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

IN RE: LIPITOR 2:14-MN-2502

TRANSCRIPT OF HEARING
THURSDAY, MARCH 18, 2016
BEFORE THE HONORABLE RICHARD M. GERGEL,
UNITED STATES DISTRICT JUDGE

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

THE COURT: This is the matter of In Re: Lipitor, 2:14-2502. Could counsel who is going to be arguing today identify themselves for the record?

MR. MARCUM: Christiaan Marcum for the plaintiffs, Your Honor.

MR. CHEFFO: Good morning, Your Honor, Mark Cheffo.

THE COURT: Thank you.

Let me sort of revisit where we have been and sort of what the purpose I view of this oral argument. As I've said to my good friends on both sides of this case before, I don't schedule oral argument to entertain the lawyers or for them to entertain me, okay? I take -- I respect very much the work y'all do, and as a demonstration of that respect, I read all your briefs, I read your cases, I read the underlying reports and I've read the depositions. It's not like I'm not aware of the facts. I'll say that I have questions I need help on and that's why you are here. And frankly, if I didn't need the help, I would issue an order without oral argument. I just, you know, I do it, it's as a utility for the Court. And I know that's a little different from what a lot of folks -- a lot of folks see oral argument, they come in and they get to restate their argument, but that won't be of any help to me. I have spent a great deal of time studying this. And to the extent I misapprehend something, you will detect it by my questions, you can

straighten me out, but I generally kind of get it.

And the -- you know, of course where we came from here is we were doing general causation. I had seen data that raised the issue in my mind whether there was a potential dose issue here. Obviously, there are cases out there that addressed that issue previously. And I reopened discovery because I thought we needed to drill down on the specific dose issues. And we are now here addressing that with that additional information.

I think the best way is -- I want some, first of all, some clarification about the specific opinions of specific experts to make sure I understand where we are and what the significance of what they say might be.

So I would like to start with plaintiff because that's sort of where my questions are in terms of understanding it. And then I want -- once I clarify in my own mind, I want to give the defendant a chance to argue, to challenge that.

So Mr. Marcum, if you would come to the podium, that would be great. Thank you, sir. You are a bold guy, you have no notebook or anything. I've always admired your memory, so you are about to test it here, right?

MR. MARCUM: Well, this brain can only hold so much.

THE COURT: Tell me about it.

MR. MARCUM: I'll do my best to endeavor to answer your questions as I always try to.

THE COURT: Let me -- and I'm going to -- I'm going to try to avoid jumping around to different experts because I myself have trouble if I blend too much, I get confused about who said what. And I'm capable of making that mistake today and hopefully we'll avoid that.

So let me -- I'm going to first have a series of questions about Mr. Singh, okay? Let's start with Dr. Singh. And I think that a decent starting point of where I'm a little bit confused is I think we need to -- we all need to be on the same page about the Cederberg study. I want to make sure we are all on the same page about what that study did and did not do, and did and did not say.

MR. MARCUM: Sure.

THE COURT: We all recognize it is an observational study, correct?

MR. MARCUM: Correct.

THE COURT: And it compared certain doses of certain statins, including Lipitor, to a group who did not take statins called a non-statin group, correct?

MR. MARCUM: Correct. Control group, non-statin group.

THE COURT: And the comparator is non-statin, correct?

MR. MARCUM: Correct.

THE COURT: They did not compare the higher dose with the low dose. That's not part of that particular study.

MR. MARCUM: Correct. I think perhaps that's the Carter observation --

THE COURT: That chart.

MR. MARCUM: -- but not Cederberg. Correct, Your Honor.

THE COURT: And what it found regarding Lipitor, they -- the group, the study lumped 20- and 40-milligram subjects together, correct?

MR. MARCUM: That is correct.

THE COURT: And found there was, the relationship between Lipitor and new onset type 2 diabetes was statistically significant.

MR. MARCUM: That's correct, Your Honor.

THE COURT: 20/40 group is statistically significant. And similarly, it found that at 10 milligrams, there was no statistical significance.

MR. MARCUM: With respect to the new onset diabetes, that's correct, Your Honor. There was, however, statistically significant findings with respect to, I believe it was decreased insulin sensitivity.

THE COURT: One of these metabolic issues.

MR. MARCUM: Metabolic. That's right.

THE COURT: But as to the ultimate issue, we don't have statistical significance.

MR. MARCUM: That's correct.

And I do want to back up for one second with the question about the comparison of the, I guess the 20- to 40-milligram doses to the lower doses. There is actually a table in the Cederberg, or a graph in the Cederberg paper that actually does sort of -- I do have a notebook back there, so --

THE COURT: Go grab it if you want to. I think I know exactly the chart. I want to make sure we are on the same page about it.

MR. MARCUM: Yeah. There is a chart that's got like four different tables in it, or graphs in it.

THE COURT: Correct. And it's the lower, right-hand graph.

MR. MARCUM: That's correct. It's D. It's the lower right-hand. And it does actually have some computer --

THE COURT: As a visual but not a statistical.

MR. MARCUM: Absolutely, Your Honor.

THE COURT: And that actually if you study that graph, which like you, Mr. Marcum, I find interesting, just, you know, it helps you visualize something you kind of read about, but it's interesting to see it at least visually

depicted --

MR. MARCUM: Sure.

THE COURT: -- is that the -- the 10-milligram Lipitor group is closer to the non-statin control group, and the 20/40 group is rather, at least visually on this chart, to be demonstrably different.

MR. MARCUM: That's correct. Although I would point that out there is a difference between that 10-milligram group and the non-statin.

THE COURT: No question.

MR. MARCUM: Particularly with increasing durational use.

THE COURT: Correct. It's there. There is no question. It's not -- it was determined not to be statistically significant, correct?

MR. MARCUM: With respect to new onset diabetes, absolutely right.

THE COURT: Okay. And then there was the study -- and just to be fair with everybody, that Cederberg came out after these initial lawsuits were filed.

MR. MARCUM: That is correct.

THE COURT: 2015.

MR. MARCUM: Came out in 2015. It actually, if I remember the timeline, I think it came out three days before our initial expert reports were due.

THE COURT: Right.

MR. MARCUM: But, yes, it came out well after the litigation.

THE COURT: Yeah, you know, one of the challenges here is when you have a sort of dynamic scientific process going on in the middle of the litigation, it's always something challenging for everybody, the experts, for the parties, everyone.

Then there is the study Navarese, the Navarese analysis.

MR. MARCUM: Correct.

THE COURT: Meta -- and it also -- I think we figured out it actually came out after the initial lawsuits came.

MR. MARCUM: I think that's right, too.

THE COURT: Very -- very close in time, but I think --

MR. MARCUM: That's right. And I don't recall Navarese being the subject of extensive discussion in the initial expert reports, but it certainly was in the supplemental reports, as well as the briefing.

THE COURT: And the effect of new data, and sometimes the older data, everybody has got their mind wrapped around the old data. And even though it might be out there, you don't tend to focus on it because your brain is

wired on the old.

MR. MARCUM: Although Navarese is a meta-analysis of the older data.

THE COURT: Right. And among the various comparator groups that Navarese focused on was comparing 10 milligrams of Lipitor to a placebo group, correct?

MR. MARCUM: That is correct. It looked back at the original ASCOT data. I'm not sure if there was actually another.

THE COURT: I'm not sure, either, I just know that part of --

MR. MARCUM: But that -- you are right. You are right

THE COURT: And it also found that the relationship between Lipitor 10 milligrams and new onset type 2 diabetes was not statistically significant.

MR. MARCUM: I would ask Your Honor to take a very close look at Navarese when you get the opportunity.

THE COURT: I have taken a very close look. That's why we are here.

MR. MARCUM: Because you are right, that that is -- the statics themselves did not reach statistical significance. But in the discussion section, the authors actually -- I think that their conclusions actually go a little further than what the statistics themselves might

suggest.

THE COURT: Well, I will go back and read that. I appreciate you mentioning that, and I will go back.

But as to the, again, the statistical presentation, no statistical significance at 10 milligrams, right?

MR. MARCUM: That's correct. I think there is a forest plot or something within the article. And if you look at the -- I don't remember if it was confidence intervals, but you are correct, on the pure raw statistics, it did not reach statistical significance.

THE COURT: Now that you and I are, I'm not surprised, are on the same page about Cederberg and Navarese -- I was struck that Dr. Singh did not mention Cederberg 10 milligrams when addressing whether there was statistically or any kind of -- when he was offering his opinion that 10 milligrams of Lipitor caused diabetes, he did not mention Cederberg. And I've got to tell you, I was expecting a lot of -- I was very anxious to see the discussion of Dr. Singh, in particular, regarding both the 10 and 20/40 milligrams.

MR. MARCUM: And I think he did address the 20 and 40.

THE COURT: He did it -- I believe we will look at it -- he -- he made a mistake about 20/40. And we'll talk about that in a minute. And because of that, I don't really

have an opinion -- and I'll talk to you about that in a minute -- that seems to straight up, in a factually correct way, give an opinion.

MR. MARCUM: I don't recall the mistake, but I know you will show it to me.

THE COURT: I'll show it to you. And I'm not -- I'm struggling with the meaning of it. We'll get to that in a minute. I'm getting ahead of myself.

The ASCOT finding, of course, is a clinical trial. And I know that Dr. Singh had his reasons for questioning whether the weight that should be given to that clinical trial. But then we have both Cederberg, an observational study, and Navarese, a meta-analysis, making the same finding: Nonstatistical significance on 10 milligrams, correct?

MR. MARCUM: Correct.

THE COURT: Can you see, Mr. Marcum, my concern with Dr. Singh failing to mention that? Because it seems to me that if you have additional studies, not the gold standard, not clinical trials, that tends to make more compelling the clinical trial results. It suggests it's not an outlier, that it's not as good. We would love to have -- in a perfect world we would have 20 clinical trials, but that's not the situation here.

So I am troubled by the fact that Cederberg and

Navarese is not addressed by Dr. Singh, does not attempt to reconcile it, does not discuss the inconsistency with his own opinion, and why I should not give weight to that. And as you know -- you know, what the answer is, I don't care. I don't have a dog in this fight. You guys fight that out.

MR. MARCUM: Should I answer, or attempt to answer?

THE COURT: What I do care is methodology, that there is not a gap between -- that there is data to support the opinion.

And, you know, one of the hallmarks of experts getting in trouble -- you've read these cases like I have -- is when you cherry-pick and you omit and don't discuss inconsistent data.

So I am troubled why Cederberg isn't there, why Navarese isn't there and why that doesn't affect what I believe is the Court's confidence in the methodology, and frankly, the data relied upon by Dr. Singh in reaching his 10-milligram decision.

MR. MARCUM: I can't answer for Dr. Singh. But what I would say in Dr. Singh's defense are these things:

Number one, with respect to the Navarese meta-analysis, I do believe -- and it's back there in my box somewhere -- but I do believe that the 10-milligram data that it looked at was the ASCOT study. I don't believe --

THE COURT: You can say that. I don't know what it

looked at. Cederberg, frankly -- I've got to tell you, Cederberg was like, you know, when I was -- when I was sort of -- I was dealing with -- I had SPARCL and ASCOT, okay? Those were the sort of bookends. I had statistical significance at 80, I didn't have it at 10.

And then Cederberg came. I remember the first time I read Cederberg. It actually was dealing with the very question I was concerned about: Do we have a dose issue here? And I didn't know -- you know, I hadn't read it close enough. I really wanted -- I'm not an epidemiologist, you are not an epidemiologist. I was looking to these experts to tell me. And I even said to y'all, Listen, I'm not going to tell you what to do, but I kind of think 10 and 80 look like we know the answer if you use reliable methodology, I'm really interested in 20 and 40.

And what I had was Dr. Singh doubling down on the 10 milligrams, which I said, you know, I'm open -- if there is a good reason, I'm open to hearing it. I'm interested in methodology. And he doesn't address Cederberg.

MR. MARCUM: And I think that's because he doubled down on it with respect to the randomized clinical trials. He addressed ASCOT. He addressed the NDA data, the '99, 2001 --

THE COURT: But, you know, even the -- a lot of this data comes up, it's not statistically significant at 10

milligrams. I mean, this is what really struck me about the Koh work, you know, that -- in which Dr. Quon is a coauthor. They actually -- you know, they are not markers for diabetes, you know, the hemoglobin studies, the insulin sensitivity, they are interesting, but they are not actually -- that doesn't mean diabetes. You can have -- you can not have diabetes when you have, you know, decreased insulin sensitivity and elevated HbA1c.

MR. MARCUM: That's very possible, Your Honor.

If I could, I would remind you that what the warning label language for Lipitor actually says, it doesn't use the word diabetes, it says increase in HbA1c --

THE COURT: I completely agree.

MR. MARCUM: So we are not talking about an analytical gap.

THE COURT: But this is not a lawsuit about simply Lipitor causing a decrease in insulin sensitivity.

MR. MARCUM: No question.

THE COURT: So I think it's fair comment to talk about these metabolic markers. I think that is fair. It's not the same. Nobody acts like they are the same.

But it's -- but when the markers follow the pattern, that is, they are not statistically significant at 10 milligrams and are at 20 and 40, or at least some degree at 20, at 40, other than that one oddity in the thing about 40

in one of the Koh studies, and it just seems to me that we are -- again, you go to methodology here. You have a lot of things that tend to -- that would look to me just logically to corroborate the view there is not statistical significance, that ASCOT got it right, and they are just not addressed.

Are there not -- there is an argument given to me that I should look at trends. I should abandon statistical significance and look at trends. And the argument basically is we are really going back to dosage. That is, if you've got 80 then you've really got the rest, or it's there. It's not -- I mean, we don't have a debate. It's not statistically significant. All the data, both the marker evidence and all these -- the safety data, everything we look at, it's not statistically significant at 10 milligrams, right?

MR. MARCUM: I think the argument that's been presented to you --

THE COURT: Well, first of all, am I right about that?

MR. MARCUM: For new onset diabetes, I think you are exactly right.

THE COURT: That's all -- that's --

MR. MARCUM: Based on the published ASCOT study, which is the only one at this point.

THE COURT: Cederberg?

MR. MARCUM: Well, Cederberg, correct. Correct. That observational study.

THE COURT: Don't forget it.

MR. MARCUM: Right. You are right.

THE COURT: Navarese.

And then when we look at the metabolic marker evidence, they also follow that same pattern.

MR. MARCUM: I don't think that's correct, Your Honor. Some of that metabolic evidence does reach statistical significance.

THE COURT: At 10 milligrams.

MR. MARCUM: At 10 milligrams, correct.

THE COURT: For causing diabetes or for causing -- I'm sorry -- 10 milligrams causing -- let's look at --

MR. MARCUM: Whether it's decreased insulin --

THE COURT: Let me not get these confused. Let's go -- rather than talk in the abstract here, let's look at the Koh -- let me find my Koh studies.

MR. MARCUM: While you are finding yours, I'll try to find mine.

THE COURT: And I'm looking at -- and you've got to differentiate them because there are a lot of them --

MR. MARCUM: There are, correct.

THE COURT: I'm looking at 2010.

MR. MARCUM: That's the one that is specific to atorvastatin.

THE COURT: Right. And I spent -- you know, it appears, understandably, in other studies --

MR. MARCUM: It does.

THE COURT: -- because it's important. And I'm looking, for the record, we are at Docket Entry 1159-17 at page 6, it is page 1213 of the article, and it has a series of charts.

MR. MARCUM: Correct.

THE COURT: And --

MR. MARCUM: With the changes --

THE COURT: One of them is the percent change in HbA1c, and it is clearly not statistically significant at 10, but is at 20, 40 and 80. Am I right?

MR. MARCUM: When you look at each one individually, you are correct.

But this is where we get into the discussion by Dr. Quon of this statistic at the top, the ANOVA, the Analysis of Variance, which looks at each of the groups across the dose range together, and that finding was statistically significant as a dose intended --

THE COURT: The problem with that is the weight of the higher milligrams may be creating a positive for the lower. That's why you break it out, and that's what you are

looking for. You are saying is when we lump them all together, are we simply looking at the effects of high dose or is this across the board? And when you do that study, which is what this data shows, there is a difference. It's not uniform across the board. And in fact, at 10 milligrams there is no statistical significance in each of these charts.

And it -- it strikes me that nobody has sort of -- none of your experts said, okay, every study shows the same pattern. It shows the same pattern at 10 milligrams. It does not reach statistical significance.

MR. MARCUM: What they would say, Your Honor, is that every study shows a trend. And I realize you are reticent to accept that, but --

THE COURT: And Dr. Singh was actually asked about that. And he says, you know, he kind of backs off in his deposition, he says, Listen, I'm not really saying its cause. That's one explanation -- you know, I have a hypothesis, one of them is if we had more power, but I'm also saying, it might just be that there is no statistically significant association no matter what we did. I mean, he says that.

And that really gets to this problem about when your study doesn't show statistical significance, you might, as a scientist, have an hypothesis that maybe if I had more people, maybe I would get a different result. But that's simply a hypothesis. It's a speculation. You don't have a

study.

And what I felt like was double down on 10. I had a lot of hypotheses being sold to me, or attempted to be sold to me, as a scientific opinion. And I would have to say that I accepted -- you know, it's not like the *Neurontin* case where you have a very limited number of suicides, you have a very limited pool of people. It's very hard to figure out statistical significance. These studies have had a lot of subjects studied. This is not an unstudied area or an inadequate pool of people who may have gotten -- we know a lot of people who have been on Lipitor also have gotten diabetes. It's not like -- and there is a debate about why, why that is so.

MR. MARCUM: In fairness, though, even the defendants would admit that none of those studies, with the claimed exception of ASCOT, was prospectively designed to look at that particular issue.

THE COURT: But it doesn't mean that if you -- that if you did a prospective study, you wouldn't get identical results. You don't know. That's the problem.

MR. MARCUM: It's also not proof of no effect, though.

THE COURT: Well, that's not -- the question here, you've got to -- you've got to provide me experts that -- I mean, I'm just a gatekeeper here. But my role is that

you've got to have reliable data. And if the data is, is nothing but speculation; that is, I think if we had a prospective study, I think if we had a longer duration, I think if we had more subjects we would get a different result. That's not science. That's -- I mean, that may be a fair basis to get funded a study based on this, but that's not evidence. And that's -- that's the very analytical gap the Supreme Court talked about in *Joiner*. There is an analytical gap there between the opinion and the data.

And, you know, so what lights up right at the beginning is we don't even mention two additional studies that are really consistent with ASCOT. I mean, I understand you want to go in and argue against the clinical trial, fine. That's fine. But --

MR. MARCUM: Well again, Navarese was ASCOT, okay? It's repeating it.

THE COURT: But certainly Cederberg is an interesting --

MR. MARCUM: That's a different --

THE COURT: And it's not addressed.

And -- but let me move to the -- my confusion about Dr. Singh and his 20-milligram -- his 20-milligram opinion. I want you to go to his deposition, somebody can hand it to you, at page 475. It's actually 474.

MR. MARCUM: Bear with me one second, Your Honor.

I'm there.

THE COURT: Okay. He is asked by defense counsel on line 16: "What studies, if any, produce a statistically significant finding that Lipitor at 20 milligrams or 40 milligrams increases the risk of type 2 diabetes?"

Do you see the answer?

MR. MARCUM: I do.

THE COURT: He says none.

MR. MARCUM: And I think he says that in his report, as well, but what he's referring to are randomized control studies.

THE COURT: Well, I don't -- I don't think he does that, frankly. I think because he -- well, let's assume for a minute he is in his opinion. Because now we go to the next question, which is asked at 475 and line 12: "And if 10" -- in talking about 10 milligrams -- "doesn't cause diabetes, how, if at all, are you able to reach conclusions about 20 milligrams and 40 milligrams?"

Do you see that question?

MR. MARCUM: I do see that.

THE COURT: He says "I can't."

MR. MARCUM: And again, I refer you to his report, because what he's clearly talking about is the lack of randomized controlled trials. We know, Judge, there are observational studies that find statistically significant

results at 20 and 40.

THE COURT: Well, he says he can't offer an opinion -- this is not a randomized study. He's saying: "I can't offer an opinion about 20 or 40 milligrams independent of the fact if I don't have 10 milligrams."

MR. MARCUM: Correct. And in the conclusion of his report, he sort of says the same thing.

THE COURT: Well, I just want to make sure we are on the same page here. He's factoring in -- you are telling me he he knows about Cederberg, correct?

MR. MARCUM: It's discussed in his report.

THE COURT: Well, I'll show you. He describes it incorrectly, but at another point he does describe it correctly. But I just want to make sure we are on the same page here. Even with the correct under -- you believe he correctly understands that Cederberg and observational studies find statistically significant association at 20 and 40 milligrams, correct?

MR. MARCUM: Correct.

THE COURT: Okay. And not withstanding his knowledge of Cederberg, he still concludes he cannot offer a causation opinion at 20 or 40 milligrams unless he has a causation finding at 10 milligrams, correct?

MR. MARCUM: Again, he is referring specifically, it's clear from his report, to the lack of randomized control

trials at 20 and 40.

THE COURT: But his ultimate opinion is, he says: "If 10 doesn't cause diabetes, how, if at all, are you able to reach conclusions" -- just conclusions, your opinion. He is saying: "Unless I have 10 milligrams, I can't offer an opinion about 20 or 40 milligrams."

Correct?

MR. MARCUM: What he said --

THE COURT: Correct or --

MR. MARCUM: I don't know if I can say correct, Your Honor. I think the conclusion of his report is clear.

THE COURT: It's not. That's why I've got you here asking this question.

MR. MARCUM: Wait. At the conclusion of his report, which is at the last page, is that his conclusion that there is evidence, sufficient evidence for him to opine at 10, and clearly sufficient evidence for him to opine at 80. And while there is a lack of evidence at 20 and 40, I believe his language is, it's hard to believe scientifically that there is not an effect at 20 and 40 if there is at 10.

THE COURT: Okay. And then the other side of this is which, what defense counsel was asking him: If you don't have 10, then you don't have 20 and 40, correct?

MR. MARCUM: Based on the state of the evidence as Dr. Singh, I believe, views it, if he wasn't comfortable at

10, he would be uncomfortable at 20 and 40.

THE COURT: Different question. If the Court finds there is not sufficient data to support his opinion at 10, and I don't find his opinion acceptable at 10, so he's got 20 and 40 have got to stand alone, his opinion is there is not sufficient stand-alone evidence at 20 and 40 for him to offer an opinion.

MR. MARCUM: With due respect, he would disagree with your finding at 10. But if your finding at 10 convinced him, Okay, I, Dr. Singh, am wrong about 10, then I think he's said it. He's said, I don't think --

THE COURT: I can't offer --

MR. MARCUM: I couldn't get to 20/40 without 10, is what Dr. Singh has said.

THE COURT: So I have not misunderstood his opinion?

MR. MARCUM: I don't believe so.

THE COURT: Okay.

MR. MARCUM: But again, that's -- it's clear to me and it's clear from his report that what he's talking about is the lack of randomized controlled trials.

THE COURT: You are giving me the explanation. But they are talking here about his opinion. I'm concerned, does he have an opinion at 20 and 40 independent of the finding at 10? And you are telling me it's -- it is dependent, not independent.

MR. MARCUM: I can't tell you other than what his report says. And to me, I agree with you, I think it's clear from his report, his opinions at 20 and 40 flow from his opinion at 10.

THE COURT: Thank you.

MR. MARCUM: I'm going to step back for a drink of water. I'm not running from you.

THE COURT: Go ahead. We are not having an endurance contest here.

Let me talk to you for a minute, if I might, about -- about methodology -- normal methodology. First of all, for epidemiologists, the standard -- the standard methodology is that there is -- there is basically a two-step process.

Step one is whether there is the relationship between a particular, in this case, drug and a disease, in this case diabetes, whether there is -- that relationship is statistically significant. That's the first step normally in the methodology, correct?

MR. MARCUM: I believe finding a valid association.

THE COURT: Right. And valid association means statistically significant, correct?

MR. MARCUM: Um, I think we could argue about that; but yes. Typically, yes.

THE COURT: I'm talking about in the field of

epidemiology, that's what they -- that's what they operate --

MR. MARCUM: You want to find a valid, statistically significant association. That's correct.

THE COURT: Right.

And then though you have now found that it's not the result of random chance, that doesn't end the analysis because you now go to step two, which is the Bradford Hill analysis. And then you have these multiple factors that are applied to determine whether there is genuine causation. And that is sort of an epidemiological judgment call, correct?

MR. MARCUM: That's correct. Those are guideposts. Obviously they don't all --

THE COURT: They are not controlling.

MR. MARCUM: That's right.

THE COURT: But you normally have to -- you normally have to satisfy step one to get to step two, correct?

MR. MARCUM: Um, in the purely, I believe, yes. I mean, ideally you satisfy step one, you move to step two.

THE COURT: Right.

And if we applied that standard epidemiological methodology here at 10 milligrams, we would not get -- we would not get to statistical significance?

MR. MARCUM: I'll be doing this a lot today. I'm afraid I respectfully disagree because there are statistically significant findings of these metabolic

markers. They may not be new onset diabetes, Judge, but --

THE COURT: Okay. We agree that as to -- as to the relationship between Lipitor 10 milligrams and new onset diabetes, there is no published study that shows statistical significance, correct?

MR. MARCUM: With respect to the end point new onset diabetes, you are correct.

And if I could, at the risk of angering you, for the record, I have to say that the focus we are putting on ASCOT in this case makes the exclusion of Dr. Jewell's analysis of ASCOT that much more egregious in error, with all due respect.

THE COURT: Well, listen, you can have that.

MR. MARCUM: There is so much emphasis on this study, you deserve a closer look. And I realize we've been there, we've done that, but for the record I just want to say that.

THE COURT: And I've said all I'm going to say about Dr. Jewell. I was not impressed with his work. And I thought it was very result oriented and litigation driven. And I didn't appreciate a lot of his strategies, which seemed to me did not follow professional strategies. But I'll let my order speak for itself.

MR. MARCUM: Right.

THE COURT: And, you know, I noted -- and I've got

to tell you something, you know, sometime after I issued my order, I noticed there was another District Court that had some of the same criticism of Dr. Jewell.

MR. MARCUM: The work he did in that case, Judge, was completely different.

THE COURT: Listen, and I didn't even know about it. I only learned about it, you know, when the order came out later. I mean, I wasn't aware of it. It is just interesting that two District Judges in different parts of the country dealing with Dr. Jewell reached the same thing. But this is not about Dr. Jewell, this is about the -- the opinions of Dr. Singh I'm focusing on.

MR. MARCUM: I agree. And again, with due respect I just want to make a point.

THE COURT: Mr. Marcum, I would think less of you if you just said, Okay, Judge, I accept your finding. I respect you to fight my conclusion, okay? I don't -- you know, again, I don't have a dog in this fight. I'm just trying to do my best. And what the good news is is you are always going to have another court to look over my shoulder.

MR. MARCUM: You are going to show me that map to Richmond at some point, aren't you?

THE COURT: That's okay. I don't say it with any regret or anger. That's the way the system works. These are complicated questions, and I've given my best work on, and

I'll have another court to look over my shoulder to see if I got it right or not.

MR. MARCUM: And I don't want you to take my comment as a lack of respect because I know you've done a lot.

THE COURT: You know, I have many, many lawyers tell me that they think they don't agree with me. It's about 50 percent of the lawyers who leave every day, okay?

MR. MARCUM: It won't surprise you that other judges have told me they don't agree with me, right?

THE COURT: So if I was -- you know, as they say --

MR. MARCUM: You are not the first.

THE COURT: -- if you want a friend in this business, get a dog, the old Harry Truman statement.

Now, you made mention of the fact that there are these markers, and I call them, as a shorthand, these metabolic markers that Koh has written about that shows -- we just looked at it -- statistical significance at 20. I think one of them doesn't show it at 40, but shows it at 20 and 80. The HbA1c shows it at 20, 40 and 80, and the other shows it at 40 and 80, I think.

MR. MARCUM: Yeah, I believe that's a measure -- as I recall that's a measure of insulin sensitivity.

THE COURT: Right. Which I think Dr. Koh describes as the best available right now, in any regard.

There -- even these -- if you are going to say, Okay, Judge, you know, we recognize that -- that these markers aren't basically diabetes, they are -- they may be relevant. They are indirect -- I think they are described by your experts as indirect evidence, not direct evidence, correct?

MR. MARCUM: Correct. They are the things you look out for. They are the things frankly the FDA has told doctors and patients to look out for in the warning label.

THE COURT: There is an interesting case out -- I'm sure you read it -- it says, you know, the FDA has a different standard than courts in looking at issues. They have a different role and a different function. And their -- their mission is to be cautious. And there is actually an excellent discussion in one of the cases about how they are different. And it's not unimportant to look at and to consider, but the fact that the FDA did not make a dose determination doesn't settle the question. I mean, the question is, is you've got to go -- you know, it's striking to me that the studies have shown a fairly consistent pattern.

And the point I was getting ready to make here is all of them, every one of them, at least in the Koh studies -- let's focus on those -- do not show a statistically significant association between 10 milligrams

and diabetes, or 10 milligrams and the factors that they are studying. I'm sorry. They consistently at 10 milligrams are not statistically significant.

MR. MARCUM: As the Court acknowledged, there is many different Koh papers. I can't concede standing here right now if that is consistent.

THE COURT: I'm looking at the 2010.

MR. MARCUM: The 2010, you are correct. If you look at 10 milligrams alone with respect to the HbA1c, neither of those isolations reaches it. And if you look at ANOVA, the group reaches it.

THE COURT: The group reaches it.

But then you've got to ask: Is the group the effect of the higher dose or is it -- is it across the board? And when you look at it and break it down, the question, at least as to these fact -- metabolic factors, is that it is not uniform, the finding is not uniformly statistical significance, correct?

MR. MARCUM: It is not uniform, that is correct.

THE COURT: You know, Dr. Singh at some point says ASCOT doesn't exonerate Lipitor, okay? You know, he uses that term exonerate. But we are not -- the case here is to determine whether there is data to support an opinion that it causes it, not -- we are not here offering opinions to exonerate anybody.

MR. MARCUM: I understand we have the burden.

THE COURT: Right. And we are not in the business of exonerating drug companies. That's not what we are doing here.

MR. MARCUM: I'm certainly not.

THE COURT: I haven't had any -- well, you know, I do have some cases -- not here, okay? This is not -- that's not the issue here. The issue is, as you say, it's the burden. And whatever the end is, the end is. I've just got to make sure we've got a reliable methodology, and I say reliable data.

We would agree with the fact that simply because SPARCL says there is a statistical -- statistically significant relationship between 80 milligrams of Lipitor and new onset type 2 diabetes does not necessarily mean that we would find the same thing at 40 or 20 or 10 milligrams?

MR. MARCUM: It does not necessarily mean that. But we have showed it to you before, and I can show it to you again today, that when you look at both SPARCL and TNT together, and when Pfizer did in 2009, they agreed unequivocally, unambiguously, that the -- Lipitor increases the risk of diabetes and that the risks of 10 and 80 were similar.

THE COURT: Okay.

MR. MARCUM: And you get there, Judge, if you look

at the risk difference between 80 milligrams and the placebo in the SPARCL study, and then you look at the risk difference, which is much tinier between 10 milligrams and 80 milligrams in TNT, that conclusion easily follows.

THE COURT: Well, it's -- it's a sort of hypothesis, but --

MR. MARCUM: It's --

THE COURT: You know, actually Dr. Singh combined SPARCL and TNT.

MR. MARCUM: He does discuss them.

THE COURT: Then he doesn't. And he -- and he did some -- he was able to -- because I think TNT doesn't have a placebo group, a control group --

MR. MARCUM: That's correct. It's 10 milligrams.

THE COURT: He's trying to extrapolate certain data. And when he put them all together he did not have statistical significance, correct? Page 27 to --

MR. MARCUM: I don't recall that off the top of my head. But I know that even when Pfizer looked at 10 versus 80 in the TNT study --

THE COURT: Well, I'm focusing on Dr. Singh right now. And I'm looking at whether -- he actually -- he actually --

MR. MARCUM: Bear with me one second.

THE COURT: Go right ahead. Take your time.

He actually did that very analysis you were talking about. He took TNT and SPARCL -- you know, I don't have the expertise to talk about whether his methodology of how he extracted that, I haven't heard a lot of criticism of it -- but he took it, and which I thought -- assuming he used a good method, no one has really challenged it -- was pretty creative. He then concluded it did not have a statistically significant effect. The lower part of the confidence interval was below 1.

MR. MARCUM: Your Honor, could you point to me where you are in his report?

THE COURT: Sure. Page 28, line 4.

MR. MARCUM: Yeah. But again, though, Your Honor, this is a comparison of Atorvastatin 10 versus Atorvastatin 80. This is similar to --

THE COURT: No, he tried to -- he extrapolated, he tried to convert it so you would have the equivalent of a placebo.

MR. MARCUM: I see what you are talking about. He found a hazard ratio of 1.25 and the confidence interval was .93 --

THE COURT: Correct. So he actually did the analysis that you talked about. If you took the data, he actually did it.

Now, you know, it's above my pay grade to figure out

the extrapolation of TNT data. But assuming no one has challenged it, he did it and he actually found no statistical significance in 10 milligrams.

MR. MARCUM: It is marginally nonsignificant, Your Honor.

THE COURT: Well, you know, that's not the way epidemiologists work.

MR. MARCUM: I think --

THE COURT: You know, you say, Oh, if we just had more people, oh -- but, you know, every study keeps -- you know, one of the answers -- you know, I think my friend Judge Vance had this recently in a case, and she talked about it. And she says, Yeah, I hear of the argument that if we just had more power, but the answer may well be, if you actually finished it, is that there really is not a statistically significant association. That that may really be the answer. And you just can't speculate.

So what I'm getting is a lot of people saying -- and actually, it's interesting, I now am confusing Singh and Quon -- but I think it's Quon that actually says, I think we need to do more studies. Fair question. But for him to come in my court and offer the opinion when you haven't studied, you don't know the answer, on the basis of a trend doesn't -- that's not the way -- let me tell you, that's not the way they do it when they are --

MR. MARCUM: With due respect, especially with regard to Dr. Quon, as the Court knows, his opinions are opinions he reached well before this litigation started based on his research with Dr. Koh and his co-authors. They are not litigation driven.

THE COURT: I mentioned it, so it's my fault. We'll get to him in a second, because I have -- I have now read a number of his articles; some which were not the centerpiece of y'all's discussion about this. And I have real concerns about inconsistency between his opinions here and what he's published. And I'll point those out to you. There won't be any confusion about them.

But let me finish with Dr. Singh, and then I'll move to Dr. Quon. So just to address the issue, in fact SPARCL and TNT, there was an effort by Dr. Singh to do apples and oranges and make them together as apples. So he did it. And when he did, he could not produce a statistically significant result at 10 milligrams.

MR. MARCUM: Yet he concluded the same thing that Pfizer had concluded back in 2009. I mean, that is an admission by Pfizer, Your Honor. I know it may not impress you, but --

THE COURT: We are talking about these e-mails.

MR. MARCUM: That's correct. Talking about the acknowledgement of the vice president of global medical

affairs over the cardiovascular unit at Pfizer that Dr. Waters was correct when he said unambiguously Lipitor increases the risk of diabetes and that the risks of 10 and 80 are similar, setting aside the science or the methodology. And that wasn't a hypothesis. They had looked at an analysis of the data at that point, Judge.

I apologize. I'm going through water like Marco.

THE COURT: I was about to say, you and Mr. Rubio may be getting in a wrestling match over water.

MR. MARCUM: I'm not sweating as much.

THE COURT: No. Let me turn, if we might for a moment, to Dr. Quon.

I know Dr. Singh -- I understand Dr. Singh's methodology. You know, in his original report he follows an understandable methodology. I read and re-read his deposition and report, Dr. Quon, I could not discern what methodology he used.

MR. MARCUM: Well, Your Honor, the reference guide on scientific evidence acknowledges that the causality -- type of causality assessment that he's doing doesn't have a cute name or a discernable methodology. This is the application --

THE COURT: But he's --

MR. MARCUM: -- of his training --

THE COURT: He's got to have -- I don't care about

what name it has, and I don't care that it's not the Bradford Hill, none of those things concern me in the slightest. But it's got to be a reliable methodology. It's got to be a methodology that I can understand that uses standards that have some integrity. And let me just -- let me stay on this. You call it the weight of evidence methodology.

MR. MARCUM: I actually didn't call it that; Pfizer called it that.

THE COURT: Whatever it is, that term has been used. But I don't care about the titles, okay?

And -- but my question is: What does that -- whatever he uses, I'm game with you that Bradford Hill is not the exclusive method to prove causation, but what method does he use?

MR. MARCUM: He's using the method that any author writing a review paper would use --

THE COURT: Hold on.

MR. MARCUM: -- Your Honor.

THE COURT: What is a review paper?

MR. MARCUM: A review paper is a paper written, published in a peer-reviewed journal, where scientific authors review the available evidence, whether it's clinical trial evidence, whether it's observational studies or any other kind of epidemiological data, and they use their scientific training and judgment and draw conclusions from

what they reviewed. This is from the records on scientific evidence.

THE COURT: Believe me, I'm familiar with it, but the question is: You are saying -- so he's doing a literature search?

MR. MARCUM: He did do a literature search, I think both times with respect to his reports, although obviously he's limited the second time around.

THE COURT: You know, Dr. Quon gets dinged pretty good in his deposition for having not addressed conflicting data. And he's pressed on that. And he says: "Well, I only put the stuff in that supports my view." That's what he says. He says: "That's what I do. I'm trying to do the stuff, and if it doesn't support my view, I don't use it." That is not the way review papers are done.

They are -- in fact, if you look at Dr. Koh and Dr. Quon's literature search review paper, they do, in whatever it is, 2013, they -- 2011, I'm sorry -- they -- they actually discuss conflicting data.

MR. MARCUM: They do. And I think with respect to what he said in his deposition, what he said was, I put in the papers what I thought were important. And again, this second round of reports was guided by your CMO. And I know we got the issue of Dr. Roberts putting in an extra article that she found and citing a review paper, but they were told

what they could look at, Your Honor.

THE COURT: Well, this is a different issue here. And that is, he -- he -- you know, one of the areas in which there is a grave concern about experts, and this is an area that gets -- is when they cherry-pick data. And, yes, you could put all the data in and then you could show a methodology in which you analyze and reconcile these findings to reach a conclusion. But if you only cherry-pick the studies that you like and you dismiss the rest as flawed without telling us why, that they are inconsistent with his views, contemptuous of them because they have a different conclusion, that's not a methodology I understand. That is certainly not a professional methodology that is used in which you basically tell one side of the story. And what struck me about the article, the 2011 article, was that in fact that's not what he did. He -- for instance, the insulin sensitivity issue, he clearly has, according to his own studies, a minority view on that.

MR. MARCUM: I don't think that's true. Again, I don't think that's true.

THE COURT: He cites nine articles.

MR. MARCUM: He does. He acknowledges the existence of those articles. But look at the conclusion of the paper. The conclusion of the paper is that Atorvastatin increases the risk of diabetes. Even in his 2010 paper,

which was specifically related to Atorvastatin, there is an acknowledgement early on in the paper that there have been conflicting results in some of these studies.

THE COURT: Well, my point is when he comes into this Court, what he -- he doesn't give -- he doesn't attempt -- I mean, you've got to have a methodology where you address the conflicting data and have a valid methodology for reconciling and explaining the inconsistencies. What he essentially does is comes in, picks the studies he likes and tells me that's his conclusion. That, Mr. Marcum, is not a methodology that meets *Daubert*. That is not a methodology that meets *Daubert*.

And now you talk about his studies. And let me tell you one which I was addressing earlier. He has offered the opinion that at 10 milligrams Lipitor causes diabetes. He's offered that opinion, correct?

MR. MARCUM: That is his considered opinion. That's what he believes.

THE COURT: Yet in 2013, he co-authors with Dr. Quon a study, an article, in which he recommends for treatment the use of low dose statins. That's his recommended treatment. And he does not disclose that opinion. He does not --

MR. MARCUM: That's because -- I think he would come into this courtroom and tell you that he would recommend for treatment low dose statins. I mean, you ask him what he

means by that, he's going to tell you, What I mean is Pravastatin because it's the lowest --

THE COURT: That's not what he says here.

And you are now saying that's what -- you are trying to fill in -- I'm telling you what he published to his peers, okay? His peer-reviewed article, he says -- and this is, for the record, Docket Entry 1441-1 at page 45 -- he says: "In patients with stable angina or in primary prevention, low doses of statins or metabolically safe statins are recommended." He distinguishes. Because he had talked earlier about these others. And --

MR. MARCUM: And that is 100 percent consistent with his opinion that 10 milligrams of Lipitor --

THE COURT: Is 10 milligrams low dose?

MR. MARCUM: Well, Lipitor, you are getting into some weird areas, because Lipitor is a high potency statin.

THE COURT: He uses this as low dose.

MR. MARCUM: He says low dose, but he would say --

THE COURT: But my question is this: You are telling me that he thinks, he's given this considerate opinion in 2015 to this Court, or 2016 --

MR. MARCUM: Which he held in 2010, well before this litigation, Judge.

THE COURT: Okay. But he's telling the peers to use this medicine, use this medicine to treat a metabolically

stable person. I mean, a primary prevention. He's saying for primary prevention, use this medicine. He comes here and tells me that very therapy causes diabetes and he fails to disclose that opinion when he's making that recommendation.

Mr. Marcum, isn't that the very thing the plaintiffs claim the defendant has done?

MR. MARCUM: He's disclosed that opinion in countless other papers, Judge.

THE COURT: Listen --

MR. MARCUM: His job in that paper was not a failure to warn case, okay? That's what we are talking about here. He would tell you --

THE COURT: No. He is recommending -- let me tell you -- he is recommending a therapy to his peers that he is coming to this Court and says causes diabetes.

MR. MARCUM: Correct.

THE COURT: And he has not said that 10 milligrams --

MR. MARCUM: Well, in 2012, which is before he authored that paper, that warning is in the label, Judge.

THE COURT: He --

MR. MARCUM: With due respect --

THE COURT: Let me tell you something: If he thought -- and I know he has this whole discussion about different varieties of statins and some have carried a lower

risk, he has some theories about that.

MR. MARCUM: Correct.

THE COURT: And he has said the metabolically safe statin, we know what he's talking about, but he includes low doses of statins, or he's including, he is recommending, among others, 10 milligrams of Lipitor in this study while he's telling us a year later or two years later it causes diabetes.

MR. MARCUM: Again, he said it in 2010, Judge. We are -- that's not the point here, okay?

THE COURT: I'm going to find that that is inconsistent, and that he -- that he is taking an inconsistent view.

MR. MARCUM: It's absolutely consistent with his opinion, which is the lower doses, or the metabolically safe statins, which he believes Pravastatin is one of, that those are going to be your safest option.

THE COURT: Let me tell you something, if he had come in and said -- if he had come in and said that you should only use Pravastatin, if he had said that, that's my recommendation, that would be consistent with his opinion.

MR. MARCUM: I think this is consistent, with all due respect, Your Honor, okay? His opinion is the lowest dose carries the lowest risk. So if you have someone who needs a statin, obviously the choice is the lowest dose they

can handle.

THE COURT: Can you point me anywhere where he has offered the opinion, Dr. Quon, that 10 milligrams of Lipitor causes diabetes, other than in the report in my case?

MR. MARCUM: In his papers.

THE COURT: Show me where it says 10 milligrams causes diabetes.

MR. MARCUM: The ultimate conclusion of the 2010 paper isn't dose specific, it's general. Atorvastatin increases the risk of diabetes.

THE COURT: His 2010 paper shows us there is no statistical at 10 milligrams.

MR. MARCUM: That's the way you view it and that's the way it looks at the individual dose. He has given reasons for that --

THE COURT: Let me just tell you, I've got real problems with Dr. Quon. I think he has a litigation-driven opinion that is different from what he has offered, because he has come in and recommended a therapy that is, he's telling us, causes diabetes.

MR. MARCUM: Your Honor -- pull up those ACC slides.

In 2013, the American College of Cardiologists, who put out these guidelines that basically each time they come out expand statin use for patients across the country in

their 2013 guidelines, nine times they also say statins are associated with an increased risk of diabetes.

THE COURT: And they --

MR. MARCUM: But they still think you ought, in some patients, to use them. That's not the debate we are having in this courtroom, Judge. That's the debate doctors and patients should be having.

THE COURT: But you see, you all want to conflate the high -- the documented problems at high dose with all doses.

MR. MARCUM: We firmly believe the problem exists. We are not trying to conflate anything.

THE COURT: And the data in 10 milligrams doesn't support it.

MR. MARCUM: We can argue it does.

THE COURT: And -- I understand -- and your expert tells me at 20 and 40 it doesn't either, if it doesn't at 10.

So the problem here is he is recommending a -- you would agree with me that his language here, "low dose statins or metabolically safe statins," that that would include 10 milligrams of Lipitor. You agree with me?

MR. MARCUM: I don't know without reading the full article, and I confess, I don't know if I have or haven't.

THE COURT: It's in the record.

MR. MARCUM: But I would -- in my mind I would

think a low dose statin would be 10 milligrams of Lipitor.

THE COURT: Thank you.

MR. MARCUM: But again, I see no conflict in that conclusion and the opinions he's rendered in this case. I realize we can agree to disagree.

THE COURT: We agree to disagree.

Now, you agree with me that this discussion about insulin sensitivity in his report does not disclose the articles which show either no effect on insulin sensitivity or positive effect. He does not disclose that in the report.

MR. MARCUM: He discloses his actual review paper.

THE COURT: Well, right. And he doesn't discuss -- I mean, he's offering an opinion to this Court and you say, Oh, well, it's in another piece he wrote and I should incorporate that by reference. That's not the way you come in here. You are offering an opinion, you address the inconsistent evidence, you reconcile it and you offer that opinion. If you use a valid methodology, a minority view, that's okay. But he's got to have -- he doesn't do that. He basically goes, he just says, that's because I said it.

That's what I'm getting here. And it's not -- it's not a method -- it's not a literature search, it's not a weight of the evidence, it's not a totality, because all of those, you take all of the evidence -- now that's not

normally done and there is -- most cases you are going to require to use a more -- the standard epidemiology -- but there is certain circumstances where you can use different methods, I recognize that, but it doesn't -- it's not an excuse to do ipse dixit. I mean, that's just not an excuse.

MR. MARCUM: Again, I respectfully disagree that that is what it is.

THE COURT: Now let's talk about Dr. Roberts for a second. You know, I issued an order and I said, I want a discussion dose by dose. I wasn't ambiguous about that, was I?

MR. MARCUM: You weren't to me, Your Honor. But with due respect, I don't think you could read Dr. Roberts' report and not understand what she's saying. And I realize it's not structured the way the Court asked that it be structured.

THE COURT: Well, it was because I thought it needed to be individualized by dose. I know you don't agree with me, Mr. Marcum, I know the plaintiffs don't agree with me, that's fine. You have every entitlement not to agree with me, but you do have a duty to obey what I tell you to do, okay?

MR. MARCUM: And I always endeavor to.

THE COURT: And, you know, I was tempted -- I was tempted just to strike her report because I thought it did

not follow the instructions of this Court. But I've got to tell you, once I got into it, I couldn't figure out what her methodology was.

MR. MARCUM: Again, Your Honor, she's doing a review just --

THE COURT: Well, doing a review, she couldn't even figure out where she got the articles from. It's obvious y'all gave them to her. I mean, she couldn't figure out, she couldn't explain, she said, I don't do searches.

MR. MARCUM: She actually did do searches, but I didn't give her the article that she put in there.

THE COURT: I don't know how she got her articles, but she doesn't do a thorough -- there is the same problem there. There is all this data out there. And, you know, it's conflicting. I mean, you've got -- and particularly conflicting with the opinion of that 10 milligrams. And to say, I'm just not going to discuss it is a way to avoid the problem -- the inherent problems.

MR. MARCUM: With due respect, Your Honor, you told her what articles she could review in the CMO with the one exception, that's what she did.

THE COURT: And I'm okay. I read the Mansi article. I mean, but I wasn't going to send y'all on a whole new -- I was trying to keep y'all from starting all over again. It was entirely proper and you should rely on the

studies you had and not to reshuffle the deck again because the first time didn't work. I wasn't trying to do that. I gave y'all -- you know, I felt there were real problems in your presentation. I gave you another chance to come out. And I wasn't having you start all over again. This wasn't a reset button.

MR. MARCUM: I understand. We didn't have time to start over again.

THE COURT: It was an effort to give y'all every opportunity to prove your case. That was my effort there. And I've taken the responsibility to this MDL very seriously. It's not a single case, you know, and I have done things that have caused your opponents a lot of heartache regarding discovery decisions and other decisions because I think that under the circumstances that the plaintiff ought to have every opportunity to prove, to make its case in every way possible. And I tried to do that. I know that --

MR. MARCUM: To be clear, we and our experts took it just as seriously.

THE COURT: Well, not Dr. Roberts, but the rest of them did.

MR. MARCUM: Well, we think Dr. Roberts did, as well.

THE COURT: Well, I couldn't discern -- you know, the rigor that I wanted, I wanted to say, okay, at 10

milligrams here is the data, here is how we are going to reconcile it. Dr. Singh actually, you know, does that, okay? I mean, he does at least try to use a methodology that is recognized, and he -- he -- there is just -- the problem is the data doesn't support his opinion, it just doesn't, Mr. Marcum. And at 20 and 40 -- you know, I'm not the epidemiologist, he is -- he says he can't make the case without 10. Okay. That's fine. I don't -- whatever his conclusion is is his conclusion, I don't have a dog in that. I think there is plenty of data at 80 to support his conclusion.

I go to Dr. Quon. I can't figure out -- I can't figure out what his method is. I don't -- I just can't figure it out and --

MR. MARCUM: His method is applying his scientific judgment to the epidemiological evidence.

THE COURT: Not in a way that is -- that I find -- I mean, if you are going to do essentially a literature search, you are going to take the data and put it -- you put it all in there. I mean, he has only the favorable data.

MR. MARCUM: Neither your order or our timing gave us the luxury of a do-over or a literature search, as you yourself acknowledged.

THE COURT: There is data right in the record. I mean, there is -- he had every opportunity. There is plenty

of data. It may not reach the conclusion he wants, may not reach the conclusion, but there is plenty -- I mean, you guys have had enormous time to do this. And to go back and start over again, no, we are not doing that. But I wanted it -- you had -- I mean, y'all -- how many documents have been produced in this case? God knows. I mean, it's not like you guys haven't had a chance.

MR. MARCUM: I lost count.

THE COURT: And, you know, I could have just tossed general causation, but I gave y'all another chance to do it. Now you are criticizing me for not letting you do it over again.

MR. MARCUM: It's not a criticism, Your Honor, it's a response to the criticism of our experts who we think did use reliable methodology and marshaled and answered the questions you asked.

THE COURT: It didn't seem to me to be that hard. That is, okay, you have this opinion that generically it causes it. I think with SPARCL that it certainly at some level it does. I mean, I don't think the defendants agree with me on that, but I think there is --

MR. MARCUM: They don't. But the ADA agrees with you, the ACC agrees with you. That's not the debate happening outside of this courtroom.

THE COURT: Obviously, how much below 80 does it go?

That was my question. Where does it go? How far does it go? And I wanted to give your folks a chance, taking the data they've already done, and tell me that, and not try to start the litigation over, not to start the discovery over again, no new experts, don't start bringing in new studies. You know, I didn't want -- we weren't going to do that again. But I wanted to give them a chance to squarely address it within the context of my concerns.

And I will say that at least Dr. Singh and Dr. Quon, for whatever, did address it dose by dose. And, you know, among the things I've got to decide is whether they have a method that is valid and reliable and whether there is data to support their opinions. Those are my questions.

MR. MARCUM: Sure.

THE COURT: Now, I've kept you on kind of a tight rope here. I know you have --

MR. MARCUM: You have.

THE COURT: Of course I want y'all to know every time somebody brings in a PowerPoint, my staff breaks into laughter, okay?

MR. MARCUM: That's why I made a very tiny one.

THE COURT: There is this hilarity in the courthouse.

MR. MARCUM: Mine might be 20 slides.

THE COURT: Nobody has ever gotten through a

PowerPoint with me.

MR. MARCUM: I didn't expect to show you maybe but one, and we'll hand it up at the end of the day.

THE COURT: By the way, my clerks value the things, and they frequently will bring in and put a stamp and I'll look at it. In fact, you gave me one one time that was very important, I used it in specific causation.

MR. MARCUM: I'm the one that showed it to you.

THE COURT: I'm sure your colleagues said thanks, Mr. Marcum, that is great.

But I want to hear -- I have some questions for the defendant, and then I want to give you a chance to reply to them, okay?

MR. MARCUM: That's fine.

THE COURT: Is that fair enough? Thank you very much.

MR. MARCUM: Thank you, Your Honor.

MR. CHEFFO: I guess I'll leave my PowerPoints.

THE COURT: Boy, what a subtle hint that was, huh?

MR. CHEFFO: Somehow I'm not surprised. We've learned that lesson. We will leave these, though, because they are helpful.

THE COURT: Let's go to Dr. Singh and 10 milligrams.

Tell me -- you know, the argument is, is that, yes, it's not statistically significant, but there is a trend.

Its incidence is higher than 1, but it's not statistically significant. But at higher doses it is statistically significant.

So why is that not good enough, Mr. Cheffo?

MR. CHEFFO: Sure, Your Honor.

I think, first of all, you know, it's a trend that doesn't really exist, you know, for the reasons I think you were discussing with Mr. Marcum. I mean, we have, you know, an ASCOT, we have a study. And then the plaintiffs have spent a lot of time essentially saying let's wipe all this away, which was not --

THE COURT: Not long enough, it's --

MR. CHEFFO: It's not long enough.

THE COURT: -- use adjudicated data, all these things.

MR. CHEFFO: Right. So, you know, we don't think that is a fair criticism. And obviously, it's a peer-reviewed study, no study is perfect, obviously, but it's certainly something we have.

They have also kind of conceded, as I think they need to, that they have the burden here. So you say you can't really get over ASCOT, they haven't done that. Then what else is it? Then they, by everyone's concession, there are no studies. I mean, you know our view. And I think frankly our view, Dr. Gale and Dr. Singh's view, that

observational studies alone can't produce -- they can't show causation.

THE COURT: Let me say this: Not only does it not -- is his opinion it doesn't show it, even with other things, it's not good enough.

MR. CHEFFO: Correct.

And then he says -- you know, we can go kind of point by point, I call them the four C studies -- but I think in the deposition you read, he said, I'll go one further, you could put Cederberg, you can put Chen, you can put Culver, you could put Carter together, you could put all four of those together --

THE COURT: They said they are not good enough.

MR. CHEFFO: Don't show causation.

And then you have these kind of what we'll call argued biological plausibility resistance, which frankly everybody also says, and I think Dr. Singh specifically says, at best, you know, at best they are interesting. No one is suggesting -- we are not saying that you shouldn't do these studies, but they don't lead to causation.

In fact, Dr. Singh says they are at best hypothesis generating. So if we are talking about -- to answer your question, we have -- this isn't even a little bit of weight over here, a little bit of weight over here. We have zero on this side, and we have a bunch of stuff that some of it they

criticize.

THE COURT: Every time we have gotten -- I mean, it's not like -- ASCOT is not there by itself. There are actually -- you know, one time they say if you don't have enough power, enough people in your study, sometimes you use meta-analysis to do that. Well, it's been done. Same result. And then you say, Well, we'll do an observational study, maybe it will alert us that maybe that clinical trial was off base, and sometimes we'll do that and we'll go back and revisit. Same result.

And then these metabolic markers, which everybody admits are not perfect, but may at least indirectly be interesting, produce the same pattern. It's odd. It seems to me to help validate the thing a bit. At 10 milligrams you don't have statistical significance in them, other than -- I thought one of them was the glucose rise, it was like did not affect it, you know, which --

MR. CHEFFO: I know there is a bunch of Koh studies.

But the one I thought was particularly interesting where there is eight of nine. And basically if you look -- you know, the one that he wants to draw a conclusion from is in the middle, which talks about insulin sensitivity decreased. But there is five that say no change, I think, or four, and the other ones actually show benefit.

Now, you don't hear us coming in and say, Well, look

at that, Judge, that shows we should get a label changed to show that this increases -- you know, it's going to stop people from getting diabetes. They are interesting but they have a place in science.

THE COURT: But see, my problem with the way Dr. Quon used that was he didn't say, I have an opinion, I'll recognize it's a minority. You know, Mr. Cheffo, just because it's a minority view doesn't mean it's wrong. He could be right.

And one of the advances of *Daubert* is to say, just because you are not the majority view doesn't mean you get thrown out of court, okay? I mean, you get a fair -- if you use valid methodology, that's a jury question, okay? There is enough data for it, that's a jury question.

But when he comes -- Dr. Quon comes in, he doesn't discuss the fact that he's a minority. He doesn't say why those four studies that show it's a benefit. He doesn't even address the fact that he himself said it was a benefit at an earlier time, okay? None of that is addressed.

And y'all asked him about that. You said, Why didn't you do that? And he says, I only put the things in there that support my view that it causes diabetes. That doesn't invoke a lot of confidence in me.

MR. CHEFFO: As you read, he got a good deal frustrated by some of those questions.

THE COURT: Yeah. I mean, it's just, you know, the experts got -- the value of the expert to us -- and the only thing I will -- I mean, I could count on one hand the experts before this case I've kept out. I mean, I'm kind of a light touch on *Daubert*. But there is a responsibility to have an opinion that actually has support and uses a valid methodology. I never -- I have always thought of all the plaintiff's experts Dr. Singh was the more serious guy. I've always said that. And I was very interested in his -- of his work by dose. And I've got to say his discussion at 10 milligrams left me very confused, left me profoundly confused how he could do that because his own -- you know, the data goes exactly the opposite direction.

MR. CHEFFO: Well, I think we had the same reaction, Your Honor.

And I think the one -- you know, in fairness to Dr. Singh -- and I think you discussed this with Mr. Marcum earlier -- what he then did say was, essentially this is a cascade, right? You know, if you don't -- here is my view on 10, but if you don't agree with me on 10, I don't have anything on 20 and 40, I think the plaintiffs -- indulge me in one slide. If I can have slide four?

THE COURT: I think you have that one-slide rule. Mr. Marcum got that one slide.

MR. CHEFFO: It can help me. It's in front of me.

You can take a look.

And when I went through -- and as usual, Your Honor, I think you preempted much of the 50 slides that we had here -- but, you know, I tried to identify, at least in my own mind, what were the things that could answer the question for the Court today, right? You gave them a time. We had a difference of view as to whether they should have gotten it.

THE COURT: You about had a heart attack when I let them do that.

MR. CHEFFO: That's true.

But I also think you can kind of quickly move past that. And the plaintiffs said, you know, We can do this at 10, 20, 40 and 80. And you said, Okay, I'm going to give you an opportunity. And it really hasn't turned out that way.

Because I think we start with Quon and Gale say you need clinical trials, of which there are none. And then you have Dr. Singh that talked about you look at all four and we don't get past go. Then they say there is no clinical trials that show a statistically significant increase at 10, 20 or 40. In their brief they say 20 and 40 is sparse. And then again, I guess to me the penultimate is you can't get -- we'll talk about 80, I know you are going to have some questions about that, and I understand I have a higher hill to climb with respect to 80 -- but if you will give me a few minutes we can discuss that. But at least as to 10, 20 and

40, I think where we are right now is having a full and fair opportunity, the plaintiffs have said, Here is our best shot, you know, we know you may disagree, but if we can't get past 10, we can't get past 20 and 40.

THE COURT: I find the assumption that if it's statistically significant at 10 and at 80, then if you have no data in between or not sufficient data standing alone, then perhaps the fact that you have bookends, there might be a reasonable scientific judgment that you would have 20 and 40. I don't find that a crazy idea in the absence of, you know, just because there are studies and some cases that say that, just because there is no clinical trial doesn't mean the defendant automatically wins. I mean, you look to other data. What -- so 10 milligrams is like important. And I did wonder would Cederberg with the other, you know, indirect data be enough, didn't know. Dr. Singh tells me no, not enough. Not enough.

MR. CHEFFO: Cederberg, as you know, has a negative --

THE COURT: Right.

MR. CHEFFO: Even if you were to look for some guidance, it doesn't help you on 10.

THE COURT: Right. You know, I had no idea would Doctor -- I had a question in my mind would Dr. Singh take Cederberg and some of the indirect data from Koh and others

showing statistical evidence in some of these metabolic markers and say, My opinion is based on this and go through the Bradford Hill and tell me. I didn't know. I thought that might happen. Didn't happen. He has been pretty consistent, observational studies aren't enough, and he doesn't say they don't matter. Again, I don't care what the conclusion is. I don't have a dog in that fight. I just need methodology and he was consistent about that.

So we all -- we are kind of drilled down to 10. And when you think about it, you have the full panoply of studies: You have a clinical trial, you have an observational study and you have a meta-analysis. And then you have indirect markers: HbA1c, insulin sensitivity, you've got a number of -- all follow the same pattern of nonstatistical significance until you get to 20 milligrams. And to then come in and say to me, trend, they don't do that in their business, okay?

Now, it's a hypothesis. I think it's a -- it might be a reason you would go do a study, but it's entirely speculative what the result is. Because all the studies thus far have reached a different conclusion, right? I mean, so how do you get that?

Now, let's talk about the 80 milligrams. Now, let me just lay out to you why -- I mean, I think Dr. Singh uses -- you know, he uses the Bradford Hill. He has a

statistically significant finding with SPARCL. It's not a perfect pool, you know, it's a kind of people just had a stroke. There is in the same sort of class of drugs, a Crestor study, the equivalent, it has a similar result. There are these markers that show fairly consistently at 80 milligrams statistical significance with these biological markers. And, you know, to me is there an argument on the other side? Sure there is. And I just raised some of the things. But I would let a jury decide that, you know? I let them sort it out. Because I think there is enough data there to get across and I am comfortable with his methods of doing it. And the exercise of that discretion, I think, is uniquely within his expertise as an epidemiologist.

What I'm bothered with on the others is just the opposite, the lack of data. Actually, the data showing to the contrary.

MR. CHEFFO: Um-hum.

THE COURT: And so I feel frankly, Mr. Cheffo, as strongly about the plaintiffs carrying their burden at -- of the -- of the experts establishing sufficient methodology, at least Dr. Singh and data at 80, I feel as strongly about that as I do about the 10.

MR. CHEFFO: And you've -- you know, you've made that point, and we certainly appreciate, you know, understanding that. And I think, you know, both sides, I

think have, you know, have tried, because of our regard for the Court, respect, you know, it would be disingenuous for me to stand up and say the level of proof at 80 is the same and you should look at them the same. Just like we said that there is differences amongst the experts. So we recognize that.

And we recognize that, you know, kind of where Your Honor seems to be and that we have a hill. Having said that, just the quick responses, I guess, are that our view is -- you know, we -- and I think the company actually believes this, this wasn't a throwaway, let's just throw everything -- and the reason why I think we've kind of moved on these is really when you look at SPARCL, right? And Your Honor I think focused on this at one point when we were talking about potential trial picks, right? You know, because, first of all, it is a different population. That doesn't mean excluded, but it is different, folks that had strokes. You know, the finding becomes one where you have 80 milligrams with people with multiple risk factors and, you know, and those aren't just people with multiple risk factors.

THE COURT: 80 milligrams has statistical significance. The fact that the one with four risk factors was actually over two, the -- that the hazard ratio was actually over two which made it more likely than not. And my

point there -- and Mr. Marcum had pointed out to me -- he had more than two, which I frankly hadn't noticed. And that then led me to say, well, that might be a method by which the deficiencies in the plaintiffs' specific causation testimony might be solved? That me might have --

MR. CHEFFO: Sure.

THE COURT: It would be more likely than not that their data actually reached that.

But I think what we discovered that while in theory that might be an interesting way to get a trial -- and I wanted to try one of these cases for a bellwether -- when we got down to reality, we just didn't have anybody who seemed to actually exist who met the SPARCL profile, right? I mean, when we finally got down to it.

MR. CHEFFO: That's right.

THE COURT: So the best laid plans of mice and men, it didn't happen. But I wanted to give the plaintiffs a chance to try a case if we could. If they could get over the threshold of *Daubert*, I wanted to give them, afford them the opportunity to try one of these cases.

And what they've told me, Mr. Hahn has been very straight up about this, he said, I just, you know, we don't have a plaintiff that can meet that standard. Fair enough. I mean -- and, you know, Mr. Cheffo, we are going to have to deal with sort of where are we going from here? What does

all this mean? I felt a need to do both general causation and specific causation. And we've got a number of orders to be issued still on both and several other issues.

But, you know, I issued an order in which I said, Listen, I have been told by lead counsel that if the *Murphy* order stands, standard stands, they can't meet -- they can't meet the -- they can't offer testimony that would survive *Daubert*.

And I -- I didn't want a situation down the road where another counsel, perhaps one not even on the steering committee said, you know, plaintiffs' counsel, they are a bunch of cowards, I want to try one of these. So I issued an order that said, if you disagree with lead counsel, come forward with your case, but by the way, you need to be prepared to name your experts and we are going to go through discovery, and my understanding is we didn't get a response.

Is that right?

MR. CHEFFO: I've not seen any.

THE COURT: I hadn't seen any. And surprise. I mean, I have nothing but the greatest respect for Mr. Hahn's work in this case and I wasn't surprised that when they got -- when the rubber met the road they wouldn't -- they -- no one would really challenge that conclusion. I don't think he reached it easily or casually.

So where does it lead us? Where are we heading

here?

MR. CHEFFO: I have a thought on that if you would like to hear it.

THE COURT: I would love to hear it.

MR. CHEFFO: I would also might like to buy a vowel and put up a slide.

THE COURT: You used up your -- unless Mr. Marcum has got one in his hip pocket, you don't get another one.

MR. CHEFFO: In all seriously, if I take it, obviously for this is my thought on maybe a process -- and again, I don't mean to be presumptuous, so I have to make some assumptions based on a process that might make sense.

First is it seems to me that you have a potential, or you have a summary judgment motion on specific causation based on that. Then what you would do -- and let's just say for argument's sake you were to find on 10, 20 and 40 that, you know, their experts couldn't get past, but you were to find something different on 80.

You then essentially have -- you issue those orders. I don't think there would be a lot of disagreement, though I don't want to speak for them, we would do an Omnibus summary judgment motion on both grounds. It would be on specific causation. We work together and say, Here is the folks from the pool who we believe are 10, 20 and 40, give you that list so your staff doesn't need to go through all that. And then

you would basically have a situation where the PSC could file -- to the extent that they wanted to, you know -- any opposition to that. And you might even have a situation where people can file something different if they wanted to, just to make sure if there was something. I would be surprised if you saw anything, but again, so there is no issues of that.

Then the benefits of that, I think for everybody, is certainly the circuit would be, you know, you wouldn't have to, you know, have hundreds or thousands of records. Everybody could brief it and you would still give people an opportunity, if they wanted, to have it separate. But then essentially all of that would go up and it could be kind of column A and column B.

THE COURT: You know, I have wanted -- you know, one could argue that if I reach the conclusion that specific causation could not be satisfied, that we just close it down at that point, but we have done a lot of work in this case. And I thought it was important to address general causation. In the event there was an appellate court disagreement as to the Court's view on specific causation, we wouldn't have to ramp up again just to address general causation, and y'all would have an opportunity on appeal to address both issues. The appellate court might say. Before we go into general causation, we are going to address specific. That may be

their own strategy. And these are complicated questions. That's for another court to decide.

MR. CHEFFO: I agree.

Our view -- again, I don't want to speak for the plaintiffs -- but the idea -- if I was them, you know, the idea of getting up and even if I was kind of successful and then coming back and spending another year on appeal and briefing, it seems that's not in anyone's interests.

And I think, frankly, to the extent that -- you know, your orders, as you know, obviously are not necessarily self-effecting, right? So if you issued an order saying, you know, I find X on 10, 20, 40, that is just the predicate for a summary judgment motion. So the motion that would go up would actually have all of those issues.

THE COURT: Correct.

MR. CHEFFO: And you could also have efficacy, and depending on --

THE COURT: We are intending to issue orders on all of those issues.

And let me say this: I am mindful, you know, that in addition to the many District Courts that have, you know, have referred cases, that have been referred here under the MDL, there are a large body of state court cases -- and of course, they may have different standards and so forth -- but a number of the state judges have communicated with me and

are, you know, anxious to see this Court's determination because a lot of them don't have the resources we have here to address these issues, and they have looked for help. And they've -- they communicate with me about when am I going to issue decisions because they are -- you know, it will help them.

And I do have an interest that we don't have this uncontrolled litigation expense on either side. And to the extent we can narrow and focus where the disputes are, it will allow -- you know, allow this issue, you know, to be addressed and in an efficient way.

Of course Rule 1 of the Federal Rules of Civil Procedure is a just, speedy and inexpensive determination. Sometimes we are not as speedy, though I've got to say, I think we have been as fast as any MDL.

MR. CHEFFO: My head is still spinning, Your Honor.

THE COURT: And I've tried to do it -- I think doing it this way has made it less expensive. I know your client resisted the MDL, but I suspect it saved enormous sums not to be litigating in dozens of venues at one time.

MR. CHEFFO: That's fair.

THE COURT: It would have been extraordinary, I mean --

MR. CHEFFO: There is no question about that, Your Honor.

THE COURT: I presume this is -- Ms. Boroughs, you are asking me this question here?

Does it matter of whether -- what Adair is raising with me -- does -- would we want to do a *Daniels* and *Hempstead* motion for summary judgment before we do an Omnibus motion for summary judgment?

Mr. Hahn, what's your thought about that?

MR. HAHN: Your Honor, I think we have a fair understanding of where you are heading.

THE COURT: Yes.

MR. HAHN: If you just ask for my wish list, I would ask that you issue your orders and then give us a week, perhaps, to provide a letter to the Court as to how we think it is best to go up; because yes, Your Honor, we do disagree with some of your --

THE COURT: Listen, I fully respect that. I don't take it personally.

MR. HAHN: It's a tricky situation, Judge. As you well know, we've got an MDL, we've got thousands of plaintiffs, we've got all sorts of issues. And I, quite frankly as I stand here, until I know exactly what your rulings are, I don't know the best way to handle it.

THE COURT: Yeah. And we are all sort of -- all of us are going into sort of a little bit unchartered territory here. I don't want to prompt you -- you know, one hesitancy

I would have -- I haven't given a lot of thought to this -- if I rule in *Daniels* and *Hempstead*, it starts the appellate process; whereas if I do an Omnibus case, including we address them in there, then it's cleaner that y'all go up on -- you don't start briefing it while we are still arguing other issues. And I'm really trying to figure a way -- I mean, there are several discrete issues which plaintiffs take issue with the Court's ruling, I understand that. And I want to figure out a way that helps y'all and the appellate court to efficiently address those issues without being buried.

MR. HAHN: Yes, sir. We do, as well.

And just to be honest with the Court, one of the issues that we had and talked about, let's take *Daniels* up. If we take *Daniels* up, the Fourth Circuit might stop and not even talk about general causation. Well, then that was a wasted trip. So we don't know the best way to do it. So we would like to have the benefit of your orders and a little bit of time to think it through.

THE COURT: I want to consult with all of y'all and get your input.

My initial sort of thought about this is that an Omnibus order would probably put everybody on the same calendar, and then y'all may strategically -- and you may decide -- let me just say this: Any court reviewing this is

going to be immediately overwhelmed, right? The volume of this. You guys know more about this, and I've had the benefit of a couple years, I've had an extra law clerk, I mean, they are just doing nothing but this. And it -- it's fairly overwhelming. And y'all may want to strategically talk to the appellate court about doing this in some stages, so that you don't bury them, and pick out a couple of the issues that you think are really -- I mean, we kind of know where they are, I mean, right? It's the *Daubert* issues on specific causation. There are the issues about dosage. I mean, I know where the dispute points are, and I fully expected whoever didn't prevail on this would take it up. I didn't take this job thinking I wouldn't get my decisions reviewed. That's part of the process and I respect it.

Let's do think about -- I mean, I've tried not to be coy with y'all. I've tried to be candid about where my, you know, where my thoughts are. And I -- I did -- I know where I'm likely heading here is that I'm going to find that there is sufficient evidence to offer 80 milligrams but nothing less than that, and that would put me in the category of having both of y'all disagree with me. I'm going to be the minority of one on that. And maybe you will both end up appealing that, I mean, that's fine.

And I think -- I've tried, you know, in the *Daniels* and *Hempstead* cases, we are working through, but I think

y'all know that, at least on the issues of specific causation, you don't have an expert that can survive *Daubert*, and you don't have summary judgment, right? I mean, that's the answer unless you have got some other theory. I want to give y'all a chance to brief that.

But I think sort of we are cutting to the chase here where we are going. And I think y'all are entitled to a thoughtful and comprehensive order on that, so that an appellate court will have a full and ample basis to review the Court's decision on this.

So we are working actively on it, I'm telling you. We are in the middle of working the order on this and we are working on these other orders that are still outstanding. We have a series of experts to review and we are actively working on them all.

MR. HAHN: Does Your Honor have any timeline when we could expect the orders?

THE COURT: We are -- you know, it's hard to predict. Sooner, not later, okay?

MR. HAHN: Yes, sir.

THE COURT: And we are actively -- and we will -- as they are prepared -- we are actively working on general causation. I frankly had some issues I needed help addressed today, and Mr. Marcum helped me clarify, to make sure I understood. I thought I did, but he confirmed my

understanding of what those opinions were and are.

So I think the general causation is soon and the other orders are not imminent, but also in the foreseeable future. So we are fairly early going to have those. And, you know, my goal would be that sometime in the summer we would have arguments on summary judgment, okay? I mean, that is sort of where we are, and so y'all would be in a position to take up sometime late summer or so of these issues. That would be my goal. And frankly, the summary judgment issues, to the extent they overlap the *Daubert* issues, aren't that complicated, right? I mean, the complicated work has been done on the *Daubert*.

MR. HAHN: Yes. If the Court would indulge us, I know Mr. Marcum had a couple of points he wanted just to make a record.

THE COURT: I kind of cut him off.

Anything else further?

MR. CHEFFO: I'm done, Your Honor.

THE COURT: I want to hear anything else, Mr. Marcum.

MR. MARCUM: It's just one more very brief. It won't even have a slide.

Just with respect to the issue of Dr. Quon and the cherry-picking accusation, again, while he did not discuss those studies cited within his review paper, he cited his

review paper. His deposition testimony, I don't think is as simple as has been said. He actually testified that when he reviewed those studies in 2011, he thought they had various flaws. He didn't view his job as including flawed studies.

THE COURT: Basically he said I only put the studies in that supported my question.

MR. MARCUM: Actually, I disagree vehemently that that's what he said.

THE COURT: The record will stand for itself.

MR. MARCUM: Just one more time, for the record, after reviewing those studies in 2011 in his review paper, he reached the very same conclusion that he's offered to this Court. And that was one formed well before litigation and it's not result oriented.

THE COURT: Here is the simple question: Can you point to me anyplace he offered the opinion that 10 milligrams of Lipitor causes diabetes, other than in the report in this case?

MR. MARCUM: In the paper -- the answer is no because in the papers that he authored, they were not discussing dose specifics as you requested they do in these expert reports.

THE COURT: Well -- the first part is he's never offered that opinion. And now you've given me an explanation why. But he's never offered the opinion. And in fact, he

recommended 10 milligrams Lipitor, among others, for treatment.

MR. MARCUM: Which is consistent with the opinions he's offered here, Judge.

THE COURT: Very good. Thank you, Mr. Marcum.

The hearing is adjourned.

***** ***** *****

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

Amy C. Diaz, RPR, CRR March 22, 2016

S/ Amy Diaz