you have to say at every level, but you know, folks, let me just say that if it looks like that you can't credibly argue that ten milligrams causes diabetes, don't break your back doing it. It undermines your experts to get them to do something that's ridiculous. If there's a good basis for it, go ahead and do it, but I'm saying to you, I think you enhance your credibility by not asking your experts to do something that brings their judgment into question and their abilities and integrity into question. But y'all do as you wish.

And I say that to the defendant, that to the extent there's not a plausible argument at 80 milligrams for Daubert, don't argue it just because you feel like you have to argue

it. And if there's a real horse race at 20 and 40, let's focus on where the horse race is.

Let me ask the plaintiffs, because I asked Mr. Cheffo this. Approximately, among those dose levels, do we have a rough idea, Mr. Hahn, about what percentage took ten, 20, 40 and 80?

MR. HAHN: Very rough idea, Your Honor. Eighty percent is less than ten percent of --

THE COURT: I would have thought it would be very low. And I would think most of those people, I'm guessing this, would have multiple risk factors, because why would you be on 80 milligrams if you weren't --

MR. HAHN: Eighty milligrams is pretty much a horse dose. Ms. Daniels was only on 40.

THE COURT: Which is a high dose itself.

MR. HAHN: Yes, sir. The ten, 20 and 40 appears to be somewhat evenly split --

THE COURT: Okay.

MR. HAHN: -- 30, 30, 30. Might be more like 35, 35 and 20 at the 40 milligram dose. We just don't know. But that's -- for the whole MDL.

THE COURT: To the extent that your dose-related theory has some validity, you might expect about half the -- I understand about half the doses are ten milligrams, sort of out there in the real world; that may not reflect half your

plaintiffs because, you know, there might not have been much of a dose response. I'm just saying that may well be.

MR. HAHN: That very well could be.

THE COURT: That could potentially explain that. But I'm hoping with this, we're going to get this thing narrowed down to the issues that are really important to deal with. And I'm going to tell you, Mr. Hahn, I was so unimpressed with Dr. Handshoe, that I put Miss Hempstead aside because I didn't think it was fair to her. And I wanted to clear the decks and deal with that with a fresh mind and not have it bleed in. Because I really thought his deposition was sort of embarrassing. It was just sort of embarrassing. And it really hurt Miss Daniels' claim. I mean, maybe there's not a better argument to be made, but my own guess is somebody else could have made it better. I don't know.

But I want to give Miss Hempstead every chance, looking at that, I think your other expert is a -- has a better claim to give an opinion. Whether that's going to be one that he has a method or something, I want to consider with a fresh mind and independent of Miss Daniels.

MR. HAHN: Thank you, Your Honor.

THE COURT: Okay? Anything further?

MR. CHEFFO: No.

MR. TANENBAUM: Just for the record, so that we know before final action is taken on Miss Daniels, would Your Honor

consider allowing us to see whether there's another case-specific expert?

THE COURT: No. We're not -- at some point we have to close the door on this. I think on the case specific we've done it. It's been done.

And I was getting ready to say this. I think we're going to probably, in the near term, issue orders regarding Dr. Jewell and about efficacy, and Abramson and Fleming, we may go -- those are discrete and to themselves, we'll issue those orders. I'm going to wait till general causation until I get the dosage briefing done, opinions in, and the Daubert, before I reach that question.

Anything further from -- first from the plaintiff?

MR. HAHN: Nothing, Your Honor.

THE COURT: From the defense?

MR. CHEFFO: No, Your Honor, thank you.

(Court adjourned at 12:20 p.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

Debra L. Potocki, RMR, RDR, CRR