

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

IN RE: LIPITOR

2:14-MN-2502

TRANSCRIPT OF MOTIONS HEARING
THURSDAY, SEPTEMBER 7, 2016
BEFORE THE HONORABLE RICHARD M. GERGEL,
UNITED STATES DISTRICT JUDGE

APPEARED FOR PLAINTIFFS:

Blair Hahn, Esquire
Mr. Derek Ho, Esquire
Christian Marcum, Esquire
Mark Tanenbaum, Esquire

APPEARED FOR DEFENDANTS:

Mark Cheffo, Esquire
Michael Cole, Esquire
Lucas Przymusinski, Esquire

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

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

AMY C. DIAZ, RPR, CRR OFFICIAL COURT REPORTER

1 THE COURT: Okay, folks. Good morning everyone.
2 Welcome back, to those who are not from Charleston, welcome
3 back to Charleston. I think we have a new visitor for the
4 first time. Good to have you here.

5 Let's -- we have pending motions for summary
6 judgment filed by the defendant. Unless y'all have an
7 objection to this, what I think might be helpful is let's
8 address general causation first and -- hold on just a second
9 here -- yeah, let's address general causation first, and then
10 let's turn and talk about specific causation as to each case.
11 Okay? I just have some trouble speaking in the abstract
12 about a lot of these things.

13 And then I would suggest that since it is the
14 defendant's motion, defendant go first. So why don't we
15 first -- Mr. Cheffo, unless you have some better proposal,
16 that you address the issue of general causation.

17 MR. CHEFFO: Yes, sir.

18 MR. HAHN: Your Honor, before we get started, I
19 wanted to introduce to the Court Derek Ho who will be making
20 the argument for us.

21 MR. HO: Thank you, Your Honor.

22 MR. CHEFFO: If you have questions, I will be happy
23 to try to answer them, but I think our position on, frankly,
24 both general and specific is relatively straightforward, and
25 our view on general causation is that we spent a lot of time

1 and effort with Your Honor's assistance working through the
2 issues, and I think this is probably cleaner, because I think
3 there is no question I'm aware of -- I can say that in
4 complete good faith -- that the issue of general causation
5 from the get-go would not be decided essentially on a -- not
6 a class action, but you understand, an MDL-wide basis.

7 And we did that, and, Your Honor and at least as to
8 10, 20 and 40 milligrams, determined that the experts could
9 not offer reliable testimony.

10 THE COURT: The defendant -- the plaintiff now --
11 the plaintiffs now argue that you -- even if you don't have
12 expert testimony, you have these alleged admissions and that
13 the admissions are a substitute for expert testimony. And,
14 you know, I certainly heard from time to time an isolated
15 reference to these alleged admissions. But now they've come
16 sort of centerpiece to the case, and I think it's probably
17 worthwhile, Mr. Cheffo, to have you -- I mean, there is some
18 case law out there that would recognize in very clear,
19 concrete admissions that that can substitute, correct? There
20 is some case law to that effect.

21 MR. CHEFFO: What I would say to this is I think --
22 yeah, there is some case law. I don't think it would
23 necessarily state there. What I would start with by saying
24 this, is that the cases -- and I think we've talked about
25 this from some of the conferences that we've had -- to the

1 extent that someone were to, you know, hit themselves with a
2 hammer, for example, on the head and then have a contusion in
3 their head, you know, one might argue you don't need an
4 expert to determine that from a general causation
5 perspective, or a car accident, obvious types of cases. I
6 think here the only case that, you know -- the interesting
7 thing, Your Honor, is you have actually dealt with all of
8 these supposed admissions.

9 There is essentially four categories. Every
10 situation, which is somewhat ironic to me, is folks who are
11 dealing with general causation. They have a stable of them,
12 and then there were four of five of them that specifically
13 dealt with them. And part of their reports and their
14 testimony, particularly Professor Jewell, was you should look
15 at the Domingo e-mail, or you should look at the Japanese
16 label, or you should look at -- there were one or two
17 other --

18 THE COURT: I mean, I've seen all of these at some
19 point in the process. They just hadn't been the center point
20 of the case. And, you know, specifically, as I understand --
21 the specific causation gets into can you prove it? You know,
22 sort of things that -- you know, that there are certain
23 examples that you can prove causation. We do it all the time
24 in common tort cases, automobile wrecks and so forth, that if
25 someone breaks an arm in a car accident, you don't need an

1 expert to tell you you can break an arm in a car accident.
2 It's within -- I want to address that issue when we get to
3 specific causation.

4 MR. CHEFFO: Okay.

5 THE COURT: As I understand it, the plaintiffs'
6 argument on general causation is, listen, the -- there are
7 these admissions by the defendant and that these admissions
8 can substitute for the absence of general causation experts.
9 And there -- you know, there is some very limited case law
10 that says -- and, you know, very clear, very specific
11 admissions can -- could actually do that. And the sort of
12 two cases that sort of stand out in my mind are the similarly
13 named *In re Aredia* case, and then the *In re Mirena* IUD case
14 where they discuss this issue of admissions.

15 And, you know, the way I sort of approach this,
16 okay, let's look at these documents that constitute
17 admissions because it is really easy to sort of lob out there
18 this theory and not drill down on what the facts actually
19 are. Okay?

20 MR. CHEFFO: Fair enough.

21 THE COURT: So I was kind of hoping to -- to focus
22 on -- on just, if you would, just what are these alleged
23 admissions, and are they, in fact, the type of specific,
24 clear, concrete admissions that might in a proper
25 circumstance be an adequate substitute for adequate

1 testimony.

2 MR. CHEFFO: Thanks for that, and I think I'm
3 prepared to do that. So let's start with the kind of e-mails
4 and deposition testimony first. And I think there are a
5 number of cases that address this, both -- the *Zolof* case is
6 another one where basically this claim came up about internal
7 testimony, e-mails, as well as the *Mirena* case specifically.
8 And I think, you know, a few things: One is these are --
9 Your Honor has commented on them. These are the informal
10 types of discussions between often, you know, internal and
11 external folks. They are not peer reviewed, you know, so in
12 and of itself, I think you have to look at the context, and I
13 think as Your Honor said in CMO 68, at most they discuss an
14 increased risk or association.

15 So even if you were to somehow look at these
16 specific, you know, e-mails -- and we'll talk about some
17 public policy issues, and some of the Courts have addressed
18 that what would be inappropriate was to somehow have folks
19 who were discussing scientific issues amongst themselves in
20 preliminary, non-peer-reviewed ways and somehow have a gotcha
21 for a company.

22 So I think the first thing is, if we actually look
23 at these e-mails and deposition testimony, CMO 68, Your Honor
24 said: "It's well established in case law that an association
25 is insufficient to prove causation." So at most, even I

1 think taking the plaintiff's spin, if you will, that they are
2 at most talking about associations. I think if -- also the
3 *Zolofit* case and the *Mirena* cases have specifically rejected
4 attempts to premise general causation on employee statements
5 or company documents for good reason, as I just said, that it
6 would be contrary to public policy because it would stifle
7 discussions of adverse events and potential label changes.
8 So both I think, frankly, these little snippets -- and we saw
9 them --

10 THE COURT: First of all, you mentioned the e-mail.
11 We'll go through each one of these. The e-mail statement
12 sought to be attributed to the defendant is not a statement
13 by the defendant, but by a third party, which theoretically,
14 the plaintiffs argue, the defendant then adopted it in toto,
15 in full, absolutely, and it's an admission.

16 I have read and re-read that e-mail. I'm not sure
17 what it says because, you know, it is -- it is commenting on
18 two complicated studies, like SPARCL and TNT. And the real
19 focus of the memo -- and I read it, this is my take on it --
20 was this fascinating finding that metabolic syndrome was
21 associated with a real marker for predicting diabetes. And
22 much of Dr. Waters' focus in the e-mail is on how to do
23 follow-up studies. So my first take on it was that, you
24 know, principally what was being the focus of it.

25 I was a little perplexed. It was hard to read and

1 hard to understand the context. Then I read the deposition.
2 I only read the deposition after I read the e-mail, and, you
3 know, Dr. DiMicco basically said the same thing. He was
4 focused on -- he had the same taking on it that I had in
5 reading it. And I read with great care the plaintiffs' take
6 on the document, which I had heard previously an argument,
7 which, you know, is a lot of extrapolation of what Dr. Waters
8 meant. I didn't honestly see it that way, but, you know,
9 I -- if you turn it sideways, you can see what their point
10 is. But I didn't take it that's what -- what -- this was
11 sort of like a request to admit -- number one, admit it,
12 number two, admit it. I didn't take it like that.

13 And I really think that the IUD case is a good --
14 this can't be sort of a guess or ambiguous or -- this has got
15 to be clear and concrete. And the example in the *Minera*
16 order is that -- is the one where they say -- I think a
17 package insert or something -- specifically that it
18 substantially increases, and the judge kind of -- that's a
19 very clear statement. So I haven't had any example where
20 someone, a third-party statement, supposedly adopted in an
21 e-mail can somehow then become the defendant's admission.

22 It certainly -- I mean, I just -- it's a kind of
23 muddle what exactly it said. I mean, as I said, Mr. Cheffo,
24 my take on it was, was the whole focus about metabolic
25 syndrome and the marker and the need for additional study,

1 and he proposes two different groups. And I mean I thought
2 that was the major point of the e-mail.

3 MR. CHEFFO: That is exactly what Dr. DiMicco said.
4 It was an informal exchange with someone -- I think he also
5 mentioned, you know, a glass of wine, has your fantasy
6 football, and -- I don't want to suggest it, but, you know,
7 it can only be read with a gotcha kind of moment if you try
8 to say that somehow is the end-all and be-all. I think what
9 you are referring to is, you know, the -- in Aredia where
10 you -- Aredia substantially increases blood pressure in some
11 patients, regular monitoring of blood pressure is required.
12 There are these very definite statements both in labels.
13 That was an informal e-mail --

14 THE COURT: We'll get to the labels in a minute.
15 Okay? But this e-mail is -- I mean, I get where the
16 plaintiffs want to get, is you've got to extrapolate a lot
17 from it, and, you know, if, in fact, they have gotten across
18 the threshold -- and listen, they got across the threshold, I
19 know you agree with me, on the 80 milligrams. If they -- if
20 they could also address the issue of specific causation, then
21 this might be a piece of evidence that -- you know, that
22 would be relevant to the case. Okay? And they could put up
23 the witness and cross-examine and all that, but does it -- is
24 it a legal -- as a matter of law a legal substitute for
25 general causation?

1 MR. CHEFFO: And, in fact, I think, you know, Your
2 Honor -- and forgive me on specifics, but, you know, one is I
3 think for the reasons you said, but also even their own
4 experts didn't come forward and say, "Well, we have, you
5 know, the end-all and be-all proof here." It was part of the
6 things that they have commented on, but they relied on some
7 other things. So I think this is an informal statement. At
8 most it's ambiguous, and I don't think it is, frankly, what
9 it meant. It was clearly explained under oath by Dr.
10 DiMicco. The other thing is with such a critical important
11 factor, remember the plaintiff didn't even take Dr. Waters'
12 deposition. Right?

13 THE COURT: They published something that would
14 reach the conclusion they seek claimed in his e-mail.

15 MR. CHEFFO: Just the opposite.

16 THE COURT: Right. So I mean, I think they are
17 extrapolating more from this, but they are trying to cobble
18 together causation, and I don't think they planned this to be
19 the centerpiece of their case, but sometimes you get in
20 litigation where things don't go your way. I'm sure,
21 Mr. Cheffo, you've had that position happen to you from time
22 to time.

23 MR. CHEFFO: From time to time, I have.

24 THE COURT: It's way down the list, but you make it
25 because you don't have anything else. The responsibility of

1 counsel here is to make the best argument they can with what
2 they have, and I don't fault them for making an argument. I
3 just, looking at -- this would be unprecedented that I would
4 rely on such a document with such an ambiguous communication
5 written by a third person which allegedly the defendant's
6 vice president then adopts in some way verbatim, and then it
7 binds the defendant to it as an admission. I just don't see
8 it that way.

9 MR. CHEFFO: I know we want to talk -- I just want
10 to make sure, at least from our perspective, and I think Your
11 Honor understands this: We are in a specific -- and I'm
12 happy to go through each one of these, right? But remember,
13 we fundamentally disagree that you can essentially just pull
14 pieces of evidence out and somehow say in these complicated
15 cases you can get past general causation without an expert.

16 THE COURT: Listen, the only cases where it's ever
17 been allowed, defendants have always objected. So I get
18 that. But I'm saying, even assuming arguing, that that is an
19 available theory, you know -- and that's why I think it's
20 very important in these cases not to get theoretical. You
21 want to get specific, okay? Would this statement constitute
22 an admission? And I just don't -- I don't read it that way,
23 and it would certainly be the most extraordinary
24 extrapolation to bind a defendant that has ever been
25 recorded. I can find in the case law in the cases like

1 this nothing like this that's ever been deemed the admission.

2 And, you know, I made it a sort of point not to read
3 Dr. DiMicco's own deposition until I had thoroughly studied
4 this document. I didn't want it influencing my view of what
5 the e-mail meant. Okay? I wanted -- I didn't want him to
6 come back after the fact and sort of, you know, reach up on
7 what it means. But it was just eerie the way I read it and
8 then I read his e-mail, and it was exactly how I -- what I
9 thought he meant by it. And I did not take it as a, you
10 know, request to admit one, two, three, which, you know,
11 which is not the nature of this communication.

12 So -- and I imagine part of the argument might be
13 it's not just one document. Maybe all of them sort of
14 collectively means something as well. I just don't get
15 anything much out of this document to be in the form of a --
16 of the defendant's admission of anything.

17 MR. CHEFFO: And, again, I think that is, Your
18 Honor, fully consistent. You know, it's not even a document
19 that we feel or felt that we needed to -- this is someone who
20 was off on a frolic or detour, or trying to say, no, he
21 didn't mean that. This is a situation everybody had a chance
22 to read it. To the extent that I think it's hard, frankly --
23 you know, zealous advocates might read it one way. I think
24 it's hard for a normal person to read this.

25 THE COURT: You guys are all -- I'm trying to play

1 it straight. And I just read it just as straight up what
2 a -- you know, what a person who understood it, obviously
3 with a little expertise, to read the thing to understand what
4 it might mean. And so, anyway, why don't you move to the
5 next. What is the next?

6 MR. CHEFFO: Japanese and labeling.

7 THE COURT: Let's look at the Japanese. And I know
8 there are a whole other host of issues we don't need to get
9 into right now about whether, you know, you can use the
10 Japanese label, all that. Let's assume for argument that you
11 can use -- plaintiffs can use the label. And I, you know,
12 I -- my copy of this is page 4 of 9 in Exhibit 1586-5. And
13 the statement I was focusing on, and maybe there are others
14 somebody needs to direct me to, it says, "hyperglycemia and
15 diabetes mellitus" -- "hyperglycemia and diabetes mellitus
16 may occur." Is that legal causation?

17 MR. CHEFFO: It's not. And, in fact, I think Your
18 Honor has also addressed this in CMO 68 with respect to this
19 labeling that the 2012 warning, which I think you are talking
20 about, it can't show or support reliable expert causation. I
21 think what the Court said, and certainly we agree, is that it
22 would be -- and I'm paraphrasing here -- unreliable for
23 plaintiffs' experts to draw inferences about causation from
24 the label because -- first of all, that is not what that says
25 on causation.

1 Second of all, as we all know -- I think everybody
2 concedes the FDA has a different standard here. And to the
3 extent that somebody could come in and basically take what is
4 at best an ambiguous, but even if it was different label from
5 Japan, which everyone admits has a completely different
6 situation, and come in and say, "Well, here is what the
7 labeling says in the United States. Here is what Japan" --
8 certainly that can't be used for causation.

9 One of the most telling points about the Japanese is
10 in addition to it doesn't show causation, is what it says is
11 to the extent you have reports, what should you do? You
12 should stop taking the medicine. That is basically what the
13 Japanese folks have said, Japanese regulatory authority. I
14 don't mean to be pejorative. That is essentially completely
15 at odds with what, for example, the FDA would say in terms of
16 it's indicated -- Lipitor and other statins are indicated for
17 people who have diabetes.

18 So there are a whole host of other issues. Your
19 Honor said this earlier. We ultimately may agree or disagree
20 on some of these, whether they be admissible, you know, in
21 the face if they had proved causation, and whether there is
22 some evidence or maybe impeachment if we got up and said, "No
23 one in the entire universe ever said X, Y, and Z." Could you
24 then show, well, things like that could occur. But certainly
25 that label even read most, I think, liberally, does not

1 establish general causation as to diabetes and Lipitor.

2 THE COURT: It's -- it -- you know, that's why it's
3 important just to drill down each of these documents and say,
4 "Is there any other language you are aware of they point to?"
5 I read the whole label, and that's the only thing I could see
6 that might address that theory.

7 MR. CHEFFO: I don't. Again, we've also -- I think,
8 you know, there is a good amount of evidence that we've put
9 forth, and, you know -- so some of this is -- even if it's a
10 little bit in dispute, you have to look at the context. So
11 the quick answer is no, I'm not aware of anything else.
12 Maybe counsel will have something, and I will respond if I've
13 missed it, but I think that is what they talked about. I
14 think we've talked about the fact that it doesn't say
15 causation. There is, you know, different -- a different
16 regulatory scheme, and as we've also talked about, the
17 labeling has not changed, you know, in the United States with
18 respect to these -- these core issues of causation.

19 THE COURT: Okay. What's the next item?

20 MR. CHEFFO: I think the next one is -- the four I
21 guess I have, the two we've covered and then I have NDA
22 glucose data and the website statement about adverse event.
23 I think those are the categories.

24 THE COURT: Lipitor website obviously, something you
25 look at. That's --

1 MR. CHEFFO: And if we can just -- the NDA --

2 THE COURT: The one I'm looking at is elevated blood
3 sugar had been reported with statins.

4 MR. CHEFFO: Correct. And that is on the -- that is
5 a statement. But like the label, that's not causation. I
6 mean, if it was that clear, if it said, you know, "Lipitor
7 causes diabetes. You should be careful," you would expect to
8 see something like that probably in a black box warning. We
9 probably wouldn't have spent as much time, effort, and
10 resources if it was that clear. Basically saying that there
11 are reports of elevated blood sugar is really where we are
12 from the beginning when we kept saying, "Okay. We got that.
13 Where is the evidence here of causation with respect to
14 diabetes."

15 THE COURT: That is the amendment of the labeling
16 everything, right?

17 MR. CHEFFO: Correct.

18 THE COURT: That is what it is caused by.

19 And, you know, it's important to remember that
20 association is not causation, and that -- um, you know, it's
21 just -- it's -- and that the fact that something is reported
22 does not mean causation. Okay? There is a lot -- there are
23 a lot more steps getting there. And --

24 MR. CHEFFO: I think that's right.

25 THE COURT: That's why we have all these experts to

1 kind of get us -- we had the whole Bradford Hill thing. All
2 that is way down the line.

3 How about the U.S. label? The Lipitor label itself?

4 MR. CHEFFO: Well, I think that is really the same
5 analysis, Your Honor. I would say one further thing. You
6 are right, association --

7 THE COURT: I think it's the same. It brings up
8 increases in HbA1c, and glucose levels have been reported,
9 same language.

10 MR. CHEFFO: There are two issues here which are
11 clearly not causation, same for the website statement. The
12 first is just the plain black letter, that association is not
13 causation, right? That certainly wouldn't be enough in and
14 of itself without experts. As we talked about, perhaps it's
15 something that an expert might look at, might talk about in
16 terms of them reaching, but in and of itself, it's certainly
17 not the kind of admission that absent expert testimony it
18 says that.

19 The other thing is -- you know, there is guidance
20 from the FDA on this. These are adverse event reports as
21 Your Honor first indicated. I think you pretty much can go
22 to the FDA website, and I'm not suggesting they are not
23 important in some regard as a safety tool, but they basically
24 say these are reports kind of --

25 THE COURT: Usually a list.

1 MR. CHEFFO: And they say without reference to
2 essentially causation. So we want to hear about them, right?
3 So if somebody walks across the street in a clinical trial,
4 they will report car accident. Those things should be
5 reported. But it doesn't mean that there is a causal
6 connection. That is not the point of them. So what this is
7 doing is basically saying, "There have been reports. "There
8 are" -- which is true, which is factual. If there were
9 reports and they weren't important, I suspect that would be a
10 different lawsuit that the plaintiffs might bring for failure
11 to warn about these. So now it basically says, "There have
12 been reports. Doctors can take that information into account
13 when they prescribe." But it certainly doesn't say, and
14 can't be read to say, Pfizer admits that Lipitor causes
15 diabetes.

16 THE COURT: Then there was reference of Parke-Davis
17 drug application.

18 MR. CHEFFO: Yeah. I think that is in the -- the
19 NDA glucose data. And, again, I'm happy to talk a lot about
20 this, but I think we have in some regards with -- as you will
21 remember with Dr. Jewell, basically the three, and, you know,
22 he didn't look at or, you know, it -- I think there was some
23 question, if you will, about what that data actually meant
24 and showed.

25 THE COURT: Right.

1 MR. CHEFFO: People had diabetes before they even
2 took Lipitor and whether it was the small sample size was
3 used, and there is a host of things that rendered it
4 completely unreliable, at least for the point that Dr. --
5 Professor Jewell was trying to make.

6 THE COURT: Yeah. And, you know, the -- both the
7 statement and the application and the Medical Monitor both
8 said, "It doesn't have any" -- you know, "In sum, there is
9 little evidence to the effect of Lipitor on glucose
10 metabolism." I mean, you know, all of this, are these
11 admissions? Are these admissions? Okay? An admission of
12 what? And, you know, the race to the courthouse began when
13 it was revealed that Lipitor had some effect on glucose
14 elevation. I think it's always been instructed. They didn't
15 say it caused diabetes. Okay? And that didn't mean that it
16 didn't. That's what plaintiffs came to this Court to prove.
17 But, you know -- and they have, I think, on general causation
18 crossed the line with 80 milligrams. So it's not like they
19 haven't proven some portion of their claim as to general
20 causation.

21 But they say these statements are an admission of
22 sort of universal causation, and that I should disregard
23 ASCOT, all the experts and all of that. I should just ignore
24 all that reliable expert testimony and just say, "Okay.
25 We've got general causation." I just -- I just don't think

1 that is intellectually honest to do that. I don't see it.
2 And, you know, you and I might part ways, I think if there
3 was a clear admission, that, you know, in the right
4 circumstance, yeah. I mean, it's easy to talk in the
5 abstract, and I think the IUD case interestingly, says --

6 THE COURT: Yeah, in the abstract, you've can
7 imagine a circumstance where an admission might be
8 sufficient. It's just not here.

9 MR. CHEFFO: Well, agreed. If the question here
10 was -- and I think you asked also the right question, is it
11 an admission? I'm not going to argue both sides. If the
12 question is, would it be an admission that there had been
13 reports of elevated glucose levels, right --

14 THE COURT: The issue of general causation.

15 MR. CHEFFO: Right. So it's not -- it's an
16 admission of what it said. I mean, in some regards if
17 someone says and they believe that is true, but you can't
18 then extrapolate and say, as you said, in the kind of the
19 face of really an overwhelming, really lack of evidence, that
20 it somehow pushes you over the edge. Either I would argue
21 individually because none of them individually say it, so
22 even if you put them all together, you have a bunch of things
23 that don't show general causation. It doesn't get you --
24 just by lumping them on top of each other doesn't change it.
25 It's not that you have incremental issues here that somehow

1 you put them together and push you past the end zone.

2 THE COURT: Zero and zero equals zero. We have a
3 new lawyer in the case. What's your name, sir?

4 MR. HO: Derek Ho.

5 THE COURT: Yes, sir, Mr. Ho. Let me give you a
6 chance to address this, and we like some new blood. I love
7 Mr. Hahn, but I'm getting tired of him and all of the rest of
8 the crowd. It's good to have new blood in the case.

9 MR. HO: I drew the short straw today. Thank you,
10 Your Honor. It's a pleasure to be here.

11 And I do want to address the general causation
12 issues. I want to start with our legal position. Our legal
13 position is that we have satisfied the standard that I think
14 you are attributing to both the *Mirena* case and the *Aredia*
15 case which is there has to be some kind of a clear statement.
16 But we also think that the legal standard there is not right.

17 It's too narrow, and the reasons are twofold: One
18 is to the extent that those cases attribute a kind of clear
19 statement standard to state law, we think that they have
20 mischaracterized state law. The defendants have put in front
21 of the Court an appendix that is replete with cases that say
22 that some expert testimony is required, and that may be
23 generally true. We think that in many states you don't need
24 expert testimony, and you can supplement -- in other states
25 you can supplement expert testimony.

1 THE COURT: You know, Mr. Ho, every time I've heard
2 that argument, when I drill down on the facts of this case
3 and the law of the particular state, and I've now done it in
4 *Daniels* and I've done it in a few others, that argument does
5 not hold up. I know you say it in the abstract, and you
6 throw it out there, but -- and we'll get into it, and -- when
7 we are talking about *Daniels* and *Hempstead*. But it just
8 doesn't -- that argument just doesn't carry water. If you
9 had that, and you don't need expert testimony to prove what
10 really is specific causation, what we are talking about, but
11 also just general causation, that statement would have -- all
12 of the drug cases in the country, that would be like the
13 black hole of pharmaceutical liability. Everybody would race
14 there. No one has talked about such a state.

15 And one of the things I'm pressing y'all to do is if
16 you claim in this set of facts -- now, you are new to this
17 case, and I think it's kind of instructive. You are up
18 arguing instead of Mr. Hahn, this argument, which I take it
19 from our last telephone conference is your creation. It's a
20 completely different view than lead counsel has taken
21 throughout this litigation. It's just not so. And I know
22 you come at us -- I have been there. I have been in these
23 hearings, I have been in these meetings. It's different.
24 And one day, you know, that might not matter. If there is
25 merit to it, maybe you can change our course right as you

1 finish crossing the river. I don't know.

2 But I think it's important to drill down on these
3 issues, and when I drill down in *Daniels* and in *Hempstead*, I
4 don't find the law in those states allowing facts such as
5 this, that you don't need experts for some complicated
6 disease. And, you know, I mean, you look at this
7 particular -- in these cases, I have looked now at -- I have
8 over 2,000 cases, over 5,000 plaintiffs. I have read dozens
9 of medical articles, case notes. I have yet to see a case
10 that was within the common lay knowledge of people -- lay
11 people -- to determine causation on diabetes. I haven't seen
12 one yet. I'm not going to say there isn't one, but I haven't
13 seen one.

14 And I was in the meeting, and you were not, with
15 Mr. Hahn where Mr. Cheffo made the statement -- I was in the
16 conversation, where Mr. Cheffo made the statement, how do
17 we -- we were discussing how do we get to summary judgment.
18 And Mr. Cheffo recommended that -- that we wanted to get
19 in -- we wanted to test these *Daubert* cases, and whether the
20 Court's determination on *Daubert* was correct. And Mr. Cheffo
21 says, "Listen" -- well, first of all, Mr. Hahn said, "I
22 can't" -- you know, I kept saying, "Give me a case to try.
23 Give me any case to try."

24 No one said, "Oh, you don't need experts. Come on.
25 I've got the Smith case. We can try that."

1 I repeatedly said, "Get me a case to try." I set
2 time aside and everything. No case. I can't do it if I
3 can't overturn your *Daubert* rulings. We then -- this is when
4 the conversation was, how do we -- I want to make sure this
5 applies to all the plaintiffs. So I signed an order and
6 said, "If you don't agree with lead counsel, you think your
7 case can survive summary judgment, come forward." Silence.
8 Now, I did it again. Again, I got no response. This time
9 15 days wasn't enough. We had two years.

10 Now I'll give you 60 more days. And I'm going to
11 look at every one of these cases to see if they are somehow
12 different from the understanding I have acquired from in
13 this. But the bottom line here, what is common in every one
14 of these cases is that you are trying to prove a drug caused
15 diabetes, a multifactorial disease in which everybody
16 presents that I have seen with multiple risk factors, and
17 causation is not apparent. It's a sophisticated injury as
18 Missouri describes it. I haven't found a state that said,
19 "You don't need experts; it's within the lay knowledge."

20 I've got to say to you, I come -- I know you come
21 late to this, and you come with a great deal of energy and
22 enthusiasm. I come from years of reading and listening to
23 very able counsel on both sides. And, really, your view,
24 Mr. Ho, is that the lead counsel didn't know what he was
25 doing, that there really was this whole other theory in this.

1 I respectfully disagree with you. I think he gave the best
2 argument he could. He's ably represented his clients, and I
3 think this is a Hail Mary. That's my own take on it, and I
4 have read carefully these briefs.

5 And maybe there will be more cases. Maybe you will
6 come forward and show me cases, and I say, you know, that is
7 a set of facts which is just apparent. I haven't seen it
8 yet. And I haven't seen it one time. And, you know, this
9 is -- you know, I've spent 30 years litigating
10 medical-related issues. I'm pretty familiar with medicine.
11 And I'm very familiar with diabetes, and that's why the MDL
12 assigned me the panel, assigned me this case. And what I've
13 learned further through this case is just how complex that
14 determination of causation is. And so -- you know, that
15 specific causation, general causation, you know.

16 So you say to me, "Oh, there are states," and you
17 list those states. I'm looking forward to you giving me the
18 facts of the case, specific facts, and let me look at the law
19 of that state, because every time I do that, it just doesn't
20 wash. So, anyway, I want to be honest with you about my view
21 of this, Mr. Ho, and, you know, I'm open to -- I read these
22 briefs, assuming that you contributed heavily to them and had
23 a new take, and I said, "Maybe he's got something we've all
24 missed." I don't think so. Maybe I'm wrong.

25 MR. HO: Your Honor, I don't want to change the

1 subject. I understand that Your Honor wants to talk about
2 general causation. I do want to address specific causation
3 when we get there. But the reason I --

4 THE COURT: The issue about these states just don't
5 really require it. And I'm just saying to you, I
6 respectfully disagree with you, that in circumstances like
7 this -- now, are there cases that have addressed the issue of
8 can you in the absence of expert testimony prove causation by
9 admissions? I mean, I'm aware there are -- there is a
10 limited body of case law on that issue. And I think that is
11 where you are generally on general causation. I think
12 specific causation, you go to the point that there is -- you
13 know, that you don't really need expert testimony for -- to
14 prove specific causation either. You could do some
15 combination.

16 MR. HO: The point I was trying to make is the state
17 law cases that are cited by the defendants, they do not
18 address the admissions question.

19 THE COURT: I understand.

20 MR. HO: So --

21 THE COURT: So you are arguing -- let me make
22 sure -- I had understood the focus -- and, listen, to the
23 extent you think you can prove general causation without
24 expert testimony, um, I know the two cases we have. I've
25 studied carefully the law in those two states, and I think

1 you are wrong. Okay? I don't believe those states would
2 allow it. I focused also on the issue on general and
3 specific causation. I also focused on the issue of whether
4 admissions might substitute for expert testimony. And there
5 is a limited body of cases, we have been talking about them
6 today, that recognize that as an alternative path. But when
7 I have sat and studied these alleged admissions, to me they
8 are a bunch of nothing. And there is a reason that your lead
9 counsel has not focused on these. Certainly mentioned them,
10 has not been the centerpiece of their case because it's not
11 much of an argument. But when you've lost on the *Daubert*
12 arguments, I don't fault them for making an argument. I
13 mean, I think they are doing exactly what they need to do.

14 But it doesn't -- it doesn't mean that I should just
15 sort of accept -- when you throw out, 'Oh, there are all
16 these states,' come forward. I've got two states right here.
17 We are here on *Hempstead* and *Daniels*, Colorado and Missouri.
18 I've got facts in these cases. Show me why you don't need an
19 expert on the law of those cases, why the facts here would
20 allow you to survive summary judgment. Very specific.

21 And I think -- I think it's going to be the
22 universal answer. My own opinion is it's likely going to be
23 the universal answer because of the complexity of proving
24 causation associated with diabetes. I mean, there are other
25 reasons, too, but that is a really big one here.

1 MR. HO: Your Honor, I want to make sure we are on
2 the same page as to two different questions that are on the
3 table. One is can nonexpert testimony be used in conjunction
4 with expert testimony to prove causation by a preponderance
5 of the evidence.

6 THE COURT: Are you talking about specific, general,
7 or both?

8 MR. HO: I think they are intertwined. But the
9 second question is --

10 THE COURT: They are two different questions, right?
11 You've got to prove general causation, and you've got to
12 prove specific causation.

13 MR. HO: They are two different elements. But I
14 think the question of whether you can use expert and
15 nonexpert testimony together applies in some ways to both
16 because the two are intertwined. There is a separate
17 question which is can you use admissions instead of or in
18 addition to expert and nonexpert testimony.

19 THE COURT: I already said that.

20 MR. HO: I just want to make sure.

21 THE COURT: Yes. I recognize that.

22 MR. HO: And on that question, my -- the point that
23 I was trying to make is that the state law cases that the
24 defendants cite do not address that question. They are not
25 talking about admissions. The cases don't involve an effort

1 to use admissions.

2 THE COURT: Right. This is a creature of some
3 recent case law about product liability cases and efforts
4 to -- when the expert testimony didn't work out for the
5 plaintiffs, they then retreated to these admissions. And
6 there are several cases, not many. I agree, it's a different
7 path, but the one path is can you, without expert testimony
8 that -- I mean, I held that the testimony doesn't satisfy
9 *Daubert*, so you don't have expert testimony that meets a
10 legal standard that as a gatekeeper I would allow to be
11 presented.

12 And then you ask, "Oh, um, we think you can prove it
13 through other means." And what I've looked -- when I drilled
14 down in Missouri and Colorado, very specific, it talked about
15 the need for expert testimony for a sophisticated injury,
16 that these things that are beyond the lay knowledge, beyond
17 the lay knowledge of jurors, then you've got to have an
18 expert; and otherwise, it's just speculation. I'm just
19 quoting from these cases. That's what they say. And I have
20 yet to see a scenario -- and you can drill down on *Daniels* or
21 *Hempstead* and tell me what is so apparent about causation in
22 those cases? You know, the defendant -- I don't know if
23 you've had a chance to read all of the stuff, but, you know,
24 the defendant's expert -- the plaintiffs' experts were asked
25 by the defendant a whole series of questions about their

1 ability to pick out of a crowd who had diabetes, how could
2 they diagnose, how could they identify specifically, and we
3 don't have a method. There is no test. There is no clinical
4 presentation for a Lipitor-induced diabetes. So --

5 MR. HO: Your Honor, I think we are talking now
6 about specific causation, and I just wanted to --

7 THE COURT: Tell me how you can prove general
8 causation without experts.

9 MR. HO: We think that we can satisfy the test that
10 Your Honor has attributed to the *Mirena* case and the *Aredia*
11 case. In other words, we think that these statements --

12 THE COURT: You think these admissions -- I've got
13 the admissions. Come back to that in a second. What else
14 other than the admission path to general causation, if any?

15 MR. HO: We do think that the fact that Dr. Singh
16 has been admitted on 80 milligrams does also play a role,
17 because one of the admissions that we attribute to the
18 defendants is that 10 and 80 are the same. So we --

19 THE COURT: I know that. I've heard that theory
20 before. I don't buy it. What else?

21 MR. HO: I think it's the admissions plus
22 Dr. Singh --

23 THE COURT: Okay.

24 MR. HO: -- on general causation, but the point that
25 I'm trying to make is that in addition to --

1 THE COURT: Dr. Singh himself says that unless he
2 could use the remanipulation of the data by Dr. Jewell, he
3 can't give an opinion about 10 either. So now you are trying
4 to attribute something that he himself does not buy.

5 MR. HO: Your Honor, I think that argument
6 misapprehends the fundamental point which is that under
7 Rule 801, there is no trustworthiness criteria for
8 admissions. And the Advisory Committee notes to 801 make
9 absolutely clear that the rule on opinions, Rule 701 to 703,
10 do not apply to Rule 801.

11 THE COURT: It says something -- you are arguing
12 that these are admissions, and I welcome you to do the same
13 thing I put to Mr. Cheffo and tell me why that is an
14 admission on causation.

15 MR. HO: I would be glad to, Your Honor, but I want
16 to make one other legal point before I do, and that is we
17 also believe that the legal test that Your Honor is
18 attributing to *Mirena* and *Aredia* is too stringent and --

19 THE COURT: These are the ones that you are relying
20 on. Are there other cases that got it right?

21 MR. HO: Well, we think that the cases -- I wouldn't
22 say that there is a case that got it fully right. I think
23 that we --

24 THE COURT: Nobody has got this theory down, but the
25 plaintiffs' argument here, that's the only one that has got

1 it right.

2 MR. HO: I -- I don't think that there is a single
3 case that we would agree with everything that is written in
4 it. I think that *Mirena* and *Aredia* actually support the
5 plaintiffs' argument.

6 THE COURT: The defendant constantly disagrees with
7 cases that go against them, too.

8 MR. HO: It's a tried and true fact.

9 THE COURT: Surprise.

10 MR. HO: But the reason we believe that that --
11 those cases -- to the extent that those cases articulate some
12 kind of clear standard of the facts, that that test would be
13 too stringent.

14 THE COURT: What test?

15 MR. HO: The proper analysis, we submit, is as
16 follows: Under Rule 801, a statement by a party opponent or
17 by the party opponent's employee within the scope of the
18 employment is admissible for the truth of the matter
19 asserted. So you take the admissions or the statements, you
20 look at them, and the substance of those statements is
21 admissible. And then the question is under Rule 56, do those
22 statements create a genuine issue of material fact? And on a
23 Rule 56 motion, all inferences from those statements have to
24 be drawn in favor of the nonmoving party. That is
25 inconsistent with a clear statement rule that says that

1 ambiguities ought to be taken in favor of, here the moving
2 party, or the defendant.

3 And the reason why *Mirena* gets it wrong is because
4 *Mirena* attributes to the states a rule that says you have to
5 have expert testimony. That's not the rule. Again, not on
6 the lay versus expert point, but on the admissions point.
7 The state law cases that the defendants have cited don't talk
8 at all about admissions.

9 And more than that, even if there were a state that
10 said, "You know what? In products liability cases, we just
11 categorically prohibit consideration of statements by a party
12 opponent or admissions," that would not apply -- that rule
13 would not apply in Federal Court in a diversity case because
14 Rule 801 supersedes state law as a procedural rule under the
15 Supreme Court's decisions in *Hanna* --

16 THE COURT: Show me how the statements themselves
17 constitute an admission. What is the language? Because your
18 brief says they admit causation. I frankly didn't read them
19 that way. But I would love to see your take on the language
20 and how you get there.

21 MR. HO: Absolutely, Your Honor. I will -- I will
22 say that, just as a threshold matter, that the most important
23 thing is to look at the document itself. There were some
24 references to Dr. DiMicco's deposition testimony, and I
25 understand that, Dr. DiMicco wants to walk away, or walk

1 back --

2 THE COURT: Listen, I told you that I was suspicious
3 about that, that I didn't want to read it until I read the
4 document myself. And because I didn't want his take on his
5 own thing, potentially self-serving, to explain it away, so I
6 focused on the e-mail itself, and it's a muddle to me. I
7 mean, I know the plaintiffs -- I mean, my first introduction
8 to it, frankly, was Mr. Marcum mentioned in an argument, and
9 I went back and read it then. I don't see how he's getting
10 there, but I see what -- how he's -- I see where the argument
11 is coming from. And -- but I have been hearing about
12 these -- this admission for a long time in this e-mail, and
13 I -- I mean, I don't see it in the documents. And so --

14 MR. HO: Your Honor --

15 THE COURT: -- it reminds me a little bit about does
16 the -- you know, the Beatles song say Paul McCartney is dead
17 when you play it backwards. Everybody hears what they want
18 to hear. I don't see it. Certainly not something that even
19 using the standard for summary judgment, the light most
20 favorable to the plaintiff, casting all inferences in its
21 favor, I don't see it getting there.

22 MR. HO: Your Honor, before we dive into the
23 document, and, again, I'm happy to, this is the frame of mind
24 with which I would suggest that Your Honor look at the
25 document: There is no different rule under 801 and

1 Rule 56 -- or Rule 801, rather, for pharmaceutical drug cases
2 than there is for narcotic drug cases. If this were a
3 statement by a coconspirator in a, you know, a cocaine
4 distribution case, and you had the coconspirator on tape
5 saying, "We did one kilo a week and it was 75 percent pure,"
6 and the -- the Federal Government had never recovered the
7 drugs so it's not able to test whether or not that statement
8 is true or false, and, you know, that --

9 THE COURT: I find that a very odd analogy, frankly,
10 but go ahead. I don't consider that similar.

11 MR. HO: It's similar in the sense that a lay juror
12 would not be able to tell by looking at some powder in a bag
13 whether it's cocaine and certainly not the level of purity of
14 the cocaine. What would ordinarily happen --

15 THE COURT: A clear and unambiguous statement about
16 what I have here is cocaine. Now, get to the statements. I
17 know your theory. Show me in the statement where it says
18 causation.

19 MR. HO: Let's start from the beginning of the
20 e-mail chain if Your Honor is willing.

21 THE COURT: Okay.

22 MR. HO: The first e-mail is from Mr. Waters --
23 Dr. Waters I should say -- to Dr. DiMicco, and he says, "Just
24 wondering whether Andre has done the diabetes and SPARCL
25 analysis yet." And as Your Honor knows, that is Andre

1 Brezenoff who is a Pfizer statistician. This is all in the
2 context of Pfizer statisticians doing re-analyses of the
3 SPARCL data. The next e-mail is Andre is having another
4 statistician work on it. And then when you get to the top of
5 the second page of the chain, "Attached please find the
6 outputs from the analyses," now we have actual --

7 THE COURT: So we have a document --

8 MR. HO: We have an attachment.

9 THE COURT: -- which is referenced but is not
10 included here.

11 MR. HO: That's correct. It's not exhibited to the
12 summary judgment papers.

13 THE COURT: It also references to the TNTs.

14 MR. HO: That come later.

15 THE COURT: I understand, but I'm saying that is all
16 the background of this e-mail. It's not -- what -- my point
17 is this is an iceberg. There is a lot of underneath the
18 ground here -- underneath the water about what is going on
19 here. There is a very complicated discussion about several
20 studies and what those studies may teach us.

21 MR. HO: And I think it's an important point that
22 when we are talking about analyses that Pfizer is doing, this
23 is not -- there is no argument here that this is some frolic
24 or detour by Dr. DiMicco or by Dr. Waters. This is their --
25 they are focused on these analyses. It's not an offhanded

1 comment. And, frankly, I still think, just as an aside, that
2 those are the kinds of arguments that are properly presented
3 to a jury. But, you know, the -- but to the extent that Your
4 Honor is considering them, I think it is relevant that this
5 is not some kind of offhanded, informal thing as the
6 defendants have tried to suggest. They are doing analyses of
7 this data --

8 THE COURT: The data that you seek to contribute to
9 Pfizer are the statements made by Dr. Waters; is that
10 correct?

11 MR. HO: Well, we'll go through the e-mail.
12 Dr. Waters then says, "Having received these analyses" -- and
13 this is to Dr. DiMicco -- "very nicely done analysis. The
14 results are certainly unambiguous." So in Dr. Waters' view
15 the results are unambiguous. That's the plain language of
16 the e-mail.

17 THE COURT: You and I both know that he's referring
18 to the SPARCL study regarding this analysis which only deals
19 with 80 milligrams, correct?

20 MR. HO: When you say -- the e-mail goes on,
21 because --

22 THE COURT: I understand, but I'm saying to you
23 there is a lot more -- you are trying to -- you are trying to
24 extrapolate something that is a very complicated -- there is
25 a lot of data and information here. A lot is going on here,

1 and you are grabbing the -- you are grabbing language in
2 which there is a context to it, and the question -- it's not
3 by Pfizer, it is by Dr. Waters. And then you have
4 Dr. DiMicco respond -- DiMicco responding to that, and you
5 are interpreting that as like a request to admit that he has
6 adopted verbatim precisely everything in that e-mail where I
7 didn't read it that way. And I certainly don't assume that.

8 And then you want to attribute to Pfizer something
9 from Dr. Waters that Dr. DiMicco responded to an e-mail. It
10 is a very -- Mr. Ho, you know, you can -- I understand the
11 context of this. I do. But the question is, is can I read
12 that into this very obscure statement? It's not clear what
13 they are driving at here. And the focus I took to this whole
14 metabolism issue -- and when you go to Dr. DiMicco's
15 deposition, that was his take on it as well. And he said, "I
16 wouldn't try to make a line-by-line admission or addressing
17 these points one by one." That is why there's not one case I
18 could find where an admission comes from the statement of a
19 third party you are seeking to attribute.

20 I mean, have we really come to liability that you
21 can take somebody's response to an e-mail, and you've
22 suddenly gotten an admission involving 5,000 cases? I mean,
23 I -- we've got to have a little bit of standards here about
24 what constitutes an admission. And, you know, I -- listen,
25 you go ahead. I mean, it says -- he says that "increases the

1 risk of developing diabetes, but we know the SPARCL study
2 only dealt with 80 milligrams." You want to extrapolate that
3 that is an admission about everything. And then it says,
4 "The risk of 10 and 80 are similar for the TNT." You are
5 assuming that he's now attributing to that. Dr. Waters never
6 published such a thing.

7 But now you want to attribute it to that, and I'm
8 supposed to say, "Oh, okay."

9 And then the third point it talked about metabolic
10 syndrome, and they are writing back saying, "You've got to do
11 further studies on that," and that seems to be the focus of
12 Dr. DiMicco. You know, I don't know. You know, the -- you
13 have to go to the Fourth Circuit with this thing, Mr. Ho.
14 I've got to be honest with you. I think you are
15 extrapolating, and you are building one supposition on top of
16 another supposition to avoid what is sort of foundational,
17 which is that we don't have a jury guessing -- we don't have
18 them guessing, speculating about causation. There is
19 actually reliable evidence. That's why we have a gatekeeper.
20 That's why we have summary judgment, that we don't just back
21 up a truck and dump stuff in a courthouse and ask our jury to
22 sort it out. Sometimes they don't have the expertise to do
23 that.

24 MR. HO: Well, there are a lot of points in there.
25 And I understand that Your Honor has indicated his view. So

1 let me not try to respond to everything that you've said.
2 We'll reserve our appellate rights. Obviously --

3 THE COURT: By not responding, I do not take that as
4 an admission.

5 MR. HO: Thank you, Your Honor.

6 I would like to respond to the point that you made
7 about speculation because that comes from the *Mirena* case.
8 The *Mirena* case was decided after we filed our brief, so --

9 THE COURT: It comes from a whole line of cases that
10 say that you've got to have expert testimony because
11 otherwise it leads to a jury to guess and speculate. It was
12 not developed in that one case. You are wrong about that.
13 It was mentioned in that case, but it derives from a whole
14 body of law that says this. And what y'all are attempting to
15 do, you came into the case armed for battle with experts.
16 Nobody was thinking about trying to prove this case through
17 alleged admissions.

18 MR. HO: That is not our preference, Your Honor.

19 THE COURT: No, of course it wasn't. You weren't
20 here. These are -- you know, the inference of your argument
21 is these guys missed the boat. I personally think they put
22 forward the best effort and the best argument they could on
23 behalf of their clients. And it just didn't -- the science
24 didn't carry the day. It just didn't -- couldn't carry. The
25 experts couldn't get there. And God knows I gave them every

1 chance, Mr. Ho. I mean, I don't know if you compared all the
2 times over Mr. Cheffo's screaming, red-faced argument to the
3 contrary that I gave them all these chances to come back and
4 try to prove their causation, both on general and specific.
5 But these documents, I mean, you've got to extrapolate
6 extremely heavily. If all we can say is if you can just
7 imagine it in some way, ha, ha, 801, Rule 56, goes to a jury,
8 even though you don't have any expert testimony. That is the
9 law. We don't need any gatekeeper because you can just back
10 up a truck and just dump it into the courthouse, and then you
11 can just -- you can have such a light review.

12 But I'm not going to abandon the need to examine
13 these documents. And the best you've got is a third-party
14 statement that someone responds to, and you are going to
15 interpret it as a verbatim, complete swallowing of the entire
16 e-mail, and that is the admission? You are going to get a
17 court other than me to agree with that.

18 MR. HO: Just a couple of limited points.

19 One, I really have a hard time seeing what the
20 ambiguity is when there are three points, the first two of
21 which are there is general causation, and there is -- the
22 effects of 80 and 10 are the same. And then Dr. DiMicco says
23 in response, "As far as the conclusions, I concur with your
24 assessment below." There are only three conclusions in the
25 document, the first two of which are the admissions that we

1 say allow us to survive summary judgment. Your Honor's point
2 that he must have been talking about the third one to me is
3 not a reasonable reading of the document.

4 THE COURT: That's your read of it. Point number 1
5 relates to the SPARCL study which only deals with
6 80 milligrams.

7 MR. HO: Then he goes on to say 80 and 10 are the
8 same.

9 THE COURT: He says that as to -- so you are
10 extrapolating that he has reached the opinion that there is
11 causation at 10. That is what you are concluding. He
12 himself says that's not true. Dr. Singh, your expert, says
13 that he can't manipulate the data -- he can't manipulate the
14 data. He can't say it. ASCOT says it's not true. And I'm
15 supposed to take this extrapolation you take and say, that's
16 an admission?

17 MR. HO: We don't agree with that characterization
18 of the other evidence. But the proper analysis here is you
19 look at the face of the admissions, and those admissions are
20 taken for the truth of the matter asserted, and all the
21 other -- all of the other arguments that you are pointing
22 out, those can be raised to the jury. Those go to the jury.

23 And as to the point about speculation, you raised
24 this policy issue about the need to speculate. There is no
25 speculation issue here because with respect to admissions,

1 the way that the jury will determine whether these admissions
2 should be credited or not is by assessing the credibility of
3 Dr. DiMicco. Dr. DiMicco will get up on the stand. He'll be
4 confronted with these documents, and he will say whatever
5 he's going to --

6 THE COURT: He adopted some third-party statement.

7 MR. HO: He'll say --

8 THE COURT: There has got to be some evidentiary
9 standard here. And you argued, no, no, we can -- we can put
10 a document up. We read it a certain way, and we suspend all
11 other needs for evidence and for general causation. I
12 respectfully disagree with that view. I read the document
13 differently than you do. You are an advocate. You take your
14 view. You will have a chance to advocate to a higher court.
15 I don't have a dog in this fight. I read the document, and I
16 read it differently. And I don't read it ignoring the
17 context in which it is written and what he's talking about.
18 So I just -- I don't -- I just read it differently.

19 But -- and I certainly don't read it as an admission
20 by the vice president of Pfizer on behalf of Pfizer to admit
21 that Lipitor causes -- causes diabetes. I don't read it that
22 way. I don't think he meant it that way, and that's your
23 take on it. We respectfully disagree, but the good thing is
24 you are not locked in to what I say. You get to go up to the
25 Fourth Circuit. That is what you have been hired to do. And

1 you may persuade them otherwise. I respectfully disagree
2 with you.

3 MR. HO: I have to agree to disagree. I'm happy to
4 answer any more questions on that score, but I understand
5 Your Honor's position, and as I said, we'll reserve our
6 rights on that.

7 THE COURT: In your view, does the e-mail, admit
8 association at 10 milligrams or causation at 10 milligrams?

9 MR. HO: Causation, Your Honor, and the reason is it
10 says, "Lipitor increases the risk of developing diabetes."
11 You look at the plain language of what is written there, and
12 it doesn't say, "Lipitor is associated with an increased
13 risk." It says, it increases the risk. And there are plenty
14 of cases that say that is exactly what general causation
15 means, and then it says, "The risks of 10 and 80 milligrams
16 are similar."

17 THE COURT: You extrapolate from that that he's
18 admitting 10 milligrams is caused -- diabetes causes
19 10 milligrams. That is how you read that?

20 MR. HO: Your Honor, yes. I'm not trying to be
21 flip. I don't think I'm extrapolating. I think I'm just
22 reading the words on the page.

23 THE COURT: And did y'all depose Dr. Waters?

24 MR. HO: I am not aware that he was deposed. I
25 didn't depose anybody.

1 THE COURT: I'm stunned you would not depose him.

2 MR. HO: Your Honor, that is not relevant to the
3 admissibility of the document.

4 THE COURT: I mean, I'm reading it a certain way,
5 and you did ask Dr. DiMicco about it. I know that Dr. Waters
6 published things that don't go along with your read of this
7 e-mail. He has not reached that conclusion. And so, you
8 know, I'm just curious how -- you know, you are saying,
9 "Well, we don't really want to know what he says." I think
10 you all know what the answer is; that's why you didn't depose
11 him. He's published things to the contrary. So you are now
12 assuming that he wrote something -- that he had some
13 dishonestly -- he wrote something in the e-mail that he
14 dishonestly sort of doesn't really buy anymore and that Dr.
15 DiMicco adopted the entire e-mail as Pfizer's position and is
16 bound by it. I think that is too much of a stretch.

17 MR. HO: It's Dr. DiMicco's statement that is
18 attributable to Pfizer. And there is no rule that says that
19 you need to have corroboration of a statement of a party
20 opponent through deposition testimony.

21 THE COURT: I completely agree with that. Now,
22 let's look at statements that we know are Pfizer's
23 statements. Let's look at -- are you pointing to -- do you
24 want to look at the U.S. label and tell me --

25 MR. HO: If Your Honor pleases, I would like to

1 actually go to the Japanese label first because --

2 THE COURT: Let's go to the Japanese label.

3 MR. HO: To my mind the Japanese label and the
4 DiMicco-Waters e-mail exchange are the piece because they --
5 again, looking just at the words on the page, they say -- the
6 Japanese label says, "Diabetes mellitus may occur." And
7 that, I think, plainly isn't properly interpreted, or
8 certainly can reasonably be interpreted as a statement of
9 general causation. So we think that the Japanese label is of
10 a piece --

11 THE COURT: You read that to say hyperglycemia and
12 diabetes, that hyper -- that Lipitor causes diabetes. That's
13 how you read that statement?

14 MR. HO: Yes, Your Honor, and I guess I -- I'm
15 struggling to see how it could be read otherwise, because
16 although you have to, I would admit, think about what "may
17 occur" when. I mean, obviously, if the sentence ends there,
18 but --

19 THE COURT: But may, something that may -- you know,
20 the classic thing is -- the classic example is that ice cream
21 sales and crime rise in the summer. They may occur commonly
22 with each other. The ice cream sales don't cause crime, or
23 crime don't cause ice cream sales. They just coincide. That
24 they may occur in association with each other does not prove
25 causation.

1 MR. HO: You would never put a label on an ice cream
2 cone that says, "Crime may occur when you eat an ice cream
3 cone." The only reason you put this on a label is because
4 what is meant by this that is diabetes mellitus may occur
5 when you take Lipitor; and importantly, when you take Lipitor
6 at 5 milligrams or 10 milligrams, which are the dosage to
7 which this label applies. So, again, we think that the
8 Japanese label, like the DiMicco-Waters e-mail are statements
9 by a party opponent of general causation at doses as low as
10 10 milligrams.

11 THE COURT: Okay. How about the U.S. label?

12 MR. HO: The U.S. label's language is different, and
13 I will acknowledge that it is not as supportive of our
14 position as --

15 THE COURT: Had been reported.

16 MR. HO: Right. I think it's a closer call, whether
17 if we were relying on that alone, we would get over the
18 hurdle, but we certainly think that that is an additional
19 statement by a party opponent that is corroborative of the
20 statements in the Waters and DiMicco e-mail and in the
21 Japanese label, and that, in combination with all the other
22 statements by Pfizer, help create a genuine issue of material
23 fact.

24 THE COURT: Okay. And how about the Parke-Davis
25 statement?

1 MR. HO: I would put that generally in the same
2 category as the U.S. label.

3 THE COURT: You want me to focus on the Japanese
4 label and on the e-mail?

5 MR. HO: I think the others are a much closer call
6 in terms of whether they alone would be sufficient under
7 Rule 56.

8 THE COURT: Thank you, Mr. Ho. That is very
9 helpful.

10 Let me give -- Mr. Cheffo, anything you want to
11 respond on general causation before we go to specific?

12 MR. CHEFFO: The only -- well, I say not really. I
13 think two very quick points. And I think Your Honor
14 addressed most of these during the discussion with both me
15 and counsel. I mean, the first is, you know, again, I'm not
16 going to go back and say this is why we need the, you know,
17 expert testimony. I know this is kind of an alternate
18 argument assuming we don't to get to this point. That is the
19 problems that you said of dumping documents to a jury.

20 The other thing that seems to be lost in this -- in
21 counsel's argument here is that it's as if *Daubert* doesn't
22 apply. Right? So let's give kind of a little whacky
23 example. Let's assume somebody on their last day of work at
24 a company said, "I think X, Y, Z causes it or harms people."
25 Under counsel's analysis, you wouldn't need *Daubert* because

1 that is an admission. You can't look at it.

2 THE COURT: Even if you had data to the contrary.

3 MR. CHEFFO: And you can't look at -- if the person
4 was going to -- was a whistleblower, you know, you could spin
5 this --

6 THE COURT: What happens within the scope of their
7 duties and all that. But the question is -- is sort of, if
8 you can take a random comment -- and this was not even a
9 comment of the defendant. It's a comment of a third party
10 that the defendant seemingly endorsed this. And then you
11 assume that line by line it is endorsed, and then you
12 attribute it to them, and then you don't have to have expert
13 testimony. I mean, is that really what the law is?

14 MR. CHEFFO: No court has allowed that. Even if it
15 was a good faith -- that's what the case -- the *Zoloft* case,
16 the *Mirena* -- let's say when you have a good -- let's assume
17 it's not a bad faith. Someone during the course of
18 their e-mail says we are going to look into this, because
19 I've looked at X, Y, and Z, and I think it causes X. It
20 could be an automotive case, a computer case, and then you
21 pull the thread, and they look at it, and we have now looked
22 at it, and like here, like we are going to publish, and we've
23 looked at all the data --

24 THE COURT: Dr. Waters does publish something.

25 MR. CHEFFO: What Dr. DiMicco says, which we didn't

1 hear about, is in his sworn testimony, he said, "This
2 reflected Dr. Waters' first pass look at the results of the
3 analysis. It still required time to think about it, to
4 interpret it, and ultimately put it into a manuscript, and
5 was submitted and published." What the plaintiffs now are
6 trying to do, which is comparing this to like drug cases,
7 it's completely in opposite, because the idea is you have to
8 start with the premise that it's Your Honor's role as a
9 gatekeeper to determine whether there is reliable evidence.
10 It's not to basically say that is irrelevant. If I could
11 find, even if there was such an e-mail, an e-mail that said,
12 "We think that there is causation" -- same thing with the
13 labeling.

14 You know, ultimately what you have to look at is the
15 whole constellation of evidence and then make a determination
16 as to whether there is reliable evidence. You know, we
17 disagree with you at 80, but you did it at 80, and you did
18 that based on looking at all this information and the
19 constellation of evidence. So to say that all goes away, and
20 we spent all that time in courts across the country, and
21 there has not been a single case where a court has looked at
22 it and said, "Well, I've done the whole *Daubert* 702 analysis,
23 but somehow there is an e-mail over here, so all of that goes
24 by the wayside."

25 THE COURT: You are talking about adopting --

1 attributing it -- to me the things that you can really -- you
2 know, Pfizer label, the Pfizer website, this is -- you know,
3 of course in the one case that recognized you used the
4 admissions, it was something that specifically said it in the
5 label. You didn't need to turn it sideways and put -- add
6 these things together and say, "This is what I think they
7 mean." You know, Mr. Ho is a smart guy. It may hit him --
8 and I'm just a little slow down here in South Carolina, but
9 it doesn't hit me that way. I didn't read the statement that
10 way. And I don't read the e-mail that when someone responds
11 that they are saying, "I buy everything you say and I -- I
12 hereby formally adopt it and bind my company to it." It's
13 just the nature of the communication.

14 MR. CHEFFO: Yes, Your Honor.

15 THE COURT: Dr. Waters does publish it. They
16 attribute to him an e-mail. He doesn't have it either.

17 MR. CHEFFO: It's not even what their experts, the
18 folks who are the smart folks in the room, you know. And as
19 you know, we didn't challenge qualifications. We took some
20 other issues, and that wasn't the centerpiece. And I think I
21 would agree, these are smart, very competent counsel, and
22 this was a piece of the kind of constellation of evidence,
23 but no one ever said, you know, "Irrespective of our experts,
24 we think an e-mail gets us past go." With that, Your Honor,
25 I have nothing more on general causation, unless you do.

1 THE COURT: Let's move on to specific causation
2 because that's the only really issue that really would get
3 the defendant to summary judgment, because to the extent that
4 there is general causation at 80 milligrams, not in these
5 cases, but there would be cases, the omnibus cases, so it's
6 important that we address this issue of whether you can prove
7 specific causation without expert testimony.

8 MR. CHEFFO: And you will have to, you know, guide
9 probably me and counsel as well, you know, in -- I know we
10 have an argument on omnibus. I'm happy to talk as much as
11 you would like about that, or we can first start with the
12 specifics.

13 THE COURT: I intend -- you know, to me, I've got --
14 I look at these things. I certainly drill down on these two
15 cases here, but obviously generally the whole idea of how do
16 you prove specific causation is something that is universal,
17 right? How do you get there? And, you know, and we spent a
18 fair amount of time looking at two states now in these
19 particular cases, which it was represented to us was that it
20 was easy to read expert testimony in Missouri and Colorado.
21 You didn't really need it, and that these cases, you know,
22 there was other evidence of specific causation. And the one
23 thing I see -- I mean, let's focus -- I think it's helpful to
24 focus on the particular cases. Okay?

25 So let's for just a minute talk about *Daniels* and

1 the Colorado law on *Daniels*. My note is that Ms. Daniels
2 presented with family history of diabetes. Overweight, her
3 BMI was at a range of 40 times the risk factor. You had
4 adult weight gain that was a significant risk factor, high
5 blood pressure, elevated triglycerides, prior smoking
6 history, and you have Lipitor, and you are trying to prove
7 causation. For the smartest people -- that's a complicated
8 question. Right? I mean, kind of makes your head hurt even
9 thinking about it trying to figure out causation because
10 causation at Mrs. Daniels' level -- what was she? Did she
11 take 20 or 40?

12 MR. CHEFFO: She took 40, I think, she was 40 and
13 Hempstead was 20.

14 THE COURT: 40 milligrams, and we are trying to
15 prove that the -- that the Lipitor, which is less than two by
16 a factor of, right? Less than two, you know that, less than
17 two, and how do we prove specific causation? I mean, how do
18 we get there if we don't have expert testimony? And how do
19 you read the law in Colorado allowing whether you can do that
20 or not?

21 MR. CHEFFO: Two things, and I know you are going to
22 ask me that, they have an argument which is you should at
23 this point not even consider that. This is something that
24 the transferee court that after essentially we --

25 THE COURT: I'm going to send this -- all this

1 complexity, I'm going to send back to have 94 districts deal
2 with these complicated issues, all these judges, but that's
3 the purpose of the MDL in the first place.

4 MR. CHEFFO: I think it would be unprecedented, you
5 had a trial where you could render a ruling as to dispositive
6 issues. All of a sudden, they lose *Daubert* and this
7 dispositive motion, you are no longer capable of deciding
8 that.

9 THE COURT: That is a new theory. A new approach.

10 MR. CHEFFO: I have not seen that before.

11 THE COURT: As I recall, your client opposed the
12 MDL, and -- initially, and the plaintiffs wanted it, and then
13 once they got the MDL, things didn't quite work out the way
14 they wanted, they don't want the MDL anymore.

15 MR. CHEFFO: And in fairness, right, we all know
16 that there is benefits and can be negatives with MDLs, but
17 even as these very smart lawyers, the last thing I think that
18 they would want is a situation, right, where let's assume the
19 issue had gone the other way on general causation. Would
20 they really want us to go when they get sent back and every
21 time challenge general causation again? I mean, they would
22 be jumping up and down. They would say, "Wait a minute. We
23 spent all that time, and essentially here is the *Daubert*
24 issue." So, of course, that is the point of an MDL is to
25 resolve these issues on kind of a classwide MDL base.

1 THE COURT: If you are capable of doing it. If you
2 can't do it, then that's fine. But, you know, Ms. Daniels'
3 case sort of highlights to me, as does Ms. Hempstead, that
4 the phenomena here is you have a multifactorial disease,
5 diabetes, in which everybody presents with multiple risk
6 factors. They just do. Some of those things you can't
7 really rule out. You can't rule out somebody's weight. You
8 can't rule out somebody's age. Those are factors. So the
9 sort of, you know, using differential etiology is a problem
10 because you can't rule out these things. You've got to look
11 for some other method by which to do it. It's complicated.

12 We had some really smart people trying to figure all
13 of this out. And I found really instructive that the
14 general -- plaintiffs' general causation experts were asked
15 by your partners, "How did you prove specific causation," and
16 their answer was, "Beats me." They didn't know. These are
17 smart people. They didn't know how to do it.

18 And now we are supposed to say, "Oh, you don't need
19 expert testimony to prove it. Lay people can do it."

20 MR. CHEFFO: Your Honor, I have -- when I first
21 heard these, immediately I had a little bit of kind of a head
22 start because some of these arguments were raised in *Zoloft*
23 and rejected by Judge Rufe, saying very similar types of
24 arguments. Here, when I read these cases, you know, I think
25 there were two or three of them in Missouri and the *Estate of*

1 Ford case in connection with Colorado, you know, honestly, my
2 first take was these are cases that we could have cited, you
3 know, in the sense that, you know, you are basically -- these
4 cases are essentially saying when you have sarcoma, or we
5 have kind of complicated issue of land slides, you -- these
6 are not the obvious types of cases. It's kind of what we
7 have been saying all along, which is you need expert
8 testimony. I mean, how could -- and it's funny, the
9 plaintiffs focus almost exclusively on general causation,
10 right? They use -- and they say, "Well, here is evidence of
11 general causation," and their answer as to specific causation
12 when this is the time, right, on summary judgment, is let the
13 transferee court deal with that, right? So even if the
14 opposition --

15 THE COURT: I'm not letting the transferee court
16 deal with it, if it can be dealt with. I want to give my
17 colleagues around the country the least amount they have to
18 do. If there is a reasonable argument that I should address
19 this, I'm going to address it. I'm not going to dump it back
20 on them. That wasn't what the MDL was intended to do, I
21 believe. I'm waiting to hear, because maybe the plaintiffs
22 will show me their cases that are so individualized that what
23 I have sort of understood to be the presentation, there are,
24 in fact, instances where it is apparent, the cause. I
25 haven't seen one. Mr. Cheffo, have you seen one yet?

1 MR. CHEFFO: I have not. If it was, presumably they
2 would have been part of the 14, right? It would have been a
3 good case to pick. If you had the silver bullet case, you
4 wouldn't want to bury the lead and save the good cases for
5 the end. I think Your Honor has now given the plaintiffs,
6 even before this more recent round with the 80 milligrams,
7 give me a bunch of those cases.

8 We think maybe we talked about 100 of them or 200.
9 It turned out we have none. And you have now I think given
10 them four chances to deal with it. And I'm not saying this
11 in any way to fault. I think the reality is that -- I think
12 as you said, the -- ultimately these cases were all filed
13 very quickly, and I think as we closely look as the science
14 has developed and a closer look of the cases, that's why we
15 are not seeing these cases. Maybe we will when you have the
16 60-day expiration. But I, like you, suspect that we are not
17 going to.

18 THE COURT: But even -- we are going to scrutinize
19 them. I'm going to scrutinize and see if they are apparent.
20 I mean, I look at Colorado law, it talks about, you know,
21 that causation has to be fairly obvious. That case *Brown*,
22 the District Court case in Colorado, 2016, it says when an
23 injury arises from chemicals working in the body, a lay jury
24 does not have the competence to conclude from everyday
25 experience that the drug, in fact, caused the plaintiff's

1 injuries. I mean, they just don't have that knowledge. And,
2 you know, where -- so, you know, I take -- this is why I
3 drilled down on this Daniels, I mean, I went and re-read the
4 Court's earlier order in this matter, and the complexity of
5 it and why the case-specific experts didn't survive, um,
6 because they couldn't get there -- and if they couldn't get
7 there -- I guess Daniels is the one that had Handshoe and
8 Hempstead had Dr. Murphy.

9 MR. CHEFFO: Dr. Murphy and Dr. Handshoe.

10 THE COURT: I didn't make too bashful that I thought
11 Dr. Handshoe was a fairly weak witness. Dr. Murphy had
12 extraordinarily fine credentials, and I thought -- and I
13 think I said this before -- when I started the deposition,
14 now we are going to have a real expert show us something,
15 other than ipsa dixit, right? And when we got to it, that's
16 all we got. We couldn't -- we couldn't articulate a reason.

17 So now it's, you know -- and then in Missouri law it
18 talks about there is a sophisticated injury, you -- you've
19 got to have expert testimony. And it's got to be within the
20 lay knowledge of the jury. And how -- I mean, I just ask the
21 question, how in these two cases is it within the lay
22 knowledge of the jury to determine causation when their
23 experts couldn't do it? The experts couldn't do it. I don't
24 know how to do it. They haven't articulated a way to do it.
25 But 12 people I put in a box are supposed to figure it out?

1 I mean, how does that work?

2 MR. CHEFFO: You know, two things, Your Honor, I
3 mean, the first is the cases, again, that they have cited, we
4 cited, those Missouri cases, like I said, the guy getting off
5 a train, falls down, and then he says it's sarcoma as a
6 result of it, and I say, "Well, you need to have" --

7 THE COURT: That's like a 1933 case.

8 MR. CHEFFO: But even there they say unless you have
9 more there, it would be prejudicial, would lead the jury to
10 guess. So there is like a sentence I think they are relying
11 on at the end that's -- it's almost as if you haven't read
12 the whole case or looked at the analysis.

13 THE COURT: There is a whole body of case law that
14 is like completely contrary, modern case law, that even if
15 you read it the way they want to read it, that's not the law
16 in Missouri anymore. And, you know, there is case after case
17 that says if it's outside the lay expertise, you've got to
18 have an expert. And so we are cited a 1933 case, and we are
19 not cited to all of these -- these modern cases which deal
20 with this type of situation, and it makes clear that you've
21 got to have a -- where it is the cause is apparent and within
22 the common knowledge and experience of juries. You know,
23 those of us who litigated in court long, this is not a
24 revolutionary concept, right?

25 MR. CHEFFO: I mean, just think about it. You have

1 no expert, and you are going to talk about how with all these
2 factors, you know, Lipitor caused diabetes. Who is going to
3 give -- who is going to give that message? Does the
4 plaintiff get up and say, "I think it caused" -- and this is
5 why for all the reasons we have been talking about, Your
6 Honor -- and, again, I litigate a fair amount in Missouri
7 today, and, you know, plaintiffs are not coming forward and
8 suggesting we don't -- you know, "We have no experts. We are
9 going to have the plaintiff say she thinks X, Y, and Z caused
10 it." It's inconsistent with the law. It's inconsistent with
11 the gatekeeper role of the Court. It's inconsistent kind of
12 trial practice and efficiency that you would not need an
13 expert on these very complicated issues. Because all --
14 essentially you are left -- the jury would essentially have a
15 coin and just flip it: Do I like that person? Do I like
16 this plaintiff? How would they really judge without the
17 benefit of an expert here?

18 THE COURT: Let me take a brief break, and we'll
19 hear from Mr. Ho, okay? Thank you.

20 (Thereupon, there was a brief recess.)

21 THE COURT: Mr. Ho, I'm ready for you, sir, on
22 causation.

23 MR. HO: Thank you, Your Honor. I don't know if you
24 want to start with questions. I would be happy to address a
25 couple of the points.

1 THE COURT: You are excellent at answering them. I
2 did a lot of appellate advocate work. I liked it when the
3 Court asked me questions rather than me standing up.

4 MR. HO: I guess -- let me address two of the points
5 that you raised with Mr. Cheffo. One is Missouri law. We
6 are not just relying on an outdated 1933 case. There are
7 Missouri Court of Appeals cases from 1986 and from 1988, the
8 *Hills* and *Kumar* cases that stand for the same proposition.
9 So respectfully I don't think it's fair to say that the time
10 has passed this principle by. Moreover, as you know from our
11 omnibus opposition, we think that this is the rule in a
12 number of other states. And that brings me to the --

13 THE COURT: It's a body of law that really -- I
14 really date it from the *Callahan* case, Missouri case,
15 which -- and the -- how do you pronounce it -- *Parmentier*
16 case talks about the sophisticated injury and the need for
17 expert testimony. There is the *Turner vs. Iowa Fire Company*
18 case, talks about inferred, you can infer causation from
19 "visible injury or sudden onset of injury. However, when the
20 injury is a sophisticated one; i.e., requires surgical
21 intervention or other highly scientific techniques for
22 diagnosis, proof of causation is not within the realm of lay
23 understanding and must be established by expert testimony."
24 Now, that is the Eighth Circuit interpreting Missouri law.

25 Missouri Appeal, 2000, *Super vs. White*, to prove

1 causation, "unless the want of skill or lack of care is so
2 apparent as to require only common knowledge and experience
3 to understand and judge it."

4 So tell me what is -- what are the facts that a
5 layperson could determine causation here? What are the facts
6 in *Daniels*?

7 MR. HO: Let me -- if I could --

8 THE COURT: What are the -- what are those facts
9 that have escaped me, that strike you, Mr. Ho? You are new
10 to this case. What are those facts that tell us that a
11 layperson can determine causation?

12 MR. HO: If I could address one other point before I
13 answer that?

14 THE COURT: Yes, sir.

15 MR. HO: We obviously have a disagreement with the
16 defendants, and Your Honor is trying to figure out what the
17 right answer is with respect to these principles under both
18 Missouri and Colorado law. That is one of the reasons why we
19 think that this set of issues related to specific causation
20 ought to be dealt with by the transferee -- transferor court,
21 because there are neither common questions of law nor common
22 sense of fact that bind all of the plaintiffs in this MDL
23 together.

24 THE COURT: I respectfully disagree. We are going
25 to be here -- I apply laws of states all the time. I'm

1 required to do that. I do it routinely, it's not that
2 difficult to do, and we have ready access to the case law,
3 and I certainly can study the case law of Missouri and
4 Colorado. So it's not going to -- this is not going
5 anywhere. You need to stay here, and you are going to
6 address it here.

7 So the question -- tell me about *Daniels*. What
8 facts are you -- tell me why the diagnosis of causation, that
9 Lipitor caused -- was a proximate cause of Mrs. Daniels'
10 diabetes is apparent and requires -- is within the common
11 knowledge of lay people?

12 MR. HO: First of all, we think some of the expert
13 evidence in the statements by Pfizer and Dr. DiMicco are
14 relevant to the question.

15 THE COURT: These alleged admissions.

16 MR. HO: Correct. Are relevant to the question of
17 specific causation.

18 THE COURT: Okay. What else?

19 MR. HO: If I could articulate why.

20 THE COURT: I could figure it out. What else?

21 MR. HO: Well --

22 THE COURT: Because I don't buy those are
23 admissions, so I want to hear what else you've got. I want
24 to make sure I give fair consideration to what else you've
25 got.

1 MR. HO: What we think we have, Your Honor, is a
2 diagnosis history in which there is a fair amount of
3 stability in all of the other --

4 THE COURT: A fair amount of?

5 MR. HO: Stability, not a lot of change in the other
6 kinds of risk factors that each of the plaintiffs has. Yes,
7 there are -- to some extent there was -- you know, the
8 plaintiff may have been overweight, but that doesn't change a
9 lot leading up to the diagnosis with diabetes. And so we
10 think that there is circumstantial evidence from which a
11 reasonable jury could bridge the gap between what we think
12 that we have with Dr. Singh and the admissions, because --
13 and this is an important point.

14 THE COURT: Hold on just a minute. You said that --
15 was the word "stability," that it was relative stability?
16 Was that the word you were using?

17 MR. HO: Yes, Your Honor.

18 THE COURT: In the 11 months between the
19 prescription of Lipitor and the initial determination of
20 borderline diabetes in Daniels, she had a weight increase of
21 23 pounds. BMI is like one of the huge risk factors
22 associated. So how am I to sort out whether it was the
23 Lipitor that caused it or the weight gain that caused it? I
24 mean, there are other factors too. She had a family history
25 of diabetes, two brothers and a daughter. She had high blood

1 pressure, elevation of triglyceride. She had a lengthy
2 smoking history, 32 years, but then we -- it wasn't stable.
3 That's not true. It wasn't stable. And so how -- I mean, I
4 thought that -- I mean, listen, the *Daniels* case was picked
5 by the defendant. Okay?

6 I never -- I'll tell you something. I don't like
7 that the parties pick these cases. I don't know a better way
8 to do it yet, but I'm thinking about it, because I think they
9 both tend to pick cases on the outlier, and so I've taken a
10 little skepticism focusing too much on *Daniels*, but it is a
11 lot -- it's a complicated medical question. And it's a
12 dynamic situation with her weight gain. I presume that is
13 why the defendant wanted the case. So to say there is
14 stability, it's just not an accurate statement of the record.
15 Now, I don't -- I know you are at a disadvantage coming in
16 late and trying to master this enormous record in this case,
17 but that just isn't accurate.

18 MR. HO: Your Honor, I think two responses to that.
19 One is, it is important to us that the question be framed in
20 the right legal terms. To our mind, there is expert evidence
21 that creates some degree of proof as to specific causation.

22 THE COURT: It's the law of the case that that
23 evidence does not survive the *Daubert* inquiry.

24 MR. HO: I'm not referring --

25 THE COURT: You told me earlier that Rule 801

1 controls under -- under the fact that it's procedural law,
2 and I think Rule 702 controls as well.

3 MR. HO: Your Honor, I'm not referring to the
4 Dr. Singh opinions at 10, 20 and 40 milligrams. What I'm
5 referring to is the 80-milligram opinion, which is
6 admissible.

7 THE COURT: Oh, I -- and -- but the question that
8 you can extrapolate from that, though, that there is no
9 opinion on lower doses. You want to extrapolate that to
10 Mrs. Daniels' dose level. And there is no expert testimony
11 that it would survive *Daubert*, and I'm not going to infer
12 from the 80 milligrams. I found a very significant dose
13 relationship here, or that is one of the factors is to look
14 at dose. You know, dose effect is one of those factors, and
15 it was quite clear there was a significant dose effect here.
16 So you want -- so I will consider -- I mean, but my question
17 is knowing what we know, that let's take it. 80 milligrams,
18 Mrs. -- I keep getting it confused whether it's 20 or 40 --
19 it doesn't tell us anything about whether it is at 40.

20 Now, tell me in her case, what are the facts that
21 make it apparent that Lipitor caused it? Is there any
22 particular facts in this case? This is what I'm trying to
23 get you to drill down on the case itself. I've got a
24 specific -- I've got a motion for summary judgment on
25 specific causation in Ms. Daniels' case, so tell me what are

1 the facts that a layperson would know that it was apparent
2 that Lipitor caused it?

3 MR. HO: I think that -- again, I want to frame the
4 issue before I --

5 THE COURT: I want you to answer my question, and
6 then you can comment. I want you to answer my question.
7 Mr. Ho, what facts are there?

8 MR. HO: I think the totality of the facts and
9 circumstances --

10 THE COURT: What are the facts?

11 MR. HO: She was prescribed 40 milligrams of Lipitor
12 in 1997. She was already at that point overweight. So that
13 to me is an indication that if she's overweight at the time
14 that she's prescribed Lipitor, and she doesn't have diabetes
15 at that time --

16 THE COURT: But it's a -- the greater weight you
17 get, the greater risk you have. And in this case, she became
18 obese, which carries a risk factor of 40 times. And then she
19 had this adult weight gain of -- in 11 months, which is very
20 dynamic. I'm not saying to you that I know the answer. I'm
21 not going to pretend to you that I can say authoritatively I
22 know the answer here. But what I can say is, is that there
23 has got to be some threshold of evidence to support the claim
24 that you can determine it here.

25 We've had really smart people, capable people, well

1 prepared by your cocounsel for their depositions,
2 cross-examined, and this thing put through the *Daubert*
3 analysis. And it doesn't survive. So I'm waiting to -- I'm
4 looking -- in this case, I'm looking for a case. I'd welcome
5 it if you can show it to me. But in Ms. Daniels' case, what
6 is apparent when we have this, you know, a family history of
7 diabetes, that's four times the risk; overweight, 40 times
8 the risk; her BMI; adult weight gain in the 11 months
9 preceding; high blood pressure, another significant risk
10 factor; elevated triglyceride, that is another risk factor;
11 all greater than Lipitor even at the outer ranges of what's
12 considered to be risk. And what is apparent to a layperson
13 that it's the Lipitor that did it or was a factor? Because
14 everybody concedes without the Lipitor, that looks like a
15 pretty common presentation for someone who gets diabetes.

16 MR. HO: I don't have a new fact to give you that --

17 THE COURT: You can't survive specific causation,
18 because as smart as you are, Mr. Ho, we've had a lot of smart
19 people in this case working as hard as they can, and they
20 haven't been able to get there either. Dr. Murphy couldn't
21 get there. Nobody has been able to sort out how you know
22 this. There is no test that tells us. There is no clinical
23 presentation that tells us. It's a heck of a problem. And
24 so even if you overcome the problem of general causation,
25 which the plaintiffs did at 80 milligrams -- you know, I

1 said, "Give me an 80-milligram case. I'll try it."

2 They said, "We don't have one. We don't have an
3 80-milligram case." So I mean, so for Ms. Daniels, what you
4 are telling me is you can't point to a set of facts that
5 makes it apparent that Lipitor caused it.

6 MR. HO: We think that the facts that are in the
7 record allow a jury, based on that circumstantial evidence,
8 to come to a reasonable conclusion --

9 THE COURT: Those facts are?

10 MR. HO: The facts that Your Honor has already
11 recited. There is nothing new that I can offer that I
12 would -- that I think would change your view about this
13 situation.

14 THE COURT: I'm just saying give me some facts and
15 make it -- it doesn't -- it's like really complicated. And
16 to suggest that it's not complicated was never adopted,
17 Mr. Ho, frankly, until you got involved in the case. Your
18 cocounsel treated this as a complicated question, which they
19 carefully worked up to try to prove. I have -- you know, I'm
20 sure they are not -- they probably, back in their law firm --
21 I have many friends in that law firm -- are grudging about my
22 decisions in this case. I never doubted their diligence and
23 their thoroughness on behalf of their clients.

24 MR. HO: Nor do I, Your Honor.

25 THE COURT: They have vigorously pursued this thing,

1 and they used good strategy, and had the evidence gone the
2 other way, fine, but it just wasn't there. To try to
3 reshuffle the deck and say, "We don't need experts anymore.
4 All we need is, you know, these facts that are enough for a
5 jury, a layperson" where the greatest minds in the country
6 couldn't tell you how to do it, I just think it -- so the
7 suggestion that somehow we've used the record here, I haven't
8 seen it.

9 Ms. Hempstead, what about the facts of Ms. Hempstead
10 that tell you that it's apparent, obvious, clear; that based
11 on this record, a layperson would know that they could reach
12 a reasonable conclusion that her diabetes was caused -- she
13 had -- she was -- her -- you know, she had a BMI that created
14 a risk factor of 15.8; she had adult weight gain; she had
15 gained 55 pounds as a result, a huge risk factor; she had a
16 family history of diabetes by the age of her father; she had
17 prediabetes; she had metabolic syndrome, hypertension; there
18 was a complicated ethnicity issue no one could sort out, her
19 being African-American and Chakma Indian. There is a lot of
20 things going on.

21 That is the problem with every one of these cases.
22 When you drill down, it is really complicated. And that is
23 why it's just something that you need expert testimony. And
24 as I said before, until we've come to the end, no one thought
25 or suggested you didn't need that to get it to the jury.

1 Is there anything about Ms. Hempstead's -- can you
2 point me to the facts of her case that would make it apparent
3 that Lipitor was a proximate cause?

4 MR. HO: I think this is another impossible
5 question, Your Honor. I have no new fact that I can give you
6 that I think would change your mind on that point.

7 THE COURT: Tell me your best argument. Don't worry
8 about changing my mind. I'm -- I'm asking you tough
9 questions, and I have been known to be persuaded by asking
10 good lawyers tough questions and them giving me an answer
11 that -- that I found had validity. So I'm asking you
12 specifically, for Ms. Hempstead, the plaintiffs' choice, was
13 there -- you know, this was one of the cases they picked of
14 this pool -- what about this made the Lipitor something
15 within the province and knowledge -- common knowledge of
16 jurors as to causation?

17 MR. HO: Again, if you look at, for example, her
18 blood glucose level and her BMI at the time that she was
19 prescribed Lipitor in, I believe 1999, it was 26.4. It
20 doesn't change that much by the time she gets diagnosed.

21 THE COURT: Well, we know about BMI and causation is
22 the older you get, the BMI, your risk factor goes up even
23 with the same weight. So you have this interplay of age and
24 weight, which is, of course, the BMI calculation. And here
25 is something that has always gotten to me is let's say -- I'm

1 sure you've seen this in the depositions -- you have a
2 hundred people in the room, and a hundred people in the room
3 have taken Lipitor and later became diabetic. The
4 overwhelming majority of those people we know from the data
5 would have gotten it anyway. They would have gotten it
6 without the Lipitor. Under the plaintiffs' theory, some
7 minority of those people of that hundred in that room got it
8 because of Lipitor. That is the general causation argument.

9 And -- but no one has figured out who those people
10 are. No one has figured out how to tell who these people
11 are. That was a quandary on a specific causation. Even if
12 the plaintiffs ever got across the line on general, no one
13 had a -- a plausible argument how to get there from an expert
14 standpoint. They couldn't tell, and these really
15 knowledgeable people said that, their experts. And now you
16 are telling me that notwithstanding the fact that the most
17 capable people who plaintiffs could retain couldn't figure it
18 out, lay people can.

19 MR. HO: Let me try to bring this full circle. Our
20 position is that on a Rule 56 motion, the Court should look
21 at all admissible evidence, including admissions, expert
22 testimony, and nonexpert testimony.

23 THE COURT: Okay. I should look at the expert
24 testimony I found did not meet *Daubert*. Expert testimony.
25 That is your argument?

1 MR. HO: No, I'm talking about Dr. Singh's
2 80 milligrams.

3 THE COURT: I've got Dr. Singh's 80 milligrams. I'm
4 going to factor in what you call the admissions. I've
5 already voiced to you that I have a different take on those
6 documents, but fair enough. But determining -- just give me
7 the hypothetical that most people -- that hundred in the
8 room, it's not going to be caused by the Lipitor. We know
9 that statistically. They would have gotten it anyway. The
10 data tells us that. So if Mrs. Daniels or Mrs. Hempstead,
11 just one in the room, the overwhelming probability is she did
12 not get it. But under the plaintiffs' theory, some minority
13 did. How do we pick that minority out? So just simply
14 calling it general causation doesn't get you to specific
15 causation.

16 MR. HO: The point I'm trying to make, Your Honor,
17 is that it's important to take that general causation into
18 account in determining specific causation. And let me give
19 you a hypothetical: Assume you have a situation in which the
20 relative risk in the general causation evidence is 1.99.

21 THE COURT: Okay.

22 MR. HO: Not greater than 2.0. So that alone
23 doesn't get you over the preponderance standard. And let's
24 say you've got no differential diagnosis that survived
25 *Daubert* or was even offered. What you want to do is look at

1 the facts and circumstances of the case and say, "Is there
2 just an iota of evidence that would allow a reasonable jury
3 to bridge that tiny gap between 49.9 percent and 50 percent?"
4 And that's the conceptual point that we are trying to make
5 here.

6 THE COURT: That is taking a very myopic view.
7 You've got to take the view that most people in the pool who
8 took Lipitor and later acquired diabetes, it was unrelated to
9 the Lipitor. So you are telling me if it's plausible that,
10 ipsa dixit, I should recognize it, and the statistics tell us
11 they are a minority. So I've got to find a way, even if
12 you -- take your theory, I've got to then go and find a way
13 to know which of this minority of 100, who got it because of
14 the Lipitor. How do I identify?

15 And I've got to tell you, Mr. Ho, I have been in
16 cases that are really complicated, went to the judge as a
17 lawyer where I learned the science. I learned it better than
18 I did when I started, right? We've all gotten in cases where
19 we've learned it better as we go along. And I certainly was
20 learning the science of this case as I went along. And I
21 frankly felt the lawyers were learning the science better as
22 it went along. And that it -- it ultimately just didn't get
23 where the plaintiffs -- they couldn't get them where they
24 wanted to get. And one of them is, is how could we pick
25 out -- even if we survived the hurdle of general causation,

1 how do we get to proving who actually suffered an injury?
2 Every court I've ever seen, every jurisdiction I've ever seen
3 requires that you prove that the plaintiff's injury was
4 caused by it. And you can't -- it's not that it can't; it's
5 possible to cause it; it caused their injury. And that has
6 been a huge conceptual gap, evidentiary gap in this case is
7 how we get there. And the plaintiffs' specific causation
8 experts, and I specifically refer to Dr. Murphy and
9 Dr. Handshoe, they basically got the point. They took it,
10 and they got it, and that's causation. That's not causation.

11 MR. HO: We obviously disagree with that ruling --
12 characterization.

13 THE COURT: I'm sorry?

14 MR. HO: We disagree with that ruling.

15 THE COURT: Listen, I do not interpret your silence,
16 Mr. Ho, as an admission any more than I interpret Dr.
17 DiMicco's response to that e-mail as a verbatim adoption of
18 every word. I do not take it that way. I don't think that's
19 the way human communication occurs. And I don't take your
20 silence here -- I think you are obviously a smart guy, and
21 you don't want to argue about things that aren't worth
22 arguing about, and I don't blame you. I would do just like
23 you. I would be stoic in the face of some of this. But you
24 come with a long history here behind you that you weren't
25 part of. And we -- you know, the specific causation part of

1 the case has really not gone well for the plaintiffs. It did
2 not go in the direction I kind of anticipated it would go,
3 which we would have had some theory how we could get there.
4 We never -- frankly, never got close about how you prove
5 that. And it's the confounding nature of the multiple risk
6 factors, the inability to rule most of them out. And then
7 the inability to determine from the remaining potential risk
8 factors how this less probable cause was a proximate cause.
9 I mean, that to me is where the problem has been.

10 Well, let me just say, I've got -- I presume you are
11 going to be back here on omnibus, are you not?

12 MR. HO: I would bet on it.

13 THE COURT: I would bet. Glad to have you here. I
14 do appreciate, frankly, new blood in the case. It has its
15 advantages and disadvantages. I came in and handled some
16 appeals that were tried below, and I always found that very
17 challenging. How do I bring myself up to speed? You know,
18 particularly a voluminous record like this.

19 MR. HO: Could I --

20 THE COURT: Anything you wish to add before we
21 finish the argument?

22 MR. HO: Just one procedural point, Your Honor, and
23 I always hate to forecast defeat for my own side, but to the
24 extent that Your Honor is inclined to grant summary judgment
25 in these two cases, I would ask that any such judgments be

1 deferred until after hearing argument on the omnibus motion
2 and in the other -- and resolving the other cases, so that we
3 can have a coordinated appeal.

4 THE COURT: I think that makes a lot of sense. I do
5 think that makes a lot of sense. Let me ask you just one
6 additional question. Mr. Ho, I just have one question.
7 You've read -- you know, we have operated under the theory
8 that state law controls the substantive law. You know, we
9 have operated under those assumptions, and you have come in
10 and raised the fact that under 801, admissions would be, I
11 presume, a procedural question.

12 MR. HO: Correct, Your Honor.

13 THE COURT: Well, wouldn't in the same way Rule 702,
14 the need for expert testimony meeting a certain standard
15 would be required, would that also be required by federal
16 law? Would that be a procedural rule controlled by federal
17 law?

18 MR. HO: Rule 702 certainly displaces any state law
19 rules regarding the admissibility of any expert testimony.
20 For example, if a state had a rule that said for an expert to
21 be admissible, the expert's testimony had to satisfy the old,
22 pre-*Daubert*, *Frye* standard, that rule, that state law rule
23 wouldn't apply in Federal Court. But there is no rule under
24 702 that requires expert testimony on issues of causation or
25 any other issue. Rule 702 is just a rule about the

1 admissibility of expert testimony, and Rule 801 sort of by
2 contrast is a rule that says statements by a party opponent
3 are admissible for the truth of the matters asserted,
4 irrespective of the opinion rule in 701, 702 and 703.

5 THE COURT: So your theory would be if we had a case
6 where the expert testimony in a medical drug defect case,
7 that the evidence was -- did not establish causation, and you
8 can find a single e-mail which you believe would constitute
9 an admission, then all the requirements of *Daubert* don't
10 matter in terms of the summary judgment, that that one
11 statement in an e-mail would trump all?

12 MR. HO: Rule 702 does not apply to the
13 admissibility of admissions.

14 THE COURT: Answer the question. Would one e-mail,
15 under your theory, trump all?

16 MR. HO: I'm not sure what you mean by "trump all."
17 If it is the only evidence --

18 THE COURT: The requirement that you -- under state
19 substantive law that you had to have expert testimony on
20 matters of sophisticated injury or something outside the lay
21 knowledge, and you are arguing that Rule 801, that in a very
22 complex case in which causation cannot be established, that a
23 single e-mail, in this case not even one officer commenting
24 on a third-party statement, would be sufficient to trump all
25 of that other evidence and require a denial of summary

1 judgment, is that theory?

2 MR. HO: To the extent that e-mail creates a genuine
3 issue of material fact under Rule 56. Rule 702 doesn't apply
4 to the admissibility of that e-mail, and if this e-mail is
5 admissible under 801 and, again, it creates a genuine issue
6 of material fact under Rule 56, then it would create a
7 triable issue --

8 THE COURT: That's why you don't agree with the
9 *Zoloft* and *Aredia* and the IUD case, which try -- which
10 presumed there were certain standards that those admissions
11 had to meet before it would be sufficient evidence to
12 overcome the absence of expert testimony. Is that correct?

13 MR. HO: Right. Those cases basically get the
14 presumption backwards because they say the presumption is
15 that the admission doesn't come in unless it is crystal
16 clear, when under Rule 56, the presumption is it comes in
17 unless it is so crystal clear in favor of the moving party.

18 THE COURT: Very good. Thank you.

19 Mr. Hahn, you wanted to add something, sir?

20 MR. HAHN: Could I have 30 seconds with Mr. Ho?

21 THE COURT: Absolutely.

22 MR. HAHN: Thank you.

23 (Pause in proceedings.)

24 THE COURT: Yes, sir?

25 MR. HO: We have nothing further, Your Honor.

1 THE COURT: I would have loved to hear Mr. Hahn's
2 question to you. You straightened it out, like too bad. I
3 have a high regard for his thoughts and ideas, but very good,
4 sir.

5 Mr. Cheffo, have you got anything more to say in
6 response?

7 MR. CHEFFO: I don't, Your Honor, unless you have
8 any questions.

9 THE COURT: Very good. Thank you very much all of
10 you. As always, you have given me plenty to think about, and
11 I know I have tested the plaintiffs in this matter, but I did
12 it intentionally to test my own ideas to give you the best
13 chance to give me the argument to the contrary. I am going
14 to honor your request, Mr. Ho, and that we should coordinate
15 these together. I do think in the end, though y'all may
16 disagree with me, I think the Fourth Circuit's review of the
17 *Daubert* issue is a critical issue, and it ought to go up and
18 let them deal with those questions, both as to general and
19 specific causation, and -- hold on a second.

20 (Pause in proceedings.)

21 THE COURT: Folks, we -- let me just say to you, we
22 are trying to sort out, and this is completely inside
23 baseball for y'all, but there -- the Court has these
24 three-year lists of cases, and most of my colleagues in MDLs
25 just stay cases so they don't have this issue. And we just

1 need to sort of -- we are trying to sort all that out, and
2 I'm -- you know, I'm going to probably enter a stay. There's
3 just a few cases that are over three years old. I'm going to
4 enter a stay to stay them pending my decision in *Hempstead*
5 and *Daniels*, and we'll bring them off the stay list to --
6 before I rule on the omnibus cases. So it may literally be a
7 day, but there may be a brief interplay. I need to bring
8 them off the stay list to make a decision, if y'all
9 understand that. Okay? Very good. Thank you.

10
11
12 *****

13
14
15 I certify that the foregoing is a correct transcript
16 from the record of proceedings in the above-titled matter.
17
18

19 _____
20 Amy C. Diaz, RPR,

September 16, 2016

21
22 /S Amy Diaz
23
24
25