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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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IN RE: FRESENIUS GRANUFLO/)	
NATURALYTE DIALYSATE)	
PRODUCTS LIABILITY LITIGATION)	No. 1:13-md-02428-DPW
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BEFORE: THE HONORABLE DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT COURT JUDGE

- AND -

THE HONORABLE MAYNARD M. KIRPALANI
MASSACHUSETTS SUPERIOR COURT JUDGE
SUFFOLK COUNTY SUPERIOR COURT - CASE NO. 13-CV-3400

DAY TWO OF DAUBERT HEARING

John Joseph Moakley United States Courthouse
Courtroom No. 1
One Courthouse Way
Boston, MA 02210
Thursday, October 15, 2015
9:10 a.m.

Brenda K. Hancock, RMR, CRR (9:10 a.m. to 11:00 a.m.)
Kelly Mortellite, RMR, CRR (11:20 a.m. to 2:27 p.m.)
Official Court Reporter
John Joseph Moakley United States Courthouse
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P R O C E E D I N G S:

(The following proceedings were held in open court before the Honorable Douglas P. Woodlock, United States District Judge, and the Honorable Maynard M. Kirpalani, Suffolk Superior Court Judge, at the John J. Moakley United States Courthouse, One Courthouse Way, Courtroom 1, Boston, Massachusetts, on Thursday, October 15, 2015):

THE CLERK: All rise. This Honorable Court is back in session. You may be seated.

THE COURT: I think there are just a couple of scheduling things.

With respect to the Colton and Zydney redo, the idea, I think, that Judge Kirpalani and I had was by next Wednesday, with another week for the defendants to respond. We will take it on the papers.

MR. KETTERER: Fine, your Honor.

JUDGE WOODLOCK: Does that work?

MR. KETTERER: Yes, your Honor.

JUDGE WOODLOCK: Two other things. I raised the question of a June trial. Any progress on that?

MS. BROOKS: We're fine on the defense side with that, your Honor.

JUDGE WOODLOCK: But does that put pressure on the cases before Judge Kirpalani?

MS. BROOKS: It certainly would be helpful if we could

1 move the May trial maybe up a little bit earlier into May, but
2 entirely up to the Court.

3 JUDGE KIRPALANI: As I said, I am not averse to that.
4 If we start a trial on April 4th, I think it will be done, I
5 hope it will be done before the end of April, and then there is
6 ample time to get a trial in in May that starts earlier than
7 the 23rd. But, have you conferred with plaintiffs about the
8 scheduling?

9 MR. KETTERER: Your Honor, I don't see any reason why
10 we wouldn't be able to meet an earlier date in May. I actually
11 have a feeling that we will have two different trial teams, so
12 it should be fine.

13 JUDGE KIRPALANI: Why don't you confer on that and
14 come up with a date, then, that will work. You are the best
15 estimator of how long the trials are going to be, but I think I
16 am ballparking three weeks. With the 80-hour estimate, I think
17 that is probably roughly equivalent.

18 MR. KETTERER: Sure. And, again, as you know, since
19 we have agreed, at least on the first trial, to a timed trial,
20 and I think we need to see how that goes, but I think that's
21 sort of a reasonable estimate, and that's certainly the goal, I
22 would imagine, of all of the parties.

23 JUDGE KIRPALANI: So, I am content to have you confer
24 on a date and supply one to me that is in advance of May 23rd.

25 JUDGE WOODLOCK: And then you can use the June --

1 Mr. Tarricone, you were rising on this.

2 MR. TARRICONE: Well, I just wanted to let the Court
3 know that people will work with whatever date works.

4 JUDGE WOODLOCK: We will use the June 13, I think. I,
5 myself, may want to get a little bit more active on the
6 bellwether selection process, because at that point we will
7 have had some significant data points to deal with. But, in
8 any event, I will pencil in, maybe actually use a ballpoint,
9 for my schedule for the 13th for trial.

10 Now, one other thing, just timing, and that is the
11 question of specific causation in the two bellwether cases I
12 have, that is, timing for hearings and that sort of thing. I
13 have not gone back to look at it, but I want to be sure that we
14 are on the same page there. Do you have a firm recollection of
15 what --

16 MR. TARRICONE: Well, your Honor, we have been working
17 on a joint proposed schedule that has that in it, and whenever
18 you want to take that up -- actually, I'm still conferring.

19 JUDGE WOODLOCK: I just wanted to take your
20 temperature. We will see how the patient turns out after you
21 submit something.

22 MR. TARRICONE: Thank you. Perhaps we could take it
23 up tomorrow.

24 JUDGE WOODLOCK: All right.

25 JUDGE KIRPALANI: I do not think Judge Woodlock is

1 going to be here tomorrow. He is certainly welcome.

2 (Laughter)

3 JUDGE WOODLOCK: I will be sitting out in the
4 spectator section.

5 (Laughter)

6 JUDGE WOODLOCK: But, if you have got a piece of
7 paper, that would be helpful to me, even tentative. Then I can
8 confer with Mr. Lovett and try and figure out our schedule.

9 MR. TARRICONE: Thank you, your Honor.

10 JUDGE KIRPALANI: And, by the way, we will have a
11 court reporter tomorrow.

12 So, that takes us to, I think, Dr. Wei or Wei?

13 MR. ROTMAN: Your Honor, the name is spelled W-e-i,
14 and it's pronounced "way," and that's on the schedule for next,
15 and I will be arguing for the plaintiffs. I will just take a
16 second to take the lectern.

17 Your Honor, Dr. Wei is a defense rebuttal expert, and
18 he's a statistician. There are many opinions included in his
19 rebuttal report. We are challenging, essentially, two of them.
20 Although it's presented in our brief as three, two and three
21 are very related, and I'll be taking them up together.

22 So, the focus of the challenges relates to two
23 opinions which Dr. Wei offers concerning the 2010 internal case
24 control study on cardiopulmonary arrest that we talked about
25 yesterday.

1 And if we could bring up 3982, and if we could go to
2 Page 40.

3 So, what we are looking at, your Honor, is the part of
4 the rebuttal report that we are focusing on and the specific
5 opinions that we are focusing on. The first one is listed in
6 Paragraph 86, and if we could bring that out, just call it up
7 larger, the focus is the statement in the first two lines that
8 are, "The study design presented in the Hakim Memo was not
9 adequate because it did not use matching."

10 Now, the defendants acknowledge on Page 18 of their
11 brief that Dr. Wei understood that the study utilized logistic
12 regression to attempt to balance the risk factors between cases
13 in the control groups. The purpose of matching, as Dr. Wei
14 explains in the rest of this paragraph, is exactly to do just
15 that. You have got an objective in a study like this to
16 determine if there is a statistical relationship between, let's
17 say, in this case it was serum bicarbonate levels and
18 cardiopulmonary arrest, and you want to make sure that other
19 things that can be related to both bicarbonate levels and
20 cardiopulmonary arrest are not obscuring the true relationship
21 that exists, so you do some statistical methods. There are
22 statistical methods. Matching is one of them.

23 JUDGE WOODLOCK: So --

24 JUDGE KIRPALANI: So --

25 JUDGE WOODLOCK: Go ahead.

1 JUDGE KIRPALANI: The Supremacy Clause.

2 (Laughter)

3 JUDGE WOODLOCK: The hospitable thing.

4 JUDGE KIRPALANI: The host goes first.

5 JUDGE WOODLOCK: Let me just ask, if they struck out
6 the "because" and the "it," "not adequate because it." It did
7 not use matching, formal matching. They say it is a moot
8 point, as I understand it, and why are we talking about it?

9 JUDGE KIRPALANI: I was going to ask a version of that
10 question, which is, would there be support in the field of
11 statistics for him to say that matching would be superior to
12 logistic regression, as opposed to saying that the study is
13 inadequate for lack of it?

14 MR. ROTMAN: Right. So, there would be support in the
15 field for there to be some opinions that using both together is
16 better than just using one, but there is no support using --

17 JUDGE WOODLOCK: Let me just understand from the
18 defendants, because they, as I read their briefing, said it is
19 moot, he does not offer that opinion, it has got to be read in
20 context. Well, maybe it has to be massaged in context.

21 But, in any event, is there really a dispute about
22 this?

23 MS. BROOKS: No, there really isn't, your Honor. He's
24 basically saying, perhaps this is not worded as precisely as it
25 should be, but he certainly said at his deposition that

1 matching is superior, and he based it on the literature that
2 specifically --

3 JUDGE WOODLOCK: Let me just be sure. He did not say
4 that it is the study design, put to one side whether we
5 characterize it as an a "Hakim Study" or whatever, but the
6 study design is not inadequate simply because it did not use
7 matching?

8 MS. BROOKS: That's correct, your Honor.

9 MR. ROTMAN: So, if there is an agreement that the
10 parties are agreeing that we do not need the Court to rule on
11 this because Dr. Wei will not offer an opinion that the study
12 design was inadequate because it did not use matching or that
13 matching was necessary or something in words or substance --

14 JUDGE WOODLOCK: They are two different things, I
15 think. They have said -- I will not speak for them; they are
16 perfectly capable of speaking for themselves -- except that I
17 understand them to say that the design is not inadequate
18 because of matching. That is not a grounds. But I think they
19 are going to say that the study design is not adequate but not
20 because that matching was not part of the protocol that was
21 used.

22 MR. ROTMAN: I'm not clear now on what we're agreeing
23 to.

24 JUDGE WOODLOCK: Well, maybe you can state -- just a
25 moment. Let's get it from the defendant.

1 MR. ROTMAN: If the opinion of Dr. Wei at trial will
2 be that he believes that matching was superior but not saying
3 that it was either necessary or that the design or the study
4 was inadequate because it didn't use matching, we're okay with
5 that.

6 JUDGE WOODLOCK: All right.

7 MS. BROOKS: And so, your Honor, what Dr. Wei will say
8 is exactly what's on the screen. He will say that in the Hakim
9 Memo population --

10 JUDGE WOODLOCK: We are talking about the particular
11 opinion. Maybe I can make it even simpler, which is to say, is
12 matching a necessary -- if not necessarily -- not a sufficient
13 condition for structuring it as a study design?

14 MS. BROOKS: And the answer to that is -- exactly.
15 Will Dr. Wei say matching is absolutely necessary in order to
16 have an adequate study?

17 JUDGE WOODLOCK: He does not have to have the adverb,
18 just "necessary."

19 MS. BROOKS: He will say -- let me change the word,
20 then, to "mandatory," because, in Dr. Wei's opinion, a true
21 reliable study does need to do matching, but --

22 JUDGE WOODLOCK: So, then there is not an agreement.
23 So, it is not moot. So, go ahead.

24 MR. ROTMAN: So, the basis for our challenge, your
25 Honor, is that he offers no basis for that opinion. He gives

1 an explanation for what matching accomplishes and why
2 accomplishing that is important, but he doesn't offer any
3 opinion to why matching is necessary if you are already doing
4 logistic regression. He already acknowledges they're doing
5 logistic regression for this purpose, but if his opinion is
6 going to be that it was necessary to do matching in addition,
7 there is nothing offered in his report that supports that.
8 It's just a conclusion. It's just a statement by an expert
9 without any support. It's *ipse dixit*.

10 Now, I pressed him in his deposition, "Is there any
11 support for this?", and he cited to a couple of journal
12 articles, which the defendants made exhibits to their brief,
13 and they quoted from one of them. That's Exhibit 22 to the
14 defendant's brief, which we cannot project on the screen, but I
15 did bring the Court, if I may approach, your Honor, a part of
16 that article, and I am giving to defense counsel the same.

17 And the point of this is that, what the defendant's
18 quote in their brief is that the paper that's cited stands for
19 the proposition that doing both is effective, and what I have
20 highlighted is actually a statement that says, and I'm quoting,
21 "Hence, matched sampling and regression adjustment may be used
22 alone or in combination; that is, samples may be random or
23 matched, and regression adjustment may or may not be
24 performed."

25 This is exactly our position, and the one article that

1 he cited for the proposition doesn't support an opinion that
2 you need to do both, and that if only one was done here that's
3 inadequate or that it was necessary to do both.

4 JUDGE WOODLOCK: Let me just ask that. I think you
5 correctly state what the article says, but if the opinion were
6 limited to the idea that both together are better than one or
7 the other alone, would the opinion be subject to challenge,
8 then?

9 MR. ROTMAN: No. But Daubert doesn't require the
10 plaintiffs to have the best.

11 JUDGE WOODLOCK: I understand. I am just trying to
12 figure out what is the fishbone in your throat over this
13 opinion.

14 MR. ROTMAN: And, as we point out in our briefing,
15 Dr. Wei acknowledged that both are done, that it's not just
16 this one case. He acknowledges that other researchers do
17 logistic regression instead of matching. He acknowledged that
18 and, again, in the paper that I have just brought up to the
19 Bench. And I will also ask the Court to look at GFPL1965,
20 which is the Karnik paper. The Karnik paper is an interesting
21 paper, because the subject matter is "Cardiac arrest and sudden
22 death in dialysis units."

23 JUDGE WOODLOCK: Can that be blown up, at least the --

24 MR. ROTMAN: Yes.

25 First blow up the top part, the title and the authors.

1 And what we see here is that one of the authors is Dr. Lazarus.
2 We talked about him yesterday. He was the Chief Medical
3 Officer for Fresenius.

4 And another of the coauthors, the last one listed, is
5 Glenn Chertow. He is one of the defense experts.

6 In addition, if you look at the very top of the paper,
7 where it says "Methods," and it's highlighted --

8 Could you bring that up and make it as large as
9 possible.

10 We are talking about Fresenius patients, Fresenius
11 facilities, and the reason this is highlighted, this is the
12 "Methods" section of the paper, it's clear what they're saying
13 here, is they compared patients, and there were 400 of them, to
14 the entire cohort of patients that did not have cardiac arrest,
15 77,000. So, it was exactly what they did in the 2010 study in
16 that regard.

17 So, here's a published paper relied on by defense
18 experts and plaintiffs' experts, contributes to the knowledge
19 based on science --

20 JUDGE WOODLOCK: It is not expressed there, but the
21 assumption is that this is a sampling, this is regression,
22 right?

23 MR. ROTMAN: This is not using matching.

24 JUDGE WOODLOCK: I mean matching. Excuse me.

25 MR. ROTMAN: In fact, as I read the paper, they also

1 did not do regression. They did neither, and yet it was
2 published. So, anyway, the point I'm making is very, very
3 similar facts and Fresenius population, subject matter the
4 same, no matching. So, Dr. Wei's opinion has no support.

5 JUDGE WOODLOCK: I think we understand your point. I
6 do not understand the defense point. Maybe we can do that as
7 we deal with these opinion by opinion.

8 So, why are you holding on?

9 MS. BROOKS: Pardon me, your Honor?

10 JUDGE WOODLOCK: Why are you holding on? The question
11 is, is it a necessary condition, as is explicitly stated in the
12 report, even when you look at the context? He is basically
13 saying you have got to have matching for an appropriate -- it's
14 a *sine qua non*, necessary condition, however you put it. Why
15 are you fighting about that?

16 MS. BROOKS: We are fighting about it, because the
17 example that Dr. Wei gave as to what happens when you don't do
18 matching and you only do case mixing he applied specifically to
19 the data of the Hakim Study, and he pointed out that the
20 failure to match resulted in there being healthier patients in
21 the control group than in the group that had cardiopulmonary
22 arrest.

23 JUDGE WOODLOCK: That is a criticism about the way in
24 which the data was used. It is not a statement, as I
25 understand it, of what is necessary for an appropriate study

1 generically, and I am not sure your people disagree with that.
2 One can have regression analysis. You may say that is not very
3 good, but it is not wholly inadequate. It does not seem to me
4 that there is a real fight here, or, if there is one, it is one
5 that is not visible to the human eye, and I am not quite sure
6 why we should be worried about it. It seems to me that you
7 have effectively conceded that.

8 MS. BROOKS: You know, your Honor, I can't dispute
9 that. I think that if Dr. Wei is going to be allowed to
10 explain why the failure to match in this case caused a skewing
11 between the population who had the cardiopulmonary arrests and
12 the population who did not, and the population that had the
13 CPAs were, I believe, 72 percent of them had diabetes, whereas
14 the population without CPAs were only 54 percent had diabetes,
15 and, as a result of that, that biased the results, and that's
16 what he intends to testify to, we certainly can live with that.

17 JUDGE WOODLOCK: But he does not clear his throat by
18 saying, "And it is absolutely necessary always to have
19 sampling." So, it seems to me that, doesn't that answer the
20 question, that is to say, either we say it or you agree to it?

21 (Ms. Brooks nodded affirmatively)

22 MR. ROTMAN: To me, that's just a backdoor to getting
23 the opinion that they want.

24 JUDGE WOODLOCK: Well, but isn't he permitted to talk
25 about the particulars of a particular study, but he is not

1 going to be able to say, "If you do not have matching, it is
2 not a fair study"?

3 MR. ROTMAN: So, what I understood Ms. Brooks to be
4 saying is that they want him to be able to say, because they
5 did not do matching, you have a dilemma in that you have an
6 imbalance of health factors between cases and controls.

7 My point is the matching that he is proposing is based
8 on age, race, gender, diabetes status and vascular access, five
9 things, and they did the logistic regression on just those five
10 things. So, he still hasn't offered a basis for why logistic
11 regression wouldn't accomplish that same balancing.

12 JUDGE WOODLOCK: But why isn't that the stuff of
13 cross-examination at that point, once we have said it is not a
14 necessary condition that you have sampling? Now we are talking
15 about how good one is versus the other, and that is
16 cross-examination of experts who have differing views about
17 what the valences are among the several kinds of
18 considerations.

19 MR. ROTMAN: Because it still doesn't remedy the
20 original objection we had, which is that he is offering an
21 opinion without a basis. That opinion essentially is that the
22 only way you can achieve this is by doing matching on top of
23 your logistic regression, and that logistic regression alone
24 won't do it, and he doesn't offer any basis for that.

25 JUDGE WOODLOCK: I think I understand the view, but it

1 seems to me that this is where we are going between a kind of
2 generality of what do people do, his methodology in this area,
3 and then what was done here and what is the shortcoming of
4 this, and the shortcoming of this is it does not do all the
5 things you could do under these circumstances.

6 MR. ROTMAN: Your Honor, I'm wanting to keep to the
7 schedule, and I have the point. I believe the Court
8 understands our point, and so I am prepared to move on. I
9 don't believe saying anything further is going to add to the
10 discussion.

11 JUDGE WOODLOCK: Well, I suggest that an agreement can
12 be reached by the parties that would be more nuanced, rather
13 than us imposing it, and it involves essentially a rewriting of
14 two sentences of the Wei Report.

15 MR. ROTMAN: We can try that, your Honor.

16 JUDGE KIRPALANI: And I would echo that.

17 MR. ROTMAN: So, the second opinion that we are
18 challenging relates to Dr. Wei's opinion that appears in
19 Paragraphs 87, 88 and 89.

20 We can look at 89 and bring that up. And, again, this
21 is 3982. Do you have that? And it's on Page 41.

22 And the opinion is, basically, if you highlight just
23 the first sentence of Paragraph 89 and bring that up, the
24 analysis presented in the Hakim Memo -- he calls it the "Hakim
25 Memo." He's referring to the 2010 study.

1 JUDGE WOODLOCK: Right.

2 MR. ROTMAN: "-- did not account for other potential
3 risk factors that are likely to be associated with CPA."

4 And then, in the final sentence of the paragraph, he
5 basically says for that reason the study cannot establish
6 whether there's an independent relationship between serum
7 bicarbonate levels and CPA. So, he's linking what he says is
8 that the Study didn't account for other potential risk factors,
9 and he clarifies that to mean confounders, and so I want to
10 focus on that for a second.

11 So, the whole notion of confounders was explained by
12 Ms. Brooks yesterday in the example she gave about crime in the
13 summer, when it's hot, and ice cream. Ice cream can be a
14 confounder, in that it can show to be associated with crime,
15 even though it's the heat in the summer, it's the heat with the
16 crime, but the ice cream is a confounder because it's
17 associated with heat. Wait a second. I might have it screwed
18 up.

19 JUDGE WOODLOCK: Isn't the confounder the weather?

20 MR. ROTMAN: The weather is the confounder?

21 JUDGE WOODLOCK: Right. Isn't that the thrust of what
22 they said?

23 MR. ROTMAN: Yes. Okay. So, there is general
24 agreement that you don't want confounders to be in a study, and
25 there's ways to deal with it, and the idea is you want to have

1 a clean relationship between the risk factor you're examining,
2 here bicarbonate, and CPA, and if there are other things that
3 will cloud the issue because they're related to both
4 bicarbonate and the outcome, CPA, you might be measuring that
5 by mistake, so you do things to avoid that. And they did that
6 in the study, but they didn't do it for everything you can
7 imagine. They did it for a discrete number of things. And
8 what Dr. Wei is saying is they should have done it for more,
9 and the fact that they didn't do it for more means that they
10 can't reach a conclusion that there's any -- or nobody could
11 reach a conclusion that the study leads to -- supports any
12 conclusion of a relationship between the bicarbonate and the
13 CPA.

14 And our position on this is that that opinion should
15 be excluded because it's speculative, and the reason it's
16 speculative is because Dr. Wei didn't do anything to determine
17 if there is any confounder or any group of confounders that, if
18 the study was adjusted for those confounders that he's saying
19 were not done, whether the results would have changed and to
20 such an extent that that very substantial increase in risk
21 disappeared. It would have to be quite a confounder to be able
22 to do that, given the magnitude of the increase in risk.

23 And then, when I asked him the question --

24 And let's go to his deposition, which is GFPL4556, and
25 it's Page 204, Lines 10 through 14.

1 So, your Honors, this is in our brief, but I noticed
2 today that the brief -- and it says at "Exhibit 13" in our
3 brief. I noticed today that it lists it as Page 205 at Lines
4 10 through 14 in the footnote, but it's really 204, Lines 10
5 through 14, and what I'm showing you right now is Page 204,
6 Lines 10 through 14.

7 The question I asked Dr. Wei is, "What analysis did
8 you do to determine what the appropriate confounders should
9 have been?" And his answer is: "No, I didn't do it." He
10 didn't do an analysis. He could have done the analysis. He
11 has the data. He acknowledged he had the data. The group of
12 analysts that he was working with had the data. They could
13 have done the analysis and said, "See, if you plug this into
14 the model and adjusted for it, you would have then made the
15 association disappear," but he didn't do that.

16 So, he's speculating, and that's misleading to the
17 jury, and that's easily confusing to the jury, and it's
18 prejudicial to the plaintiffs for an expert witness talking
19 about such technical issues as statistical methods of
20 adjustment and confounders to say something like this,
21 especially somebody with Dr. Wei's credentials, and he's just
22 speculating. He doesn't know that it has any effect.

23 Now, I know that Ms. Brooks is going to stand up and
24 say, "Well, yes, he does, your Honor, because they did the
25 Flythe Study, that follow-on study that we talked about

1 yesterday, and your Honor brought up the fact, making a comment
2 about the Egyptian journal. That's that the one I'm talking
3 about.

4 JUDGE WOODLOCK: I will probably move to strike that.

5 MR. ROTMAN: You?

6 JUDGE WOODLOCK: The reference to Egyptian journals.
7 I will move to strike that.

8 JUDGE KIRPALANI: How about trading "Hakim Memo" for
9 "Egyptian journals."

10 (Laughter)

11 MR. ROTMAN: Just so we are on the same page about
12 what study we are talking about.

13 JUDGE WOODLOCK: Right. I do want to emphasize
14 something that I think came out yesterday, which is, maybe
15 there will have to be serviceable references to these various
16 kinds of things that do not include "Hakim Study" --

17 MR. ROTMAN: Right.

18 JUDGE WOODLOCK: -- or that sort of thing. But, "A
19 study was done, here it is."

20 MR. ROTMAN: We call it the "Flythe."

21 JUDGE WOODLOCK: And you call it the "Flythe" one.
22 Whatever. But the point is, isn't he entitled to rely on that?
23 He did not do it himself.

24 MR. ROTMAN: Of course. That's not my point. He can
25 rely on that. It depends on what he's taking from it.

1 And my point is this: The study that we call
2 "Flythe," F-l-y-t-h-e, because she is the lead author, has a
3 number of differences between it and the 2010 study, and,
4 therefore, you cannot conclude what the different adjustments
5 contributed to the different result. For example, the whole
6 concept of the study is to compare cases to controls, but they
7 had different numbers of cases and different numbers of
8 controls. In fact, they had 70,000 fewer controls because they
9 did this matching process, and that eliminated 70,000 controls.
10 Nothing wrong with doing that, if they do it right, but that
11 means, okay, is that the reason why there's a difference?

12 JUDGE WOODLOCK: Can you address the question why this
13 should not be the subject of cross-examination? That is to
14 say, you do not think that they did an effective job. So, what
15 we have is we have got a patchwork of various kinds of studies,
16 not all of them corresponding to each other completely, and we
17 have experts who come in and say, "'This' is better than
18 'that,' 'this' is better than 'that.'" They do not say it is
19 absolutely proscribed; they just say, "It is better than
20 'that.'" Why isn't that cross-examination stuff?

21 MR. ROTMAN: It certainly would be something that we
22 could cross-examine on, and the question is, is Daubert there
23 so that we avoid potentially confusing and misleading jurors?

24 JUDGE WOODLOCK: It is, but let me just ask this
25 question in this way, and that is, we have got -- I guess the

1 word of the day yesterday was "litany" or maybe a "chorus" of
2 experts. They are interrelated, their opinions are --

3 MR. ROTMAN: There's overlap.

4 JUDGE WOODLOCK: Well, they are not just overlapping,
5 but they are interrelated in some way. Somebody provides
6 Points A and B, and then somebody else does F and G --

7 MR. ROTMAN: Yes.

8 JUDGE WOODLOCK: -- and then they fill them in, and
9 somebody kind of puts the jigsaw puzzle together, or they try
10 to in their opinions, by relying on each other. If there is a
11 grounds for A and B and there is a grounds for F and G, then
12 why do we not say to you, "Have at it," with the several
13 people? "I rely on Flythe," says Dr. Wei. Then you can ask
14 him what he knows about Flythe, in addition to being able to
15 ask whoever presents Flythe as Flythe.

16 MR. ROTMAN: Your Honor is exactly right. That is
17 what we will do if the opinion is not precluded under Daubert.

18 JUDGE WOODLOCK: So, the question is why exclude it?
19 You say he did not do his own analysis. He apparently concedes
20 it and says he relied on Flythe. The second, I guess you say,
21 is he does not know from nothing about confounders as a general
22 proposition.

23 MR. ROTMAN: The point is, is Daubert appropriately
24 invoked when you have an expert opinion that is just based on
25 speculation?

1 JUDGE WOODLOCK: But that is my point, I guess, is, it
2 is not based on speculation. What it is based on is he says, I
3 think -- this is a crude way of saying it -- but he says, "I
4 like what Flythe did, and I rely on that."

5 MR. ROTMAN: He can say that he likes what Flythe did,
6 but that doesn't go to the issue of whether he's speculating
7 about whether Flythe answered the question about whether
8 additional confounders, had they been put into the 2010 study,
9 would have changed the results, because there were -- I started
10 mentioning different numbers of cases and controls, different
11 demographics for the patients and controls, different bicarb
12 distribution.

13 JUDGE WOODLOCK: It is always going to be the case
14 that there is not precise overlap among the studies, or at
15 least the condition of man is that is the case.

16 MR. ROTMAN: Exactly.

17 JUDGE WOODLOCK: So, now we are talking about whether
18 or not we exclude somebody from relying on the jigsaw puzzle
19 pieces that are created by somebody else.

20 MR. ROTMAN: It's not that he can't rely on those
21 jigsaw puzzle pieces; it's that there's nothing in those jigsaw
22 puzzle pieces that answers the question.

23 JUDGE WOODLOCK: Isn't this, then, an attack on Flythe
24 and a suggestion that we exclude Flythe?

25 MR. ROTMAN: No. It's a statement -- and I'm

1 obviously not making myself clear, so let me try one more time.

2 If you're saying Flythe proves that the Hakim Study or
3 2010 study didn't make all the right adjustments, I'm saying
4 Flythe does nothing of the sort. You can rely on Flythe for a
5 lot of things, but you can't rely on it for that, because you
6 can't isolate the adjustments because there are so many things
7 that Flythe did differently than the 2010 study. Is it because
8 there were different cases? Is it because they had 70,000
9 fewer controls? Is it because the bicarb values that they had
10 in their study were different between the two? The difference
11 in the two results may have had nothing to do with adjustments
12 for confounders. So, therefore, he's speculating still --

13 JUDGE WOODLOCK: There is a spectrum here between
14 total speculation and relying on bits and pieces and trying to
15 tie them together, and it strikes me that this is in the area
16 of trying to tie them together, which would put it, for me
17 anyway, in the area of cross-examine him and demonstrate that
18 this is not sufficient. But there is enough it is going to get
19 to the jury in some form, and it is enough to have somebody
20 stitch this together, unless this guy does not know confounding
21 at all, and he should not be talking about it.

22 MR. ROTMAN: So, your Honor, I've made all my points
23 on that argument, and I would like to just make one final
24 point. It will just take a second to do it. And that is, we
25 had an additional ground on this opinion, and that is that the

1 expert is really not qualified to give the opinion. And we put
2 that in our brief.

3 And the argument was this: Dr. Wei testified --

4 If we can go to his testimony at Page 191, Lines 2
5 through 4, and can you call up Lines 2 through 4. Wait a
6 second.

7 Something is off, so I'm just going to read the
8 testimony. We may have an incorrect cite. But the testimony
9 was --

10 JUDGE WOODLOCK: This is at Page 13 of your brief, "I
11 have no opinion on that. I'm not a clinical person"?

12 MR. ROTMAN: And also he said to determine -- he said,
13 "So-called potential confounders, it has to be decided both by
14 clinical people, also statistician. You cannot determine
15 relevance of confounders to the outcome solely by
16 statistician." And then he admitted he's not a clinical
17 person. So, we've got the two --

18 JUDGE WOODLOCK: But isn't that simply becoming
19 modesty about the scope of his opinion, nothing more than that?
20 He says, "I can give you so much, but I can't go any further on
21 that," and so somebody else has got to go further with it.

22 MR. ROTMAN: Right. But he is going the further
23 himself. He's saying, "On confounders here is my opinion, but
24 confounders requires both clinical and statistics, and I don't
25 have both. I only have one." So, he is basically saying, "I

1 don't have the expertise that I have stated as required to give
2 the opinion on what confounders are appropriate."

3 JUDGE KIRPALANI: Maybe Ms. Brooks can explain how the
4 existence of the Flythe Study fills this what I will call a
5 "gap" in his expertise.

6 MS. BROOKS: Yes. With the Court's permission, and
7 it's also just not the Flythe Study, there are others, so I
8 have a very short set of PowerPoints, if I can distribute them.
9 Thank you.

10 JUDGE KIRPALANI: And I probably should ask
11 plaintiffs' counsel, is there anything more on this point
12 before I interrupt you?

13 MR. ROTMAN: No, I'm all set.

14 MS. BROOKS: If I can ask the Court to switch on --
15 thank you. May I approach?

16 JUDGE WOODLOCK: Yes.

17 MS. BROOKS: If we could go to Slide 5, Mr. Barnes.

18 And so, here is how Dr. Wei fills in the gap of his
19 not being -- and admittedly he admits that he is not a
20 clinician, so how does he know what the potential confounders
21 would be in a study to look at whether or not there is an
22 association between high serum bicarbonate and increased risk
23 of either cardiopulmonary arrest or increased risk of mortality
24 or increased risk of sudden cardiac death? And so, what he
25 does is, he turns to the peer-reviewed public literature where

1 studies were done, not just by biostatisticians like Dr. Wei,
2 but by a team that included clinicians.

3 And the first one he looks at is the DOPPS I Study,
4 with the lead author being Dr. Bommer. We talked about this
5 briefly yesterday. Here is what the DOPPS I Study found, is,
6 the unadjusted data, which is what Dr. Hakim had relied upon,
7 indeed showed an association between high serum bicarb and
8 increased risk of mortality. However, then the DOPPS team
9 decided, to quote them, "To see whether nutritional factors
10 might partly explain the findings, Model 3 adjusted
11 additionally for such nutritional factors as BMI," which means
12 "Body Mass Index," serum albumin, and nPCR values.

13 Now, Dr. Hakim did take into consideration albumin, so
14 we'll give him that, but did not take into consideration BMI or
15 nPCR, which are also linked with malnutrition and potentially
16 inflammation.

17 And what the DOPPS team found is Model 3, which
18 adjusted for these potential confounders linking nutrition,
19 when it was adjusted, "the relative risk," which is the "RR,"
20 "associated with alkalosis became less pronounced and
21 nonsignificant."

22 So, that's how Dr. Wei can say that, "I believe, in my
23 expert opinion, that, if one adjusts for these particular
24 potential confounders, at least as far as what they found in
25 DOPPS I, the association goes away."

1 Then we turn to DOPPS 2. DOPPS 2 was done many years
2 later. DOPPS I was done in 2004. I believe DOPPS 2 was done
3 in 2012. The lead author is Dr. Tentori. She is a
4 nephrologist.

5 What did the DOPPS 2 team find? They found that in
6 their analysis "serum bicarbonate levels above 23
7 milliequivalents per liter were not associated with increased
8 mortality." And then they even discuss right below it DOPPS I
9 and how this is inconsistent with the unadjusted data in
10 DOPPS I. So, but that it's consistent -- and that is the last
11 sentence -- they say, but "Our findings are in agreement with
12 results from a more recent analysis that reported no
13 association between serum bicarbonate greater than 22
14 milliequivalents and mortality after adjustment for nutritional
15 and inflammatory markers." So, once again, consistent with
16 what DOPPS I found when they adjusted for nutritional and
17 inflammatory markers.

18 But what is the literature that DOPPS 2 is talking
19 about when they say, "Our findings are in agreement with
20 results from a more recent analysis?" You see a number "42."
21 That reference is the Wu paper. Dr. Wu is the lead author, but
22 the senior author is Dr. Kalantar-Zadeh, who is one of our
23 experts.

24 And what the Wu team found is this: If you look at
25 the unadjusted data on the left-hand side, it appears as though

1 there is even a greater increase or a greater association
2 between high serum bicarbonate and increased risk of death than
3 there is between low serum bicarbonate and increased risk of
4 death, which sort of goes contrary to what the whole nephrology
5 community always thought about the dangers of acidosis. And
6 so, Dr. Kalantar-Zadeh's group said, "This is a very
7 interesting finding, but, then again, it is only unadjusted
8 data." So, what his group did was then do a case mix, and not
9 even a case match, so they did a case mix adjustment, and the
10 "J" turn into a "U." So, now we have an association at both
11 the low end and the high end.

12 But then they took it one step farther, and they talk
13 about a "CASE MIX," M-I-X, and "MICS," M-I-C-S adjusted.
14 "MICS" stands for "Malnutrition Inflammation Complex Syndrome."
15 And so, Dr. Kalantar-Zadeh's group, after adjusting for MICS,
16 you can see that the association on the high end virtually
17 disappears, but the association on the low end got even
18 greater.

19 And this study was done well before this litigation
20 ever started, and this study has actually spurred the debate
21 about whether it's better to be acidotic or alkalotic that took
22 place last year at the American Society of Nephrology. And
23 what's interesting is, that one of Dr. Kalantar-Zadeh's
24 colleagues, a Dr. Mehrotra, took the position it's better to be
25 alkalotic. And the lead author of the DOPPS 2 paper, Francesca

1 Tentori, was given the position of it's better to be acidotic,
2 and she stood up at her presentation, and we have attached the
3 audio as an exhibit to our briefs, and said, "I don't know why
4 I was given this side of the debate, because my data showed
5 also the very same thing, that it's actually better to be
6 alkalotic than acidotic.

7 But then the debate continues --

8 And, your Honor, Judge Kirpalani, you asked me
9 yesterday if Yamamoto was cited in any of our papers, and it
10 is. It is cited specifically in both our response to
11 plaintiffs' Omnibus Brief but also in this opposition. It's
12 cited at Page 11, and it's Exhibit 16, and this, too, was
13 relied upon by Dr. Wei. So, this just came out this year,
14 earlier this year, in the *American Journal of Kidney Diseases*,
15 and it's on Page 11 of our brief at Exhibit 16. The title is
16 "Predialysis and Postdialysis pH and Bicarbonate and Risk of
17 All-Cause... Mortality in Long-term Hemodialysis Patients."

18 And what the authors found -- and, I'm sorry, I should
19 have put it on this slide -- they found that pre- and
20 postdialysis bicarbonate levels were not associated with
21 all-cause and cardiovascular mortality. So, their findings are
22 consistent with Wu that is consistent with DOPPS 2 that is
23 consistent with the adjusted data of DOPPS I.

24 But then they made a further finding, because this was
25 the study where they had two different dialysates. One was 30

1 bicarbonate plus 6 acetate, and then the other one was 34
2 bicarbonate plus 2 acetate, therefore, both equalling 36 under
3 the plaintiffs' total buffer theory, and this is their key
4 findings as to that: They said, "These findings suggest that
5 the dialysate bicarbonate concentration itself," so not the
6 acetate, the bicarbonate concentration itself, "may play a key
7 role in limiting the postdialysis bicarbonate level; for
8 example, when dialysate bicarbonate concentration is 30
9 milliequivalents, postdialysis bicarbonate level does not
10 exceed 30 milliequivalents during dialysis regardless of the
11 contribution of total alkali of 36 milliequivalents."

12 That's the heart of the dispute here, and Yamamoto
13 definitively answered that question earlier this year.

14 JUDGE WOODLOCK: Because I have not been back to look
15 at it, does Dr. Wei's opinion include references to Wu, of
16 course, DOPPS I and DOPPS 2, but also Yamamoto?

17 MS. BROOKS: Yes, your Honor. I will double check to
18 be sure. The reason I am saying that is Yamamoto came out
19 after most of our experts had written their expert report.

20 JUDGE WOODLOCK: It was in March, was it? It bears
21 the date "March"?

22 MS. BROOKS: Yes, I think so. And so, what we did is,
23 we did a "supplemental materials considered" and added Yamamoto
24 to all of our "experts materials considered."

25 Interestingly, Dr. Kalantar-Zadeh was actually one of

1 the peer reviewers of the Yamamoto paper, and another one of
2 our experts, Dr. Gennari, was invited by the *Journal* to write
3 an editorial opining on the results of Yamamoto. So, it's a
4 very close community, apparently.

5 JUDGE WOODLOCK: It is like family.

6 MS. BROOKS: It's like a family. And so, everyone was
7 very excited about the Yamamoto paper, not just because it
8 certainly, in our minds, is definitive of the issue in this
9 case, but because, unlike a lot of the previous studies, they
10 actually had pH values that they could look at, and so they did
11 a very in-depth analysis from the Japanese database and were
12 able to really tease out some fascinating data and fascinating
13 conclusions that they could base upon a very robust database.

14 MR. ROTMAN: Your Honor, just briefly on those points?

15 JUDGE WOODLOCK: Yes.

16 MR. ROTMAN: So, Ms. Brooks brought up the subject of
17 three papers -- four, actually -- Bommer, the DOPPS I, the
18 DOPPS 2, which is Tentori, the paper, and Yamamoto. None of
19 them have to do with sudden cardiac arrest. They're all
20 mortality. Bommer, which she said, when they did the
21 adjustments that made the results nonsignificant, it brought
22 the p-value to .06. .05 is called "statistically significant."
23 That difference between .05 and .06 does not, in the opinion of
24 the investigators, negate their finding of an increase in risk,
25 because they say in the paper, and I could bring it up, but

1 just to speed things up, "The significant U-shaped curve was
2 still found in this study when data were corrected for
3 nutritional factors." So, that U-shaped curve is that when
4 it's higher on the left and higher on the right, and that was
5 statistically significant, even after the adjustments that
6 they're talking about. And in the abstract where they're
7 talking about their results, they state both high, greater than
8 27, and low, less than or equal to 17, serum bicarbonate levels
9 were associated with increased risk for mortality and
10 hospitalization.

11 So, the defendants' presentation of it I think is not
12 consistent with at least the way others are reading the paper.

13 JUDGE KIRPALANI: I'm sorry. Which study are you
14 reading from?

15 MR. ROTMAN: This is DOPPS 1.

16 JUDGE KIRPALANI: That is DOPPS 1?

17 MR. ROTMAN: Right. Now, DOPPS 2, really the main
18 focus was on not the serum bicarbonate. The primary analysis
19 was based on the dialysate bicarbonate, the prescription, not
20 the blood, and they found an association between higher
21 dialysate and mortality, and that did not --

22 JUDGE WOODLOCK: They also found that, once you
23 adjusted for nutritional inflammatory markers, that
24 disappeared.

25 MR. ROTMAN: No, absolutely not.

1 JUDGE WOODLOCK: "Our findings are in agreement with
2 the results of a more recent analysis that reported no
3 association between serum bicarbonate less than 22
4 milliequivalents and mortality after adjustment for nutritional
5 and inflammatory markers."

6 What part of that am I missing?

7 MR. ROTMAN: That I was referring to the primary --

8 JUDGE WOODLOCK: Primary or secondary --

9 MR. ROTMAN: No, no, no, no.

10 JUDGE WOODLOCK: -- they included that conclusion in
11 DOPPS 2, did they not?

12 MR. ROTMAN: Yes. And so, my point was that is on the
13 serum bicarbonate part of the study. The dialysate part, the
14 prescription, which is really what this case is about and the
15 most direct evidence of the relationship between the total
16 buffer and the risk, is the dialysate. But on this part, the
17 serum bicarbonate, that's exactly what they found. But they
18 also stated that, when they did a time-adjusted measure of the
19 exposure, in other words, updated their data for closer in time
20 to the event, that there was an association, even for serum
21 bicarbonate and mortality. So, that part was not included.

22 JUDGE WOODLOCK: But, again, isn't this
23 cross-examination?

24 MR. ROTMAN: I'm just trying to clarify --

25 JUDGE WOODLOCK: Part of what we are trying to do is

1 sort out those things that cannot properly be presented to the
2 jury from those as to which there may be a dispute or maybe
3 somebody has a stronger argument or a lesser argument. We are
4 not making *that* determination.

5 MR. ROTMAN: My point is simply, and I can sit down
6 now, if I just make the point that on each one of these studies
7 that the defendants just went through we are absolutely
8 disputing the takeaway message of these studies.

9 JUDGE WOODLOCK: But Wei was properly relying upon
10 those; that is, it is within the realm of expertise for a
11 statistician to rely upon those kinds of studies in stitching
12 together the nature of his opinion, and you can test, as you
13 did, the statistician by saying, "You are not competent to have
14 an opinion on that, are you?"

15 MR. ROTMAN: Your Honor, the point is just this: In
16 none of the studies does the risk disappear, even when you make
17 all the adjustments that they are talking about. The risk goes
18 down from its highest point, but it is still elevated. Even in
19 the U- and the J-shaped curves that they showed you, it's up.
20 Even after their adjustments in the Wu paper it's up, in the
21 DOPPS 1. It may be that the adjustment for MICS, which is the
22 Nutrition and Inflammation Complex, has a reduction effect,
23 but, again, in the 2010 study they made an adjustment for
24 nutrition. They didn't put all the variables in that are
25 included in MICS, but they put in the main one for nutrition

1 that they consistently use and they've used in published
2 papers.

3 That's all I have to say on the subject, your Honor.

4 JUDGE KIRPALANI: Thank you.

5 JUDGE WOODLOCK: Can I make one suggestion? Maybe
6 this is too quick to be doing the blue pencil on this, but
7 putting to one side the last two, or 2A and 2B arguments on
8 opinion, if one were to take the -- and I am just using the
9 first page or the second page of the PowerPoint that the
10 defendant passed out -- if one were to say the Hakim Memo
11 analysis -- and, again, we are going to find some other way of
12 referring to it so that we distinguish between the 2010 study
13 and other things -- but also did not adequately control --
14 let's see.

15 The third one, Page 4 of the slides. You just simply
16 say -- I'm sorry. I should not be doing this on the fly.

17 What I guess I am trying to get out is, as to the
18 first one, the first opinion, that this is pretty easily
19 cleaned up with a blue pencil, if I could find where I can
20 apply a blue pencil, and solves this problem, and I really do
21 encourage the parties to work toward that --

22 MR. ROTMAN: Yes, your Honor.

23 JUDGE WOODLOCK: -- because this strikes me,
24 tentatively, that this is going to be, once cleaned up, the
25 subject of cross-examination, forceful cross-examination, but

1 not exclusion.

2 MR. ROTMAN: Your Honor, we are going to try to work
3 that out. We are willing to do it, in any event, and we can
4 inform the Court if we're successful.

5 Just to clarify my last statement about even after the
6 adjustment there was still an increased risk, the reason that's
7 significant is Dr. Wei's opinion is, if they had done more
8 adjustments, their risk would have gone away, they would have
9 been substantial enough to make that risk disappear, and
10 nothing in anything that the defendants have pointed out
11 provides any support for that, not the Flythe Study or any of
12 these mortality studies.

13 The Flythe Study, because there were so many
14 differences, you can't isolate that it was because of the
15 adjustments, and the others because it didn't make the
16 association go away, and there were mortality studies, which
17 are relevant but different. And so, we are left with Dr. Wei's
18 opinion. It's speculative, and then it's for the Court to
19 decide whether that is a Daubert issue or whether that's a
20 cross-examination issue.

21 JUDGE WOODLOCK: But that is addressed to these other
22 studies, I think, that is, the inconsistency of the other
23 studies. I can see the reverse J in, I guess, Wu here, but I
24 also see some of the narrative in these studies that is more
25 forceful, I guess.

1 MR. ROTMAN: There's language that the defendants are
2 not highlighting. For example, what I read to you from the
3 DOPPS 1, which was not read by Ms. Brooks, was --

4 JUDGE WOODLOCK: But that is the whole point of
5 cross-examination, I guess. If it is a mix, if it points in
6 two different directions, bring it out.

7 MR. ROTMAN: Thank you, your Honor. I'm all set.

8 JUDGE WOODLOCK: So, I guess it is Maddux.

9 MR. KETTERER: Your Honor, good morning. I'd like to
10 suggest handling, because of the points that I want to make,
11 the Dr. Maddux and Dr. Chertow motions together. And also
12 yesterday what we had done is, there was something at the end
13 of the morning, and you had said to me, you know, "Do we really
14 need to go over this now, because they're not really clear?",
15 and I said, "Okay, let's put it into context." And so, the
16 context of that particular motion was the failure of the
17 defendants' experts to consider the totality of the plaintiffs'
18 experts in making this claim of, "You don't have any evidence
19 on general causation." And I am not just glazing over that
20 motion, but I'm saying that I will be able to illustrate the
21 point that I want to make with respect to those on the basis of
22 dealing with Drs. Chertow and Maddux at the same time.

23 I want to reduce the argument, as well, a little bit
24 and sort of focus it. I'm certainly not conceding any of the
25 other points that were made in our brief as to why Dr. Maddux

1 or Dr. Chertow ought to be struck. I think that some of the
2 other points that I am not going to specifically address in
3 oral argument are made just fine in our briefing.

4 But the two major points that I would make with
5 respect to both of the experts is that they are general
6 causation opinions, and Dr. Maddux has an added layer of
7 complexity, but neither of their opinions, their general
8 causation opinions, are really supported by much of anything,
9 and I'm going to demonstrate that, because if you look at their
10 reliance list and you look at the deposition testimony, which
11 we are going to go through, there's no foundation, there's no
12 data.

13 And one of the things that happened yesterday, and
14 again this morning, is, I think that the Courts have sort of
15 given this guidepost of what it is you are looking for in this
16 hearing, some of the things, and one of the things is, as we
17 went through with Dr. Borkan and we went through with, I will
18 still refer to it colloquially as the "Hakim Memo," was this
19 idea that the opinions have to be tethered to data and to
20 specific literature or some sort of actual foundation.

21 Now, in Dr. Borkan's case we didn't actually look at
22 this, but he cited over a hundred pieces of medical literature
23 and he looked at a lot of the data points internally in
24 Fresenius, and what we are going to see from Dr. Chertow is he
25 looks at a grand total of zero pieces of literature and cites

1 four citation sources, one of which is a sales document, one of
2 which is USRDS data, and two of which are internal Fresenius
3 memos or documents. We asked him about it in deposition, and
4 we are going to actually go to this, but we asked him about it
5 in deposition, because maybe we misunderstood something, maybe
6 there was something that wasn't really there. And Dr. Chertow
7 really represents the very nature of *ipse dixit*. I mean, what
8 he did was he says, "Well, look, I've had a very long career,
9 I've done research in this area, I am an expert in this area."

10 "But the opinions that you're offering on general
11 causation as to whether or not excess bicarbonate can lead to
12 cardiac arrhythmias, or how acetate plays a role in
13 contributing to the overall bicarbonate, what's the actual
14 foundation?" Well, it's just sort of a generalized statement.

15 And that's the kind of thing that was problematic when
16 we examined the opinions of Dr. Hakim. Yesterday, when we went
17 through the memo, the problem was, "Well, Dr. Hakim is a very
18 established nephrologist. Dr. Hakim's done lots --" and in
19 Dr. Hakim's case we could actually look back at the things that
20 he looked at historically. We could see the emails and the
21 data that he was looking at, if we went through that, we would
22 be able to trace all of that. We don't have the benefit of
23 doing that with Dr. Chertow, because he doesn't actually refer
24 to anything specific, so we don't have any idea.

25 I do want to give out, and one of the things that I

1 want to also look at -- and, by the way, I didn't address
2 Dr. Maddux specifically, but Dr. Maddux has a similar issue,
3 and Dr. Maddux's issue is that he cites maybe three or four, we
4 can look at it specifically, he cites about three or four
5 pieces of literature in his rebuttal report, and we can look at
6 his actual foundational report to which he submits, I believe,
7 no literature, and he cites some internal data sources and some
8 other things. But, again, for a general causation opinion, the
9 issue is neither Dr. Chertow nor Dr. Maddux in any way look at
10 the literature that the plaintiffs have looked at it, and they
11 don't list that they've considered the DOPPS Study, they don't
12 list that they've considered recent literature. I mean, maybe
13 they supplemented Yamamoto, which is recent. That would be
14 fair game.

15 JUDGE WOODLOCK: Let me just ask this, so that I am
16 sure I am oriented on this. We knock out Maddux, we knock out
17 Chertow. Is there a general causation expert for the
18 defendants?

19 MR. KETTERER: Sure, Dr. Pun. Dr. Pun was deposed at
20 length, and we are going to actually look at some of the quotes
21 that Dr. Pun has, but Dr. Pun may disagree with the ultimate
22 conclusion of our experts, but a lot of the foundational
23 things, when we asked him about it, he supports. Some of the
24 things he's very similar, in terms of the general causation
25 mechanism, he's aligning the same way as our experts, but he

1 has a different conclusion about the role of acetate's
2 contribution in overall bicarbonate and whether or not there is
3 a clear relationship. But whether there is a relationship with
4 high bicarbonate and sudden cardiac arrest -- or the chain is
5 high bicarbonate leading to metabolic alkalosis, which may lead
6 to a drop in potassium or calcium, which may lead to cardiac
7 arrhythmia -- no problem.

8 So, if you're going to make a claim -- and he has
9 looked at some of the evidence of the plaintiffs -- so if
10 you're going to claim that the plaintiffs have no evidence, and
11 you're going to claim that you want to make statements on
12 general causation, you have to look at the totality or the
13 weight of the evidence. That's, in fact, what Milward is
14 suggesting. Milward is suggesting we have to look at the
15 entire body, and it's not enough to say in your deposition,
16 "Well, I've looked at some broad-based literature, and that's
17 it." And we'll look at the actual testimony. When Dr. Maddux
18 is asked about this, he gives a very vague, circuitous answer
19 without any specific detail.

20 So, I have a presentation, and if I could just hand
21 that out.

22 Can we switch over, too, please.

23 MS. BROOKS: Your Honor, just a couple of things.
24 This has been now put together, these two motions, and actually
25 Mr. Denning is going to address Dr. Maddux, and I was going to

1 address Dr. Chertow.

2 Based on conversations we had yesterday, originally
3 Dr. Chertow, who is co-editor of a book called *The Kidney*, we
4 had retained to simply do in his original report, "Here's how
5 the kidney functions, here's what happens when it fails, here
6 is how dialysis works," and that was really what his opening
7 general causation report was confined to. In his rebuttal
8 report he looked at plaintiffs' general causation reports and
9 he picked out places where he said they just simply failed as a
10 matter of proof.

11 But we will concede that he did not cite a great deal
12 of scientific literature, and, under the sauce for the goose,
13 sauce for the gander, we would withdraw Dr. Chertow as a
14 general causation expert for anything other than, if it's even
15 necessary, teaching the jury the fundamental principles behind
16 how the kidney functions and how dialysis works and offer no
17 additional opinions.

18 MR. KETTERER: Fantastic.

19 JUDGE WOODLOCK: All right.

20 MR. KETTERER: Let's focus on Dr. Maddux, then, your
21 Honor, and let me just set the table. I gave you a PowerPoint.
22 And one of the things I wanted to do -- and, again, I started
23 to do this when we responded to Dr. Borkan's motion, but I
24 think it's important to get --

25 And if we can just bring up that -- we have it up now,

1 great, that PowerPoint.

2 I think it's important to at least set the groundwork
3 of what our case is before we tell you that they failed to
4 consider the evidence about our case. And I'm going to just
5 borrow this chart again and drag it over here for a second.

6 We've been throwing around some numbers, and I know
7 your Honors both read the briefing, but we've been throwing
8 around a lot of numbers and just kind of talking about them,
9 and I want to make sure that our case is really clear. And
10 what I mean by that is, there has been this intimation that I
11 don't think I've clarified before the Court, which is that,
12 whether you exceed the dialysate bicarbonate prescription is
13 even relevant to the case of whether or not you are making
14 someone alkalotic, and it's not. I mean, whether the
15 prescription is 35, 38, 40, and whether or not in some
16 theoretical possibility you reach 35 or exceed 35 -- as I
17 showed you yesterday, there's data that certainly suggests that
18 you can -- but whether you reach 35 or 38 or 40 isn't really
19 relevant. It's never been relevant to the plaintiffs' case,
20 and nobody has ever made that claim. Frankly, Dr. Hakim never
21 made that claim in terms of that was the relevant inquiry.

22 The question is how does the acetate impact the
23 overall bicarbonate, and when you impact the overall
24 bicarbonate, how does that rise or that sudden shift
25 potentially affect the electrolytes? That's it in a nutshell.

1 And I'm just going to draw this simple diagram, that,
2 if we had the dialysate on one side and we had the blood on
3 another, the patient's blood, and you have a prescription of 40
4 and an acetate of 8, and the patient starts, and they come in
5 with a bicarbonate, let's say, in the normal range, 22, by the
6 definition that we've been offered, and let's say that the
7 acetate is negligible, and that's generally accepted what it
8 is. Many people put it at zero or 1. That's the amount of
9 acetate that the patient is going to start at, and that's the
10 way the patient looks.

11 Now, what happens is, as I agree with what FMC
12 counsels present, there is a concentration gradient, and this
13 is diffusion in action. There's no question that there is
14 bicarbonate that's going to move over. That's the way it's
15 designed to do, and the design is to raise the bicarbonate.
16 And it is true also that the process which they are undergoing
17 is called metabolic alkalosis -- or not metabolic -- it's just
18 "alkalosis." Metabolic is a further down the line state.

19 So, alkalosis is a process, and we both agree on that.
20 But the dispute is -- and, by the way, the acetate is moving
21 over and is rapidly converting, so, unless the patient is
22 acetate intolerant -- and one of the things you will see from
23 the 1970's literature is that, when they were dialyzing with
24 acetate-only dialysis, one of the reasons they went away from
25 acetate-only dialysis was because roughly 10 percent of the

1 population or so was intolerant and they couldn't dialyze the
2 people effectively. There were also some questions about
3 whether acetate-only dialysis was really the most effective way
4 to buffer out folks' acid.

5 So, what happened was you have this movement, and
6 unless there's a buildup or someone's acetate intolerant,
7 they're converting acetate. What are they converting the
8 acetate to in the liver? They're converting to bicarbonate.
9 Now, the purpose of the dialysate bicarbonate is to raise this
10 number up (indicating), the serum bicarbonate, so that when
11 they leave dialysis they are at a specific range or target
12 area.

13 Now, what FMC and others will say, and even our
14 experts would say, is that somewhere between 27, 28, somewhere
15 around that number, is where you're trying to get the patient
16 to leave dialysis so that their serum bicarbonate is a little
17 bit elevated. The problem is, if you don't account for how
18 much the acetate is contributing to this overall bicarbonate
19 load, instead of leaving at 27 or 28, some of these patients
20 are leaving much higher, right? So, if they leave at 32 or 33,
21 or, or, if you had someone who was on the lower end of the
22 spectrum, let's say you had an acidotic patient -- and we just
23 looked at that U-shaped curb. What if -- and this is testified
24 to, by the way, by Dr. Pun and by our experts Dr. Waikar and
25 others who testified about this extensively, that, even when

1 you move someone from 15 to 20, that is an electrolyte shift,
2 and if your gradient is higher, your total amount of buffer
3 that's available to be delivered -- and when we say "total
4 buffer," by the way, and I am going to show you this, the way
5 that they define it and the way that we define it is really not
6 any different. All "total buffer" is, is the total amount of
7 bicarbonate that's available to be delivered by (sic) the
8 patient. That's a direct quote, by the way, from Dr. Lazarus,
9 who testified this year when he was an employee of the company
10 and the former Chief Medical Officer. So, that's not from old
11 documents. So, this is what's available that the patient can
12 get (indicating).

13 JUDGE WOODLOCK: When you said "delivered by the
14 patient," you mean delivered to the patient?

15 MR. KETTERER: Delivered to the patient. My mistake,
16 your Honor.

17 So, it's available, okay? And if we raise this up too
18 high (indicating), that's when we're putting up -- or we do it
19 too fast or there's too much of a grade, you make this
20 (indicating) too much of a differential, right? So, instead of
21 a differential of, let's say, 35 and 4, 39 of available to
22 raise it up, your differential of potential bicarbonate or
23 buffer sources is greater. So, the gradient changes, you have
24 a greater gradient. So, not only are you raising the dialysate
25 bicarbonate, but you also are contributing it to this source

1 (indicating).

2 And that was the point, by the way, that Dr. Hakim had
3 been trying to make for years, was -- and everyone believes,
4 and all of their experts said it -- no one disagrees that the
5 acetate is going to move over, that some amount of the acetate.
6 Is it all 8? No, and no one ever said it was. And is every
7 bit of that going to metabolize? Nope. But that's not the
8 point. The point is you have to account for it. You can't
9 just say, "Well, we don't have any idea." So, why is there a
10 problem with accounting for it? I mean, that would be the
11 normal question.

12 The reality is, is that the way -- and this isn't
13 something that we've gotten into a lot, but it's a fundamental
14 part of the equation, which is that doctors do prescribe this
15 (indicating), but they do not prescribe this (indicating).
16 This is a function in the clinic only. This is a product
17 that's added to the dialysis process. So, they don't have any
18 control over what's ordered, they don't have any control over
19 what's put in, and they know that 8 dialysate -- or 8 acid
20 concentrate, an acid concentrate may be used, but, again, this
21 is sort of a factual issue. In many cases the physicians have
22 no idea whether its been switched, either, from one product to
23 another. So, the accounting for or the confusion, as they
24 converted all of their clinics through the years, is was this
25 being accounted for (indicating).

1 Now, in the NaturaLyte context, what that means is,
2 once the problem was identified, that adding -- that this isn't
3 being accounted for (indicating), it doesn't matter whether
4 it's this or this (indicating). This is more of a problem
5 (indicating), but this can also be a problem if it's not
6 accounted for (indicating), because it's still making the same
7 effect of raising the overall bicarbonate in the serum. And
8 then the process is, if you raise the bicarbonate too much too
9 fast, or if you develop alkalemia, what happens is then the
10 patient can develop metabolic alkalosis. They're already
11 having alkalosis. They can develop metabolic alkalosis or
12 alkalemia, which nobody disputes. Once you get to that point,
13 or you once you go through that change, you can have the
14 electrolyte shifts which can lead to sudden cardiac arrest.

15 And when I say a "litany of literature" about higher
16 bicarbonates being related to either mortality or sudden
17 cardiac arrest, we're going to look at some of the body of
18 literature, but the reason we cited so much literature in our
19 papers is because the experts were looking at the whole body of
20 evidence that exists out there about the entirety of the
21 acid-based relationship. It's a complex system, and it can't
22 be simplified into, "Well, dialysate bicarbonate is what
23 controls, and it only matters if we exceeded dialysate
24 bicarbonate." In fact, it's irrelevant whether they exceeded
25 dialysate bicarbonate. I will be the first one to say that,

1 based on the data points that are presented, that it's
2 indisputable that most patients don't get to steady state.
3 That's not the point. The point is does the product in its
4 overall totality raise serum bicarbonate?

5 And that's the foundation of knowledge and the
6 position by which Dr. Hakim was coming at it from a scientific
7 standpoint, and his goal, as he said in his deposition,
8 relevant to you or not in terms of this, was, he was concerned
9 about what he deemed a modifiable risk factor that he saw as
10 potentially causing injury to a whole host of patients. And
11 this isn't something that was brought out in litigation
12 context, because we are going to look at his article that he
13 published just this year that was published in the
14 peer-reviewed journal the *American Journal of Kidney Diseases*,
15 where he talks about this exact phenomenon refers to the exact
16 combination.

17 And I will go through with you point by point, because
18 he considered the literature and literature, incidentally, that
19 was not considered by Dr. Maddux, where he goes point by point
20 for every clinical recommendation that he made he cited a piece
21 of literature. He said, "I'm making this recommendation, here
22 is the literature, here is the recommendation, here's the
23 literature," and he also talks about this concept of having to
24 account for, and he doesn't use the term "total buffer," he
25 uses -- I think it was "total bicarbonate," was what he was

1 referring to. But it's the two together. There's nothing
2 wrong with the arithmetic sum, necessarily, in and of itself.
3 It's if you use it to try to say, "This is what winds up on the
4 serum side." And nobody is saying that, not our experts, not
5 anyone. No one is saying you're going to get to 48, or that
6 you will get to 48, or that you even probably will get to 48.
7 That's not the issue.

8 JUDGE WOODLOCK: So I fully understand, let me use a
9 homely example. I have been trying to think about the
10 arithmetic dimension to the argument. So, let's assume that 40
11 is \$2,015 and 8 is \$1,898; that is to say, they are both
12 dollars, but they, because of the time value, or let's call it
13 "metabolic development" of the time value of money, they differ
14 when they are added on the same, in \$2,015?

15 MR. KETTERER: No, no. What I would say is this, to
16 use your dollars. Let's assume 40 is \$2,015. 8 isn't even
17 dollars, okay? 8 is some other form of currency, all right?
18 But when I move it over to this side (indicating), I cross over
19 the border of a country, it's going to become \$8, okay? And it
20 can become \$8. Not all of it is going to translate over.

21 JUDGE WOODLOCK: And so, the conversion table is the
22 one that I am thinking about, in any event, to try to think
23 about what is going on here. What is a conversion table that
24 makes this effect, unless they are two independent variables?

25 MR. KETTERER: Let's talk about that, because it kind

1 of intertwines with what we talked about at the end of the day
2 yesterday. So, one of the reasons we brought in the experts
3 and we were talking about all these algorithms and these
4 equations, what we have really been talking about is the
5 prediction of how much acetate, and this is really the heart of
6 the dispute, along with what kind of impact does that really
7 make, okay? So, how much acetate really converts over to wind
8 up on the serum side? What's the conversion ratio? And the
9 reason for the modeling, or one of the reasons, is that the
10 modeling is not expected to be an exact predictor. They don't
11 have one either. The reason that, for a company that has all
12 these resources, an enormous amount of resources, the number
13 one dialysis provider in the country, and probably the world,
14 okay, they don't know the answer to how much -- and never
15 looked at the answer of what their product actually does. So,
16 they didn't know until they did the ABChD Study, the rate of
17 acetate metabolism. In fact, the way in which they used to
18 predict it was the kind of modeling that they now criticize.

19 In fact, there's litany of documents, internal FMC
20 documents, where Frank Gotch is going through and doing
21 prediction models, and, in fact, that's what Mr. Lipps looked
22 at and asked him to rerun the calculations on, was that kind of
23 model.

24 So, how do we predict how much is in here? And what
25 they are saying is, "Well, it doesn't really matter, because

1 what's going to happen is this is the only thing that is going
2 to matter (indicating); this is going to control how much total
3 bicarbonate comes in this person (indicating). And my answer
4 to that is, in terms of causation for this case, so what? Who
5 cares? Because the answer, one, I think it's wrong, because we
6 proved it was wrong from their own data, but even if it was
7 right, and the fact that the concentration gradient would
8 switch -- and that's true. I mean, you know, if you got to 41
9 on this side, if you stayed on dialysis, of course the gradient
10 switches. That's basic science, you know. It would switch
11 back over.

12 The point is, when is it happening, how long does it
13 take for it to move from 41 back over? And the real question,
14 forget all this diffusion, what's the impact on the patient?
15 What's the clinical effect of getting someone to 40, 39, 38,
16 39, 40, 41? The clinical effect, that's what the studies are
17 interested in looking at, and that's what we're interested in
18 in the Maddux, is, how do I treat the patient? How do I stop
19 the patient from becoming that alkalotic? Because if I become
20 alkalotic -- metabolic -- I'm using this colloquially -- but if
21 I become metabolically alkalotic, what happens is you can get
22 too high, and if you get too high you can have a cardiac
23 arrest. Again, that principle is not really in dispute here.

24 The question is how do you predict how much, okay?
25 So, one of the reasons we had to go to modeling on having some

1 level of prediction is because we have acetate-only studies --
2 that's somewhat helpful -- and then we have some modeling, and
3 now we have actual patient data to plug into the modeling.
4 Now, whether the data is absolutely perfect in every instance,
5 that's something that we don't know. But now we have a marker
6 to tell us roughly how much acetate is moving in, and we know
7 what the impact is.

8 And, by the way, the defense experts don't dispute
9 that some acetate moves in, right? They don't dispute it. The
10 dispute is how much and does it make an impact, okay? And this
11 is where I think it is truly a factual dispute. They say, "No,
12 you know, 1 or 1.5 or 2 or 2.5, or whatever it is, or 3, or
13 whatever it is, you know what? That doesn't matter." Now,
14 there is no data to support that it doesn't matter. They don't
15 know that it doesn't matter. They are just saying, they are
16 extrapolating out of it and saying -- and I will even concede,
17 your Honor, that's a factual dispute, that to make a
18 determination about the clinical impact of "X" amount of
19 bicarbonate extra, that's a factual dispute, because I have got
20 a mountain of evidence that says it's going to make a
21 difference, and they're going to have some level of evidence
22 which is going to say, "You know what? It doesn't make a
23 difference?"

24 And let's get back to the motion, now that we have
25 this foundation here. But, if you're going to say things like

1 that, if you're going to say things about -- for instance, one
2 of the opinions I want to challenge on Dr. Maddux is, he talks
3 a lot about this delimiter, except when he wrote his opinion he
4 bases it only on the ABChD Study. He absolutely did not
5 consider the VFX study that I showed you yesterday. How can
6 you say that this is what controls, and you can't get above, or
7 it acts as a delimiter? That's really my problem with using
8 that word. But how can you even talk about that as a field of
9 subject if you are not someone -- I argue he is not qualified.
10 He certainly hasn't done any study on acetate transport,
11 because the first study that I'm aware of that he really looked
12 at was the ABChD data, which was incomplete when he wrote his
13 report and testified. He then did a supplemental report on it.
14 Okay. But if you haven't looked at a major piece of data that
15 your company owns -- this wasn't data from outside the company
16 or some study in China where we discovered in 2015 that there's
17 something everyone in the world had missed. This is something
18 that had been sitting around since 2012, so he absolutely could
19 have considered it in his first report, in his supplemental
20 report, at his deposition. He doesn't consider it.

21 So, the idea that he is even remotely qualified to
22 talk about the delimiter or anything to do about acetate
23 transport I would argue is absolutely out the window without
24 any more data or support.

25 And then, when we go to the literature in his rebuttal

1 report, it's sparse, at best. Let's go look at that, because I
2 think -- actually, I'm not sure that we can bring up the actual
3 report, but I believe there were four -- the rebuttal report is
4 3855, and he actually does it in footnote --

5 If we can just go page by page for a second. You can
6 take down my PowerPoint off the side-by-side, so the judges can
7 see the whole thing. Just scroll through a couple of pages, if
8 you would, please. Next page.

9 And what we see is -- if you can blow up the bottom,
10 the footnotes -- what Dr. Maddux does when he's going to cite
11 anything, and we can go through this page by page, but what I
12 will tell you is, is I did the count, and he cites roughly four
13 or five pieces of literature and a couple of other things, I
14 think KDOQI Guidelines or things like that. And what he says
15 is, "I reviewed the plaintiffs' report," but that doesn't mean
16 that you reviewed the literature that's contained in any of the
17 reports. And, by the way, if you did that, let's say you did
18 that, you just looked at the reports, you would say, look, the
19 plaintiffs' evidence in terms of this piece of literature or
20 this piece of literature, or they cited that -- I'm going to
21 say, you know, they cited the Hakim-Hung article, or they cited
22 this Pun article. He does talk about Pun. Or they talk about,
23 because he talks about it because he's an expert for them, he
24 talks about whatever other pieces there are, a hundred pieces
25 of literature, or 25 pieces of literature, or whatever it is,

1 or, "I considered this piece of internal data that is separate
2 and distinct from the plaintiffs or something that the
3 plaintiffs actually considered. I looked at this particular
4 text that the plaintiffs looked at, and here is my rebuttal."
5 They don't have to do every single one.

6 JUDGE WOODLOCK: But do you have to do every single
7 one?

8 MR. KETTERER: No.

9 JUDGE WOODLOCK: I guess here is the problem that, at
10 least I saw, with Maddux is, he has a generalized statement
11 that, "I looked at everything," and then he focuses on a few
12 things. Now, what does he have to do in his expert report?
13 Does he have to engage with every piece of literature? No.

14 At the risk of trivializing this, there is a parody of
15 the restatement of the law of interstate commerce that is
16 relevant here. It was done by a Thomas Reed Powell. He said,
17 "The black letter would be Congress regulates interstate
18 commerce, and then the sub would be the States can also
19 regulate interstate commerce, but not too much, and then the
20 Reporter's Notes would be, 'How much is too much is beyond the
21 scope of this Restatement.'"

22 Now, that, it seems to me, to be part of what is going
23 on here, is, what is the scope of the Restatement that is
24 adequate for purposes of making this determination and why, if
25 somebody says the magic words, "I looked at it," is that

1 enough? You would suggest not, I think, but what level of
2 engagement has to be visible at this stage for us to go forward
3 and say he can testify to the jury?

4 MR. KETTERER: I think it's informative to think about
5 what our conversation yesterday was with respect to Dr. Hakim,
6 and this is the reason why: When we talked about Dr. Hakim, we
7 knew what he had looked at, at least on the face of the actual
8 memo: 11 cited literature sources. And we also knew that he
9 had looked at data that had been pulled by Dr. Lacson, and we
10 knew basically from the methodology about how that data got
11 pulled. But what we couldn't tie in were the specifics of, "I
12 reached this conclusion," what was the actual thing that led to
13 that statement or that conclusion. And the problem was, well,
14 if you can't show that, then it's not good enough to just say,
15 "Well, I'm a really experienced nephrologist who looked at this
16 body of documents, these 11 pieces of documentation, and I'll
17 let the data come in and they can make their own judgments
18 about it, but the actual opinions in this document, well, those
19 might come in some other way, but they are not going to be
20 causation opinions."

21 And I suggest Dr. Maddux is, in fact, rowing in the
22 exact-same boat. First of all, he is the current Chief Medical
23 Officer. His qualifications are questionable, at best, to
24 opine on this kind of thing. He has published, himself, only
25 14 times, compared to, say, someone like Dr. Lazarus, who has

1 published over 300 times in this area. He had not been working
2 as a practicing nephrologist up to his time. He had been, I
3 think, I'm working off memory here, 2006, 2007, and then he had
4 developed some sort of records consulting business, and then he
5 came to Fresenius. That doesn't make him not a good
6 nephrologist per se, but it doesn't make him an expert on
7 acid-based areas and the issues that are prominent in this
8 case. If you have never published before, say, on the issues
9 of acid base, and you've never talked about acetate transport,
10 and you've never talked about the risks of bicarbonate and
11 sudden cardiac arrest ever before in your career, and you only
12 cite four pieces of literature, and you only look at a limited
13 body of data, that speaks to two things: both your
14 qualifications as an expert and your methodology.

15 Now, can he still come in and talk about the facts?
16 Well, I think that's going to depend on your rulings with
17 respect to how this 2011 memo goes, because Dr. Maddux is only
18 after that memo. So, what's the relevance of Dr. Maddux coming
19 in and talking about all these scientific things that he is
20 looking at in the company in direct response to this data if
21 we're only referencing the Hakim analysis, or we're only
22 referencing the Hakim data, we're not referencing the Hakim
23 Memo?

24 So, Dr. Maddux, as I said, has this added layer of
25 complexity in that we've now said, "Well, we really should

1 confine the findings and the conclusions to this specific area,
2 experts can review this (indicating). "Well, this expert
3 (indicating), Dr. Maddux, and I say "expert" in quotes, because
4 I don't think he's qualified to talk about these issues, but I
5 also have a question about the methodology. You can't just
6 blanket say, "I reviewed everything," because then every expert
7 who says that can point to nothing. There's nothing that they
8 are really pointing to.

9 JUDGE WOODLOCK: Well, but he can be examined in
10 deposition to say, "Did you look at this?" And he either says,
11 "Yes, I did," or, "I did not," and if he says, "Yes, I did,"
12 then his competence is tested by further examination.

13 MR. KETTERER: Let's go look at that deposition
14 testimony, your Honor.

15 4524, please, and let's go to Page 11, Line 23. And
16 let's look at the -- and if we could just blow out line --

17 Your Honor, I don't know if you have trouble reading
18 it or not like this. If you do, I'll have it blown up.

19 JUDGE WOODLOCK: No. For me, anyway, the
20 transcript is clear.

21 MR. KETTERER: Can we go single pages at a time,
22 please.

23 Beginning on Line 23 he says -- the question: "And
24 who wrote the reports?"

25 Answer: "Those reports were prepared when I --"

1 Next page, please.

2 "-- was asked to be an expert by legal counsel. I
3 asked what that entailed, and the understanding of that was
4 that we would look at the body of data that was related to my
5 prior depositions and the body of work related to this
6 particular case, and so I had several discussions with the
7 legal team, Juanita Brooks and Michael Florey. We came up with
8 a plan of things that I thought were important that needed to
9 be discussed. There was an aggregation of materials that were
10 -- that are part of both reports that were put together into a
11 skeleton format, and then I edited that format and added the
12 areas of emphasize like I just described with regard to our
13 quality report. So, I feel that the report is, is my report,
14 although I had assistance from the people that know how these
15 reports are formulated."

16 Question: "You mentioned an aggregation of materials.
17 Who did that?"

18 Answer: "I did some of that, and the legal team did
19 some of that, 'cause they knew what materials I had been asked
20 about specifically in my prior depositions as a fact witness,
21 and so that was done by a combination of both of us."

22 Next page, please.

23 Question: "Okay. And which materials did you
24 specifically aggregate?"

25 Answer: "I don't think I can answer that question

1 right now knowing exactly which ones each of us did, 'cause I
2 participated in looking at the materials that are noted within
3 here, in both of these reports."

4 By the way -- let me just finish reading it.

5 Question: "Okay. So, you provided for each of these
6 on Exhibit B, is that right? There's an Exhibit B that's part
7 of these?"

8 "That's correct."

9 Now, can we go, just so we can see what Exhibit B is,
10 can we go to 3852B.

11 And here are the things that are part of that that he
12 is referencing that he says are the materials aggregated for
13 his report.

14 If we could blow up just 3852B for a minute so his
15 Honors can see that.

16 Here are the things that are on his list: One
17 publication, a report from Fresenius Medical Care, a peer group
18 report from a research group, and an analysis by Norma Ofsthun.
19 That's an internal data analysis. That's not something that's
20 published by a peer reviewer. And then there's a handful of
21 internal documents that he reviewed.

22 Let's go back to Page 4524 and look at Page 23,
23 please, and beginning on Line 5:

24 Question: "As you sit here today, there are no
25 exhibits, other than those you've provided us with, that will

1 be used to summarize or support your opinions, correct?"

2 "Objection" from Ms. Brooks.

3 "I don't know the other -- I know the exhibits that
4 were noted in these two documents are the exhibits that I know
5 are related to these two documents."

6 And the "two documents" are referring to his
7 supplemental and his primary report.

8 "Okay."

9 Answer: "Beyond that, I can't tell you at trial what
10 I would need or propose."

11 "Okay. Thanks. Everything that you considered, other
12 than as you mentioned today, your experience and understanding,
13 is listed in the 'Documents Considered' sections of your
14 report, correct?"

15 Answer: "I doubt that's correct, because my
16 understanding includes things that I've learned from, you know,
17 reviewing literature -- "

18 Next page, please.

19 "-- speaking with people, going to meetings and other
20 such things, and I can't include all of the things that would
21 influence my approach toward a particular topic, and these are
22 the ones that we've documented as part of this."

23 So, again, what we see is, is, we're asking him to try
24 to tell us -- and I've got one more quote -- and we're asking
25 him to try to tell us, "What is it you looked at?" And he

1 says, "Well, it's these things listed here and those things
2 listed here." It's a very short list. And there are some
3 other things in his footnotes in his supplemental report which
4 I showed you earlier, a handful of pieces of things that he
5 exhibited. And remember the breadth of what we're talking
6 about of what we've supplied and what he has actually reviewed,
7 and in this case in his opening report, not his rebuttal
8 report, he cites one piece of literature to found his opinion.

9 JUDGE WOODLOCK: Let me just ask, maybe to focus this
10 a bit more, was he confronted with contrary evidence and asked,
11 A, whether he specifically reviewed it and, B, what he had to
12 say in response to what I am characterizing now as contrary
13 opinion?

14 MR. KETTERER: He was certainly presented with other
15 literature. Now, he has answers for some of those things about
16 either their conclusions or other things that he has thought
17 about. I'm not suggesting that, if he's confronted with
18 something, that he's never thought about it, okay? That's not
19 the point, though.

20 The point is, though, that for an expert, at least at
21 this level, to talk about general causation opinion, how can
22 you formulate your own general causation opinion about whether
23 or not this happens if you never look at the whole universe of
24 what exists out there?

25 Let's take, for instance -- I'm using this as an

1 example -- but if you didn't ever consider the VFX data, right?

2 JUDGE WOODLOCK: The?

3 MR. KETTERER: The Portugal data that I showed you
4 yesterday, the VFX data. I'm using shorthand, and I shouldn't.
5 That Portugal data, if you never considered it and you've never
6 looked at it --

7 JUDGE WOODLOCK: Well, but was he asked, "Did you
8 consider this? Did you look at it?"

9 MR. KETTERER: No, we didn't have it then, so we
10 couldn't have asked him. We couldn't have asked him at that
11 point about that particular data set, because we didn't have
12 it, and the point is that they did. So, the failure to give
13 that to any of their experts -- and, by the way, that's true
14 for all of their experts, I believe, except for Dr. Sargent
15 now, who only got it, I guess, or looked at it as a result of
16 -- I don't know if he looked at the actual data, but I know
17 that he responded to the Colton and Zydney reports.

18 So, you have this set of data, right, that is
19 absolutely relevant to the case. And you know how it's
20 relevant to the case? They attached the Memo, the Hakim Memo,
21 to the back of the PowerPoint slides. And that slide
22 presentation, by the way, was presented multiple times in
23 Europe. So, it wasn't as if it was a one-off study. They had
24 access to this. It's their company. And it doesn't go to any
25 of their experts. So, that was sort of my broad, sweeping

1 issue.

2 JUDGE WOODLOCK: Well, I guess, just to focus on
3 Maddux, I am just trying to figure out how I view it.

4 MR. KETTERER: Sure.

5 JUDGE WOODLOCK: The suggestion is that he just has
6 not functioned in this area of causation or been drawn into
7 expertise in this area the way in which we think traditionally
8 of expertise, that maybe in some other setting he would be a
9 Kumho Tire expert, that he is familiar with how people work in
10 this area, but I am not sure that he is being proffered on that
11 basis. And so, I am trying to analyze the several ways to look
12 at him and what he knows. If he comes in and says, "I have
13 read everything," well, that is helpful, but that does not
14 necessarily do the job. And so, the core of what you are
15 saying in terms of competence, I think, is he just has not done
16 enough work in this area himself to be able to opine
17 meaningfully about it.

18 MR. KETTERER: That's exactly right, your Honor, that
19 core of the general causation opinion. Now, he is a fact
20 witness, and that's the other layer, and that's something we
21 will have to decide on a motion *in limine* basis about whether
22 he should even be allowed to testify, period, because I think
23 that will be informed by how some of the other evidence comes
24 in. Now, I would suggest that that other evidence ought to
25 come in, and that as a fact witness Dr. Maddux probably has

1 some province to come in and talk about the facts. But they
2 have other general causation experts. Dr. Maddux is a company
3 witness who isn't really qualified.

4 We could go through the rest of the slides. I
5 actually would like to go through the one last quotation, so
6 that I'm complete and I have given all the questions that I
7 think that are relevant that he was asked about.

8 Could we go to Page 26, for a minute, of the
9 transcript. Sorry. 4524.

10 And the question here starting, again, at Line 5 is:

11 "So, if I want to know so that I can prepare for trial
12 what documents you're relying on, I can't just rely on the
13 things that you cited in these reports; is that right?"

14 Answer: "I would say for these reports you can rely on
15 what I would say and what we documented as part of these
16 reports. But I would say that, if you were to go back and look
17 at every document that was related to my prior depositions and
18 other things, I've obviously seen all these, and they have some
19 influence in my opinions and my sense of how to answer
20 questions related to topics that might come up with this case."

21 That's like saying, "Well, if you show me something,
22 maybe I've seen it, or maybe it has some impact." But it goes
23 right to what you said before. On this issue he hasn't done
24 the work, and that's evident from the words coming out of his
25 mouth and the words that are on the printed page.

1 The point is that we have applied a specific rigor
2 when we've looked at all of these experts, particularly with
3 respect to Dr. Hakim. And I would certainly argue that, with
4 respect to Dr. Maddux, that, if anything, he is at a far lesser
5 position, he's done far less rigor or research in this area
6 historically in his own professional career, almost none, and I
7 would argue certainly that, as a matter of qualifications and
8 of methodology, Dr. Maddux ought to be struck from offering any
9 expert opinions in this case.

10 JUDGE WOODLOCK: So, maybe, if we can, we will take
11 our morning break at this point.

12 MR. DENNING: That would be fine.

13 JUDGE WOODLOCK: And move on to the rest.

14 THE CLERK: All rise.

15 MR. DENNING: Thank you, your Honor.

16 THE CLERK: All rise.

17 (Recess taken from 11:00 a.m. to 11:20 a.m.)

18 JUDGE KIRPALANI: Mr. Denning.

19 MR. DENNING: Thank you, your Honors. I'll address
20 the argument with regard to Dr. Maddux. And I'll start -- and
21 this relates to the Maddux argument. It relates to what
22 plaintiffs' counsel talked about at the beginning of his
23 argument, which is the relationship between bicarbonate in the
24 dialysate and acetate in the dialysate.

25 In this example he had, I think, 40 bicarbonate, 8

1 acetate. In this example we have 35 bicarbonate in the
2 dialysate, 8 acetate in the dialysate. And as you know from
3 the diffusion principle, bicarbonate, assuming that the
4 bicarbonate is lower, will diffuse from the dialysate into the
5 blood. The same thing happens with the acetate, assuming that
6 the acetate concentration in the blood is lower than the
7 acetate concentration in the dialysate. It will flow down that
8 concentration gradient.

9 What never happens is this 8 acetate mixes with this
10 35 bicarbonate in the dialysate. That does not affect the
11 dialysate bicarbonate at all. So in the conversion process
12 that your Honor was talking about, we never add the \$8 and \$98
13 to the \$2,015. They're never added together in the dialysate.

14 JUDGE WOODLOCK: Isn't it the state of the record that
15 there is no such transformation?

16 MR. DENNING: There's no transformation at all from
17 the acetate.

18 JUDGE WOODLOCK: Acetate stays acetate no matter when?

19 MR. DENNING: In the dialysate, the only time it can
20 turn into bicarbonate or actually cause there to be bicarbonate
21 produced is in the liver. So the only way that acetate can
22 affect bicarbonate is on this side of the equation, the blood
23 side.

24 JUDGE WOODLOCK: But that's just the scenic route to
25 get to the same point.

1 MR. DENNING: In a way but not really, because a
2 couple of things. First of all, only some acetate is diffused
3 into the blood. Not all.

4 JUDGE WOODLOCK: How much, how much is too much beyond
5 the scope of your expert's testimony?

6 MR. DENNING: How much is too much? Well, whatever --
7 under any of these amounts, remember that we used to have
8 acetate-only dialysis. 32 to 45 acetate was used. That was
9 safe. It was used for many, many years.

10 JUDGE WOODLOCK: The point I'm getting at is I'm not
11 sure either one of you has a reliable view about how much is
12 passing back and forth. That's just the state of the science
13 or whatever.

14 MR. DENNING: The ABChD study actually helps with that
15 a bit because that was one of the things they measured.

16 JUDGE WOODLOCK: It may, but there is some -- whether
17 it passes through the blood and then --

18 MR. DENNING: Some does.

19 JUDGE WOODLOCK: -- comes back as bicarbonate, there's
20 something that happens, some transformation that happens.

21 MR. DENNING: Absolutely. Some of it is metabolized
22 into the blood. Some of it becomes bicarbonate in the body.
23 But what happens to that bicarbonate then? It's added to this
24 side of the equation. It's added to the bicarbonate in the
25 blood. And what does that do? That decreases the

1 concentration gradient between the 35 that is, always has been
2 and always will be in the dialysate. It decreases the
3 concentration between that and what is in the blood. The
4 acetate metabolism into bicarbonate in the body actually
5 decreases the flow of bicarbonate from dialysate into the blood
6 because it decreases the concentration gradient.

7 JUDGE WOODLOCK: This is gradient theory, I guess.

8 MR. DENNING: Exactly.

9 JUDGE WOODLOCK: But if the blood went higher, not
10 that that's what you would be doing with someone, then it would
11 be going into the dialysate.

12 MR. DENNING: If the blood ever goes higher, in the
13 right example on this slide deck, absolutely, the bicarbonate
14 would then diffuse from the blood back into the dialysate. And
15 that's why it's important, and maybe I overemphasize it, but
16 the bicarbonate in the dialysate is always 35 in this example.
17 It's never 43. And that's why this happened. That's why if
18 the blood bicarbonate ever exceeds 35, it's going to come back
19 the other way.

20 Now, I heard plaintiffs' counsel --

21 JUDGE WOODLOCK: But just theoretically, if that 37
22 were 45 in blood, then presumably the equilibrium would be
23 reached at whatever half that is?

24 MR. DENNING: No, actually. I'm glad you asked that
25 question because that's an important point. This dialysate is

1 an open system. In effect, there's an infinite supply of
2 dialysate. So this 35 never --

3 JUDGE WOODLOCK: So it would be diluted, whatever the
4 gradient does, it would be diluted.

5 MR. DENNING: It will be diluted. If it ever exceeds
6 35, it will always come back to 35 because we're constantly
7 cycling new dialysate through here. This never increases, even
8 if some of the bicarbonate diffuses from the blood into the
9 dialysate, that dialysate is gone. We bring in new dialysate.
10 That's 35. So it's always going to be 35.

11 Okay. So I heard plaintiffs' counsel say now that
12 they agree with this and that they agree that the blood
13 bicarbonate never exceeds the dialysate bicarbonate. I'm
14 surprised to hear that.

15 JUDGE WOODLOCK: So are they.

16 MR. DENNING: That's new. Some of their experts have
17 said it.

18 JUDGE KIRPALANI: I see Mr. Ketterer is shaking his
19 head, saying no.

20 JUDGE WOODLOCK: Non-verbal expressions.

21 MR. KETTERER: That's not what I said. I said it
22 doesn't matter whether it does or not. And let's assume that
23 what they're saying is correct, that it doesn't, because we've
24 already presented data that it does exceed it --

25 JUDGE WOODLOCK: I'm sorry. That it --

1 MR. KETTERER: We've already presented data that it
2 does exceed it. We just saw it yesterday.

3 MR. DENNING: We saw the data from the ABChD and a
4 couple from the European study that showed it was over by .1 or
5 .4. That's what we're talking about. If it goes over by a
6 little bit, it starts to go back. That's exactly right.

7 Okay. So that's what's going on, and that's the kind
8 of theory plaintiffs have put forth on this case. And that's
9 what Dr. Maddux was confronted with. Dr. Maddux took a look at
10 this and said, "Gee, if the plaintiffs are right, if the
11 post-dialysis serum bicarbonate is at such a high level that
12 it's hazardous or it's rising so quickly that it's hazardous, I
13 need to know that. I'm the chief medical officer of this
14 company. I need to know that for my own purposes, let alone
15 for the litigation. I want to know what's going on."

16 And, you know, Dr. Maddux has been at the company
17 since 2009, right? He's been the chief medical officer since
18 2011. Before that, he was a practicing nephrologist. He's
19 probably seen more end-stage renal disease patients and treated
20 them with hemodialysis than any other expert.

21 JUDGE WOODLOCK: I use the crude, unadorned reference
22 to *Kumho Tire*. That's really what you're saying. If he's been
23 a nephrologist all along, we've got to expect nephrologists to
24 know what they're talking about. So anybody who is a
25 nephrologist since up to 2005 comes in here and testifies?

1 MR. DENNING: No. He's in a unique position to do
2 then what he did in this case because of his background as a
3 nephrologist and his position --

4 JUDGE WOODLOCK: So any nephrologist who did what he
5 did can be an expert, can offer opinions?

6 MR. DENNING: Anybody who did --

7 JUDGE WOODLOCK: What he did and explored in the
8 affidavit.

9 MR. DENNING: What he did in the affidavit was look at
10 historical Fresenius data and see if that comported with what
11 plaintiffs' experts said should happen theoretically based on
12 their literature. One of the real world facts here --

13 JUDGE WOODLOCK: Right. Not to put too fine a point
14 on it and not to rely too much on ganders and geese, isn't that
15 what Hakim did, too?

16 MR. DENNING: It's not, because Dr. Hakim had no data
17 to support his opinions.

18 JUDGE WOODLOCK: He had some stuff. The problem is to
19 have what I keep referring to as the star turn witnesses show
20 up and their role is that they're celebrities for a larger
21 narrative. And we're trying to focus right now on who the
22 experts are going to be, who is going to get to opine as
23 opposed to, you know, tell the story about how we got to where
24 we are.

25 MR. DENNING: Well, the story that he has to tell,

1 though, is pretty compelling.

2 JUDGE WOODLOCK: It may be, but it doesn't make him an
3 expert because he's got a compelling story to tell. And the
4 question is whether or not this person has the rigor of an
5 expert in an area that doesn't depend on being a tire-worker
6 and whether or not we let him come in. And that goes back to
7 the larger question. This is a balancing thing, I suppose,
8 too. Without him, you still have your general causation
9 expert.

10 MR. DENNING: We have several. He mentioned one. We
11 have two others.

12 JUDGE WOODLOCK: Okay. So what did you need him for?

13 MR. DENNING: We need him to present the data from the
14 perspective of the chief medical officer that he commissioned,
15 that he asked for, this data he asked Dr. Norma Ofsthan for.

16 JUDGE WOODLOCK: That's the story. That's not the
17 expertise. It's the story of how we got here. I'm not sure
18 how much we're going to get into that, but that's what we are
19 trying -- we have been trying, I think, Judge Kirpalani and I,
20 to say we want to focus on expertise right now. There will be
21 a motion in limine practice that presumably will deal with how
22 does Hakim get in here, if at all, and maybe, you know, what
23 does the new medical director have to say and that sort of
24 thing.

25 JUDGE KIRPALANI: Let me ask just Mr. Ketterer for a

1 second, if he's testifying as a fact witness and there's a
2 story to be told by Fresenius, does he get to talk about his
3 belief in the total delimiter theory?

4 MR. KETTERER: No. I would say his beliefs are
5 irrelevant. He can talk about the facts. Let me just say it
6 this way, Judge Kirpalani, and this is the reason why, when
7 we're talking about what was the problem with getting into
8 Hakim or getting into the Hakim story -- there's a story behind
9 Hakim. Now, the flip side of that is why am I not presenting
10 the Hakim story and this huge background about the memo and all
11 these other things, which is what we were trying to avoid by
12 saying, "Well, here is the data." He can say, "Here is the
13 data. Here is the data. I gave it to this person," and their
14 expert analyzes it however they analyze it.

15 The point that, Judge Woodlock, I think I heard you
16 making is, "Look, you can't come in and say, 'Because I'm the
17 chief medical officer, you ought to take these facts as these
18 are the facts and then these are also opinions.' And you can't
19 dress up your facts as opinions either, or your opinions as
20 facts." They're not.

21 This is what -- he can say, "Here is what I did," if
22 he did anything because, by the way, I think if you look at the
23 deposition testimony, some of the things he actually did or
24 didn't do may be a little bit questionable. But we can fight
25 that out at a motion in limine.

1 But again, this is all part of, if we're getting into
2 the entire story, that's where Dr. Maddux becomes relevant
3 then. If we're going to talk about the development of all the
4 things Dr. Hakim looked at -- because he did look at a fair
5 amount of data, maybe not on that specific memo, but he sure
6 looked at a lot of data over the course of a number of years.
7 And so are we going to talk about that? Are we going to talk
8 about what Dr. Maddux did? Is he going to parade himself in,
9 Judge Kirpalani, and say, "Well, you know, it's my opinion on
10 this." Who cares what his opinion is if it's not relevant to
11 actually having a rigorous methodology. That's not relevant.

12 The data is the data. And we take the data and we
13 have these other experts look at it. And they can look at it.
14 He can say, "I collected the data." Just like Dr. Hakim, it
15 would be appropriate, "I asked for someone to look at this. I
16 asked for this data to be pulled." "Well, what did you do as a
17 result?" "Someone ran the data, and then there was an analysis
18 performed," and then if we're going to get into it, "then a
19 memorandum was put together." Facts.

20 MR. DENNING: The only thing on top of that -- I think
21 that's largely right, and that's largely the role that Dr.
22 Maddux is going to have. "I asked for the data. I had Dr.
23 Ofsthan collect the data. Here is the data." By the way, if
24 your Honor will indulge me, I have some PowerPoints I'm going
25 to hand out. I think your Honors are familiar with some of --

1 JUDGE WOODLOCK: So that was all you were going to do,
2 except one other thing. What's the other thing that you think
3 you're going to do? And I suspect it's an opinion, and I want
4 to understand what that opinion is.

5 MR. DENNING: And you're right. Dr. Maddux is
6 primarily a rebuttal expert.

7 JUDGE WOODLOCK: So the guard goes down when it's a
8 rebuttal expert?

9 MR. DENNING: No. What he's doing is he's saying,
10 "The data that I ordered and looked at is inconsistent with
11 what the plaintiffs' theory is. If the plaintiffs were right,
12 this data would be different."

13 JUDGE WOODLOCK: But why is he the one to be doing
14 that? Why isn't it to be done by, you know, what I'll call
15 unadorned experts as opposed to celebrity experts?

16 MR. DENNING: Other experts can do it, too. He's in
17 the unique position to say, "I know the company. I know how
18 the data" --

19 JUDGE WOODLOCK: Knowing the company, knowing where
20 the data is positioned is not necessarily making you an expert.
21 And that's the real issue with -- part of the issue with this.
22 Part of it is also trial management. You say you have not a
23 litany but a chorus of experts. So make it an acapella choir
24 rather than a full orchestra, fully orchestrated, too.

25 MR. DENNING: Well, he'll need to testify to the data

1 in any event to present the data as a fact witness.

2 JUDGE WOODLOCK: I suspect you'll all stipulate to
3 that.

4 MR. KETTERER: Facts are the facts, your Honor.

5 JUDGE WOODLOCK: So I don't see, you know, apart from
6 a desire to appear in court, I'm not sure what he adds to any
7 of this under these circumstances. And part of the role is to
8 have an expeditious trial.

9 So I just don't see that, you know, but for the fact
10 that he is employed by the defendant in a high position that
11 he's at the forefront or even in the larger phalanx of people
12 who are expert in this area. You've got them. Both sides have
13 them here.

14 So I ask the question about that from a practical sort
15 of way without, you know, making some demeaning comment about
16 the degree of his expertise.

17 MR. DENNING: Sure. And I don't mean to rehash. The
18 real differentiator I think between Dr. Maddux and the largely
19 academic experts that you're going to see is his history as a
20 treating nephrologist combined with his position as chief
21 medical officer for the leading dialysis company in the world.

22 JUDGE WOODLOCK: So you're waiving the concern about
23 Dr. Borkan?

24 MR. DENNING: No. Dr. Borkan's concerns were many.

25 JUDGE WOODLOCK: Isn't he a treating nephrologist? He

1 provides a special mantle of expertise?

2 MR. DENNING: Nobody questioned that Dr. Borkan had
3 the qualifications to be an expert. We questioned how he could
4 square what he said in his practice with what he was going to
5 say in court.

6 JUDGE WOODLOCK: So we spend a lot of time spinning
7 our wheels over something that doesn't need to be presented to
8 the jury. That's the problem -- a problem with this. And I
9 just don't -- what else does he have to add to this by way of
10 opinion, is what I'm getting at. Is it another opinion saying,
11 "Me, too" or, "Me, too, and I'm chief medical officer"?

12 MR. DENNING: "Me, too" from a different perspective.
13 I don't mean to rehash. I'm sorry, your Honor, one second,
14 please.

15 I think I'm getting the hook. So I'll take that and
16 sit down.

17 JUDGE WOODLOCK: No, no. Tenacity is appreciated.

18 MR. DENNING: Thank you, your Honor.

19 JUDGE KIRPALANI: But noted. All right. Where does
20 that leave us?

21 MR. MELSHEIMER: Your Honor, it leaves us way ahead of
22 schedule, and it leaves us with some motions related to FDA
23 experts, which I'm prepared to handle now or at the Court's
24 leisure.

25 JUDGE KIRPALANI: All right. I have some things that,

1 because I have scheduled, I'd like to attend to. Maybe we can
2 pick up at quarter after 12:00 and then go to 1:00. Does it
3 make sense to --

4 MR. MELSHEIMER: I don't think we're --

5 JUDGE KIRPALANI: -- have lunch? I don't know how
6 long this is going to take. We have four different experts or
7 five experts to deal with, right?

8 MR. MELSHEIMER: So four of them are dealt with very
9 efficiently in one argument, your Honor. And I think that
10 Mr. Gibbs is fairly short, so we're not talking about another
11 couple of hours, in my judgment.

12 JUDGE WOODLOCK: So you have yogurt for lunch as
13 opposed to a full meal.

14 JUDGE KIRPALANI: They have a late lunch.

15 MR. MELSHEIMER: Totally appropriate.

16 JUDGE KIRPALANI: So why don't we break until 12:15,
17 and then we'll take 45 minutes. And then we'll decide where we
18 are, whether we should plunge forward and have a late lunch, if
19 that's okay with the court reporter and the other staff here.

20 I'll say something to save time on the other end, and
21 that's with respect to these motions in limine for the upcoming
22 Ogburn-Sisneros trial, obviously we have a date set down for
23 major motions in limine. I certainly want, I expect to have
24 briefed the role of the Hakim memo, assuming that it doesn't
25 come in as opinion qua opinion or as the basis for expert

1 opinion. And I say "assuming." I haven't made that decision
2 yet, but there's been some talk or some discussion of that.

3 So assuming it has a role in the story, and I think it
4 obviously, at least one side will argue it does, you know, I
5 want to know -- I want that briefed. Whether it comes in, why
6 it comes in, there's obviously been a concern about limiting
7 instructions, assuming that it's out on *Daubert* grounds. So I
8 would suggest the parties have considered that, not by way of
9 conceding defeat, but if we get to the point where it comes in,
10 what am I going to tell the jury or what do you suggest I tell
11 the jury about how they may use that evidence.

12 And I'm going to say the same thing about the FDA's
13 actions with respect to the so-called recall and the rolling
14 back of the recall, if you will, that those are -- you know, I
15 think that there's a story there. The question is does it come
16 in? Why does it come in? Why does it stay out, if that's your
17 argument. And if it comes in, what are the appropriate
18 limiting instructions? Mr. Ketterer.

19 MR. KETTERER: So the one thing I want to clarify is
20 the timing now because, obviously, today is -- I don't even
21 know what day it is anymore. The 15th or so, let's say. And
22 these are supposedly due on the 19th.

23 JUDGE KIRPALANI: Is that correct?

24 MR. KETTERER: I think that that is correct, the
25 motions in limine are due. The scope of this motion in light

1 of the discussion we've been having here is fairly broad. And
2 by the way, I would argue it certainly impacts not just the
3 story we're telling of Hakim, but as we just talked about with
4 Dr. Maddux, I kind of expect some other witnesses and who is
5 going to say what and how they might say it.

6 And so if that's the case, then I think that it
7 requires -- even though motions in limine are typically fairly
8 brief and we could hash this out orally --

9 JUDGE KIRPALANI: I don't expect these particular ones
10 to be necessarily briefed.

11 MR. KETTERER: Could we get a couple of extra days?

12 JUDGE KIRPALANI: Sure. Mr. Melsheimer, I'll ask you.
13 What do you think is a reasonable timetable? What's our
14 hearing date right now? Is it November 4 or something?

15 MR. MELSHEIMER: I think it's the 4th of November.
16 Your Honor, maybe --

17 JUDGE KIRPALANI: Sixth maybe.

18 MR. MELSHEIMER: I want to give the Court ample time,
19 obviously, to review the materials. I don't know if we're
20 talking about --

21 JUDGE KIRPALANI: Realistically I'm going to be
22 working on these things for probably several weeks.

23 MR. KETTERER: I'm just trying to think practically.

24 JUDGE KIRPALANI: I think you can have some time,
25 practically speaking, as long as I have a decent amount of time

1 before the hearing day.

2 MR. KETTERER: Hang on one second.

3 JUDGE KIRPALANI: Sure.

4 MS. BROOKS: Right now, your Honor, the openings are
5 due on the 19th and oppositions are due on the 30th. Perhaps
6 if we truncated the opposition --

7 JUDGE KIRPALANI: That's kind of longer time or
8 generous time for opposition.

9 MS. BROOKS: Perhaps if we did openings on the 23rd,
10 opening on the 23rd and then oppositions, keep it on the 30th.
11 And that way, we'd even have a weekend in there to work on
12 oppositions.

13 JUDGE KIRPALANI: Mr. Ketterer, does that work for the
14 plaintiffs' side?

15 MR. KETTERER: I'm sorry?

16 JUDGE KIRPALANI: The 23rd instead of the 19th for
17 filings and then oppositions a week later.

18 MR. KETTERER: I think that that should be okay. I
19 really hate to say no. One thing that I might suggest, I think
20 the -- sorry. Go ahead.

21 JUDGE WOODLOCK: I just want to tie it down. You
22 didn't say no.

23 MR. KETTERER: I didn't say no. And I think the 23rd
24 should be fine for the briefing. The one thing that I might
25 suggest to the defendants in terms of pushing back to give

1 everyone a little extra time is maybe the depo cuts which are
2 due the 26th, we were going to exchange on, since that's not a
3 court date, maybe give everyone a little breathing room to do
4 that.

5 MR. MELSHEIMER: We can talk about that, yes. I agree
6 with putting those off.

7 JUDGE KIRPALANI: Okay. So let's expect that the
8 major motions in limine, whatever, and I see foresee these two
9 areas being major. I don't know what else there might be,
10 maybe nothing else. I certainly have put another date for sort
11 of more garden variety motions in limine much closer to trial.

12 So the 23rd will be the filing date. The response
13 date is still the 30th, and the hearings are sometime the next
14 week.

15 MR. KETTERER: Very good, your Honor.

16 JUDGE KIRPALANI: Thank you. We'll recess until
17 quarter after.

18 (Recess taken 11:42 a.m. to 12:15 p.m.)

19 JUDGE KIRPALANI: Okay. Mr. Melsheimer, you're going
20 to address Pence, Ulatowski, Samaras and Barkelow?

21 MR. MELSHEIMER: Yes, your Honor. May it please the
22 Court? I've been joined by Ms. Drakulvich at counsel table,
23 who has not been introduced to the Court yet, along with Ms.
24 Brooks.

25 JUDGE WOODLOCK: Thank you. Welcome.

1 MR. MELSHEIMER: May it please the Court? Your Honor,
2 this motion covers four different experts, but really there's a
3 global issue that is going to I think involve all of them.
4 They are Ms. Pence, Dr. Pence, who has a Ph.D. in toxicology,
5 who is offered for certain post-market issues with respect to
6 GranuFlo; Mr. Ulatowski, who is a former long-time employee of
7 the FDA; Dr. Samaras, who is a human factors expert, suggesting
8 that there needed to be more testing of the interaction between
9 users and GranuFlo; and Dr. Barkelow, who is offered to talk
10 about whether or not there should have been a screen, total
11 buffer screen on the Fresenius machines to add a two-digit
12 number and a one-digit number in a sum and whether or not that
13 should have been done earlier or should have been done at all.

14 They are toxicologists, physiologists and biomedical
15 engineers. They do not offer a whit of dialysis experience.
16 They have no expertise or experience in that area. They spoke
17 to no dialysis experts or any nephrology experts. They're
18 purely relying on their own expertise.

19 We've set out a roadmap, and, your Honors, if I might
20 provide it to the Court. May I approach?

21 JUDGE WOODLOCK: Yes.

22 MR. MELSHEIMER: So we provided a roadmap, your Honor,
23 on slide 3 of the deck. And I'm going to take it a little bit
24 out of order. The numbered and boxed in red are arguments or
25 the ones that we're going to present orally. I think the other

1 arguments have been mooted largely by agreement of the parties
2 and will be handled, if at all, in the motion in limine
3 practice.

4 The first issue -- and this is an issue that comes up
5 in a lot of these cases where you have pharmaceutical
6 devices -- is what is going to be the use, if any, of opinions
7 that really are legal opinions. Because all of these folks are
8 going to come and testify to one degree or another or are going
9 to attempt to testify or have summarized in their reports what
10 amounts to legal opinions about what the standard of care for a
11 medical device manufacturer is in addition to their opinions
12 that that standard of care was breached.

13 First and foremost we submit that this shouldn't be
14 allowed at all, that you shouldn't have an expert coming in to
15 court providing you the law or legal opinions to the jury.
16 That that's something your Honor should do and it is not
17 something that experts should be duelling about from the stand.

18 JUDGE WOODLOCK: Is there anyone other than Pence that
19 does it? That is, legal opinion.

20 MR. MELSHEIMER: Pence certainly does it, your Honor.
21 I submit all of them do it.

22 JUDGE WOODLOCK: Sorry to interrupt. But the other
23 ones can be characterized as industry standard experts, right?

24 MR. MELSHEIMER: They are industry standard experts,
25 but they offer opinions that those standards are required to be

1 followed by Fresenius and that they were violated. So I would
2 submit that they all offer in one form or another legal
3 opinions. And there's two problems with that. One is, the law
4 should come from the Court.

5 JUDGE WOODLOCK: Let me just back this up, because
6 there are some that are explicitly so and some that are
7 inferentially so. The explicitly so I think is just Pence, as
8 I read this PowerPoint, and I think that's my recollection of
9 it. I don't know if anybody else says somebody violated the
10 law by failure to implement a CAPA, that's in violation of a
11 medical device industry standard. I guess that's an allegation
12 of a violation of law.

13 MR. MELSHEIMER: I think they're all, your Honor,
14 we've got. I'll move on here to page 7, which has a little bit
15 of a summary of this. And here are some examples of what the
16 experts do. You've got Ms. Pence saying that Fresenius failed
17 to implement a CAPA, as the Court just pointed out, in
18 violation of medical device industry standard of care.

19 JUDGE WOODLOCK: That was where I was referring to.
20 And I guess I just want to first start with, you know, somebody
21 who pronounces the law or pronounces a violation of the law.
22 The only one who comes close to that, I think, in this
23 collection is Pence.

24 Then there are people who talk about industry
25 standards, which can then be translated into violations of law

1 or failures properly to implement what the FDA calls for or
2 failures properly to advise FDA. But I just want to sort
3 through this because they're two different -- from my
4 perspective, two different arguments. They may come out the
5 same way, but they're two different arguments.

6 MR. MELSHEIMER: So the one argument would be that
7 you've got a pure FDA expert like Pence saying they violated
8 this or that FDA standard. You've got other experts like
9 Samaras or Barkelow saying that they violated certain industry
10 practices or industry standards. So with respect to the FDA, I
11 would say that she shouldn't be allowed to say what the law is
12 because that should come from the bench, and she shouldn't be
13 allowed to say that it was breached because that should come
14 from the jury box. That's a factual determination.

15 JUDGE WOODLOCK: In terms of choreography, how does
16 that work? She doesn't get on the stand, one of us just says
17 to the jury, "Here is the CFR. The CFR says this. Do the best
18 you can."

19 MR. MELSHEIMER: I submit, your Honor, that the
20 parties would brief the issue for the Court as to what the jury
21 should be instructed.

22 JUDGE WOODLOCK: Well, give me a sneak preview.

23 MR. MELSHEIMER: I think -- well, I think, for
24 example, we would say that -- you know, we would say for
25 example, we have an FDA expert that talks about various

1 regulations that he wants to talk about. For example, a lot of
2 it is rebuttal to them. They say we didn't report certain
3 things. We say, "No. We didn't have to report certain
4 things."

5 So I think that part of it is a rebuttal to what
6 they're saying. We could live without the FDA coming in this
7 case at all because we don't think -- and again, that's
8 something that we think the courts can instruct the jury on
9 what the standard of care is for a medical device manufacturer.
10 It could be informed by FDA regulations, but it may not be.

11 JUDGE KIRPALANI: Isn't the role of the regulatory
12 affairs expert here to translate to the jury something that's a
13 very complex matrix of regulation? And maybe they can't
14 testify to what the law is, but they can -- you know, existence
15 of a standard of care is a question of fact, and the problem
16 becomes when it's informed by regulation.

17 MR. MELSHEIMER: I think that what's complex about
18 this here, your Honor, is whether or not you're going to have
19 sort of duelling experts on the standard of care. So let's put
20 aside one issue. We don't think anybody ought to be able to
21 testify that the standard of care was breached. That strikes
22 us, and we've briefed this heavily, as a question for the jury
23 to decide.

24 So you might be able to have an FDA expert come in and
25 say, "Well, here's the regulatory framework that should be

1 provided," and this is what medical device manufacturers will
2 do in ordinary care. You can have an expert do that. We have
3 an expert that's prepared to do that if their expert is allowed
4 to testify.

5 Now, what they go on to do is they have some
6 experts -- and really, Mr. Samaras, for example, talks about
7 industry practices or customs or certain voluntary standards.
8 So they say, "Well, yeah, these standards are voluntary, but
9 really Fresenius should have complied with them in this case."
10 And we'd say, "Well, those are voluntary standards," and our
11 expert will say, "Yeah, they don't have to be complied with."

12 So you can have that sort of dialogue going on in
13 front of the jury where you have, "What's the standard? Is it
14 voluntary? Is it mandatory?" There could be debate about
15 that. But the other issue about whether or not they can
16 actually say, "And I find that Fresenius breached," that's
17 where we say the Court should at least draw the line there. If
18 you're going to allow testimony about the regulatory framework,
19 don't allow testimony about the ultimate issue of breach or
20 failure to meet that standard.

21 So to me, that's really the gateway issue, which is if
22 you're going to allow some legal testimony about the standards,
23 whether they're voluntary or not, we've got an expert that can
24 do that; they've got experts that can do that. What we've
25 argued against strongly in the briefing is that they shouldn't

1 be able to take the jury's job and say, "Okay. That's been
2 breached here. That's been violated here."

3 Again, we're going to have an argument. They want to
4 put forth some of these voluntary standards. And a lot of
5 their testimony, a lot of these folks testify about custom and
6 practice and voluntary standards. And, you know, our fellow
7 Mr. Gibbs is going to say, "Well, those aren't required." So
8 you could have some debate about what the standard actually is.
9 That's really not completely unusual because you could have,
10 for example, in a medical malpractice case, you could have
11 doctors disagreeing about, "Well, you ought to count the
12 sponges twice," or, "You ought to do this three times," or
13 whatever. You could have some debate about that, so I suppose
14 that's not all that unusual. But ultimately, the issue of
15 whether or not they should be able to say that it's violated,
16 that strikes us as being something that should be reserved for
17 the jury's benefit.

18 JUDGE KIRPALANI: Well, in a medical malpractice case,
19 typically they would in fact testify to the standard of care
20 and that it had been breached. They might not -- or at least
21 not in my courtroom they wouldn't be able to use the word
22 "negligence," but they can tiptoe right up to it, I guess.

23 MR. MELSHEIMER: So that's right. And your Honor,
24 obviously, the cases go both ways on this. We cite some cases
25 in our brief, the *Bard* case out of the Southern District of

1 West Virginia that talks about that the experts can talk about
2 what the standards are but they're not supposed to cross that
3 line and say to the jury, "This standard has been breached
4 here."

5 JUDGE KIRPALANI: But would it be permissible in your
6 view for Pence to say, "Well, there was never any
7 post-surveillance report" -- "post-market surveillance
8 reporting" -- I don't know if that's true or not. If that was
9 in fact a fact to determine from review of documents or
10 testimony could she say, "They never did X," not saying it's a
11 breach of the standard of care, even though she's laid out what
12 they're supposed to do.

13 MR. MELSHEIMER: I would say two things about that,
14 your Honor. One is I don't think the jury needs to hear that.
15 That's a fact. It either happened or it didn't happen. They
16 can introduce evidence about whether or not certain reports
17 were made or not.

18 Whether or not those facts amount to anything, that
19 strikes us as being something the jury should do. I mean,
20 these are obviously, you know, fine-tuning questions here about
21 how much we're going to let these experts do. We've got -- so
22 you know, big picture: What are you going to let them do
23 generally? We've got specific objections to what they've
24 actually done here. But from the big picture, are you going to
25 let them tell the jury about the law or what the standard is?

1 There is certainly support for doing that.

2 We also think the Court could just do that after
3 briefing. And if you let them do that, are you going to let
4 them go further and actually opine as to a breach of a
5 standard? And we would suggest you should draw the line before
6 you let them do that.

7 Now, specifically, and we can go through some examples
8 here, a separate issue from kind of what is the general purpose
9 of these experts is some particular things that these folks
10 have done in their reports which we think is particularly
11 objectionable and should be excluded over and apart from this
12 legal debate about whether or not they should offer legal
13 opinions. And one of them is this: They try to offer opinions
14 in effect on scientific issues, acid-based chemistry, serum
15 bicarbonate levels and alleged risk of NaturaLyte and GranuFlo
16 under what we call sort of a backdoor causation opinion.

17 And really, the examples of this really illustrate it,
18 I think. First of all, they say -- the plaintiffs admit that
19 these experts, these FDA experts are not experts in the
20 science. They're not nephrologists. They're not
21 epidemiologists. They're not medical doctors. Their
22 expertise, as they put it, is medical device design,
23 development and lifecycle management. And they say in their
24 briefing that none of them will stray into the areas of medical
25 causation or other medical testimony. They say that, but

1 that's not in fact what's happening in their reports. In their
2 reports, over and over again they offer what we call backdoor
3 causation opinions.

4 JUDGE KIRPALANI: Who is arguing for the plaintiff
5 here?

6 MR. BROWNE: Justin Browne, your Honor.

7 JUDGE KIRPALANI: Mr. Browne, I mean, it strikes me
8 that certainly the reports -- assuming it's permissible for
9 them to say, "Here is the standard of care, the industry
10 standard of care," or, "Here is what the regulations required
11 and they didn't do it." But then do you need them to go on to
12 say, "And that put people at risk of increased serum
13 bicarbonate or increased risk of heart attack"? That strikes
14 me as exactly what Mr. Melsheimer was saying was backdoor
15 general causation opinion.

16 MR. BROWNE: I think, your Honor, we need to
17 contextualize what they're saying and what their role is. The
18 context in which they're giving those types of statements is to
19 say when a company, a medical device company identifies a
20 hazard or a risk and it fails to control that risk, either
21 through labeling, through design changes like changing the
22 design interface with the machine, then that risk remains
23 present with the product.

24 JUDGE KIRPALANI: Aren't they talking here about the
25 very risk the existence of which is the central dispute in this

1 case?

2 JUDGE WOODLOCK: Let's look at, for instance, page 2
3 of the defendant's slides, the Ulatowski opinion. "As a result
4 of its failure, it put all patients receiving GranuFlo and
5 NaturaLyte at a greater risk of alkalosis," so that's the
6 ultimate --

7 MR. MELSHEIMER: Page 12, your Honor.

8 JUDGE WOODLOCK: Page 12. I'm sorry. It's the
9 ultimate issue in the case. And this guy, he can talk about --
10 he can talk about, maybe, here are the FDA rules and here are
11 the rules about corrections. How we present it, maybe a live
12 person as opposed to a more sedate judge is a better way to do
13 it. But in any event, it gets done. It gets presented to the
14 jury. But he doesn't get to say, "By the way, judgment for the
15 plaintiff," because that's what he's saying, close to saying.
16 That's an ultimate determination in this case, and it is
17 replicated as they indicated in each of these opinions.

18 MR. BROWNE: Your Honor, I think that what the experts
19 are saying in this context is they are giving the context of
20 how medical device companies monitor and control risks. And so
21 what he's saying here is that by failing to take certain steps
22 that are standard in the industry, that they failed to follow
23 industry standards and industry practices, that placed patients
24 at risk. If you don't have a warning, that's basic --

25 JUDGE WOODLOCK: This is free-floating risk you're

1 talking about here.

2 MR. BROWNE: No. It's specific risk, your Honor.

3 JUDGE WOODLOCK: Just a moment. If it's specific,
4 they can testify, "Here is what's required, and these are the
5 ways regulators deal with it or industries have had to deal
6 with it," then somebody else gets to argue the implications of
7 that. But for this, for what I will call Westlaw for juries,
8 is not the office -- it's not their office to offer this
9 opinion.

10 MR. BROWNE: If I'm understanding your Honor
11 correctly, it sounds like you feel they have crossed the line
12 because they're using causal-type language. Do I have it
13 right, in a sense?

14 JUDGE WOODLOCK: I won't get pinned down, but
15 probably.

16 MR. BROWNE: Okay. So then you're drawing the line
17 where we can say, because there's evidence of risk in the
18 record and a medical device company has industry standards and
19 practices that would require them to implement certain
20 controls, like label change or device change, that they can go
21 that far and say they did not do what they should have done in
22 this case. But then to say, "And as a result, these people
23 were placed at risk," if I'm understanding, you would say that
24 would have to come in through a medical doctor who would
25 quantify the risk.

1 JUDGE WOODLOCK: Someone, someone other than this
2 person. It's argument, really.

3 JUDGE KIRPALANI: Right. And then comes the role of
4 argument. That's where you say, "This failure to do X placed
5 this class of patients at risk." I mean, I think that's the
6 role of argument. And these experts shouldn't be endorsing the
7 general causation opinions of others, in my view, that they
8 have to stop short of that.

9 MR. BROWNE: Your Honors, I think that's certainly a
10 reasonable place to draw the line. I think there is certainly
11 support in the case law for that. There is case law to the
12 contrary, but I understand the Court's position on that, that
13 they don't have to take it that far.

14 I would say simply contextualizing what risk
15 management is about and why we do these things but not getting
16 to the ultimate causal link in this specific case. Am I
17 understanding correctly? In other words, they can say, "This
18 is why medical device companies use labeling. This is how it's
19 used. This is why it's important." But what you don't want
20 them to do is then say, "And as a result of them not doing it
21 in this case, these patients were put at risk of death"?
22 That's the line, right?

23 JUDGE WOODLOCK: I'm not sure -- contextual is one way
24 of looking at it. If the context is the back door, I wouldn't
25 look there.

1 MR. BROWNE: Okay.

2 JUDGE WOODLOCK: And so if somebody comes on and says,
3 "The whole purpose of the Food and Drug Act is to prevent the
4 kinds of risks that we have here, and here is what the Food and
5 Drug Act did both in the statute and in the CFR," they've gone
6 too close to the door, back door.

7 MR. BROWNE: I understand that, your Honor. And I
8 don't think they need to go there. If that's the Court's
9 ruling, we don't need them to go there. They would explain
10 rather what the industry standards are and how medical device
11 companies operate and why they look at risks, why they identify
12 risks, why they control risks and how they go about doing that
13 without linking it to the causation opinions as you're framing
14 it.

15 JUDGE KIRPALANI: Okay. Mr. Melsheimer, back to you.

16 MR. MELSHEIMER: All right. Well, I guess --

17 JUDGE WOODLOCK: Are you sullen but not mutinous; or
18 is there something left here?

19 MR. MELSHEIMER: There's a little bit left. When
20 someone said, "Yes, you should move on," I agree. But I just
21 want to make sure we've got this covered, your Honor, so we
22 don't have to cover this with either of your Honors again.

23 I think that if there's an agreement that they can't
24 express opinions about causation because, number one, they're
25 not qualified to do that, and number two, they have no basis

1 for doing that, what they try to do is they try to -- I just
2 want to make this last point on this. What they try to do is
3 they try to link their causation opinions to our documents,
4 which also is improper because they're not scientists. They're
5 not medical scientists in this field, and so they can't
6 buttress their opinions on causation through the use of our
7 documents. But more broadly speaking, they shouldn't be
8 allowed to talk about causation at all.

9 The other thing that they're doing that we would
10 object to, your Honor, is another broad issue, which is
11 narration of our documents. And this gets to slide 18. What
12 am I talking about here? Well, what they do is they try to use
13 these experts to publish a story that they want to tell with a
14 particular spin in their favor. We've cited a couple of courts
15 who have noted that this simply doesn't help the jury. The
16 *Boston Scientific* case that we cite has the language, "While
17 internal corporate documents and executives' testimony are
18 certainly relevant in this case, such evidence should be
19 presented directly to the jury, not through an expert."

20 JUDGE WOODLOCK: Why isn't that -- these are kind of
21 broad principles of such generality as not to be important or
22 not to be material. Let me use my concept of choreography.
23 How do they do this? You can say, "The document speaks for
24 itself," and then everybody looks at the document and waits for
25 it to speak? Or do we say, you know, someone can -- different

1 people can read the document to the jury and say it contributes
2 in some fashion.

3 Now, extended dramatic readings is not something I'm
4 that interested in, but this seems more a motion in limine or
5 maybe just a trial tricks kind of way of presenting evidence
6 but not the stuff of an expertise kind of objection.

7 MR. MELSHEIMER: Can I illustrate it for your Honors?

8 JUDGE WOODLOCK: Sure.

9 MR. MELSHEIMER: On page 22 of our slide deck there is
10 an example taken out of the Pence report. Here is what she
11 says. She says, "Over this ten-year plus period, a number of
12 internal memos were distributed to FMC medical directors and
13 some staff at varying points. A number of PowerPoints,
14 including results of retrospective data analyses, were
15 presented, and educational materials were provided without
16 resolution of the problem. Fresenius' failure to implement
17 effective corrective and preventive actions resulted in cardiac
18 injury and death." That's a causation opinion.

19 JUDGE WOODLOCK: So we've dealt with that.

20 MR. MELSHEIMER: "A chronology of representative
21 internal memos and PowerPoint presentations as well as other
22 relevant correspondence is provided in Section A below, along
23 with a narrative and key points that summarize the information
24 for each document that was critical to my analysis and
25 development of my opinions." What she's really doing there is

1 disguising a list of, "These are documents I relied on." And
2 what they want her to do is take the stand and tell the story
3 of those documents.

4 Now, certainly, your Honor, there's going to be
5 argument about what those documents mean. Some of those
6 documents will be in evidence, I suspect. Some of the
7 witnesses that have personal knowledge of those documents will
8 be on the stand. There will be deposition clips played about
9 those documents.

10 JUDGE WOODLOCK: So let's have a stripped-down version
11 of it. She says, "I've reviewed it and Fresenius has failed to
12 implement corrective and preventive actions as required by the
13 FDA." That's all she says, without going through the lengthy
14 kind of analysis. And then you're presented with this
15 challenge. "Do I cross her and say, 'What about this
16 document,'" at which point we start to get into document by
17 document by document, rebuttal, and so on. That's the
18 strategic choreographic challenge of the case. But why can't
19 she say, "I know FDA, and the actions that you took do not
20 comply with FDA"?

21 MR. MELSHEIMER: I think she can do that, your Honor.
22 I think what we're objecting to, and I certainly acknowledge
23 that we may be straying into sort of motion in limine territory
24 here, but what we object to her doing is characterizing the
25 document. She can certainly say, "Hey, they should have filed

1 these particular things. They didn't do it. The FDA says
2 you're supposed to. They should have done that." Fine.

3 But what she's trying to do, and you'll see other
4 examples here, is she's trying to characterize the documents in
5 a way that allows her to be sort of a closing argument for
6 their case.

7 JUDGE WOODLOCK: Okay. But bear in mind the way in
8 which I framed it, which is she gets to the ultimate conclusion
9 but she doesn't do the chronology.

10 MR. MELSHEIMER: Doesn't do that?

11 JUDGE WOODLOCK: Doesn't do that in her direct
12 testimony. Now you're presented with a challenge, as I say, as
13 of what do you do on cross? "Did you consider this document,"
14 "Did you consider that document," at which point then the
15 chronology gets put in play. Now, you're put to the choice, I
16 suppose, on that.

17 MR. MELSHEIMER: And I think we would be, your Honor,
18 if we certainly wanted to highlight some documents that she
19 hadn't considered. But I think, again, she has
20 characterizations of something as meaningful or important. We
21 have another witness, Mr. Barkelow, or Dr. Barkelow, who says,
22 "From reading these documents I can tell that things weren't
23 understood and appreciated within Fresenius." I just don't
24 think an expert gets to do that. That sounds like
25 characterizing a document. That sounds like a legal argument

1 to me that should be made in front of the jury in closing
2 argument. That's what we're concerned about with all these
3 experts. Because let's face it. This is not the most
4 scintillating testimony about FDA regulations and these
5 documents.

6 So what they're going to try to do is either the
7 backdoor causation, which they can't do. That's great. What
8 we don't want to do is cloak these witnesses. This isn't a
9 case agent in a criminal case. This isn't a guy who has done
10 the investigation and comes to the end and summarizes
11 everything he's found out about the tax scheme or the bank
12 robbery or whatever it is. This is an expert, FDA expert who
13 has got very limited expertise, and they should not be allowed
14 to characterize and give their impressions of documents in the
15 guise of expert opinion.

16 JUDGE KIRPALANI: So I would say, first of all, the
17 existence of a narrative report doesn't necessarily translate
18 into a narrative at trial. I mean, it's question and answer,
19 and, you know, generally witnesses aren't going to be allowed
20 to go on and on and on and tell a story. It has to be question
21 and answer. You can object.

22 Certainly, I think there's not much of a role for
23 characterization here or statements of, "This is what the
24 company intended or understood," you know, to have a witness
25 say this as opposed to a lawyer making an argument. So I mean,

1 I think there is a role, though, for the expert to identify
2 relevant documentation from the thousands or millions of pages
3 of documents that exist in this case. And there is a line that
4 I think needs to be maintained. Maybe it's best maintained by
5 a motion in limine or just at trial.

6 MR. MELSHEIMER: And again, your Honor, maybe this is
7 how much is too much, how much is enough. I understand that.
8 I'm not asking the Court at this time with no context at all to
9 be able to say that they can do that and they can't do this.
10 If we can get in sort of an understanding that they don't get
11 to interpret documents and perform a role like a case agent in
12 a criminal case would do, to sort of summarize the case in a
13 way, putting their spin on the documents, that really addresses
14 I think the concern that we've got about this particular thing.

15 I mean, they are saying, if you look at page 21 of our
16 deck, they do say that -- they say that these experts "will
17 summarize and interpret Fresenius' internal documents." They
18 say, "The documents and inferences within them are not all
19 simple. Thus the experts can help the jury better understand
20 their contents and implications." Well, I don't know what that
21 means.

22 Content, sure, if there's a word that they know that's
23 not in the ordinary ken of a juror, they can say, "Hey, here is
24 what this word means to me." But what they can't do is give
25 the implications of those documents because that's something

1 that either is -- they're not experts in, they're not
2 mind-readers, right? But also that would invade the jury's
3 province, which is to interpret these documents and decide
4 whether they mean anything at all.

5 And that's the concern that we have if we go down the
6 road with using too many documents. Because again, this is a
7 fairly narrow issue about FDA, and they have given them
8 boatloads of documents to review. So they could say, "Hey, I
9 considered these documents in my opinion." And under the guise
10 of saying, "Well, tell us, Dr. Pence, what did you look at,"
11 for them to say, "Well, let me tell you what I saw," and then
12 to give this whole story or her spin on the Fresenius story
13 with respect to GranuFlo, that's completely improper, and
14 that's why we do think it's an appropriate *Daubert* motion.
15 It's also a motion in limine. But it's certainly not something
16 an expert ought to be able to do from the stand.

17 JUDGE WOODLOCK: A way of dealing -- there are various
18 ways of dealing with it. One is to say, "No more than 15
19 minutes from these people," which clarifies the mind; what is
20 important for them to deliver in that time period.

21 The point is they can't -- I mean, choreography is the
22 way of talking about, do you intend to lobotomize the jury with
23 this testimony? The second is, do you mean to use it as
24 backdoor? And the third is, frankly, why not simply the
25 summary determination that, "They don't comply with," or, "They

1 haven't complied with various of these provisions based on my
2 analysis," and see what they do with it. They may decide to
3 walk through an open door, in which case, shame on them. But
4 I'm not sure that your original, your direct examination needs
5 to be so long.

6 MR. BROWNE: Your Honor, first, we're not going to put
7 an expert on the stand to read 27 pages of an expert report as
8 is suggested in their motion. It leads --

9 JUDGE WOODLOCK: So what -- sorry. But what does it
10 mean to draw inferences to better understand contents and
11 implications?

12 MR. BROWNE: That's an excellent question, your Honor.

13 JUDGE WOODLOCK: That's why I offered it.

14 MR. BROWNE: It's within the purview of 702.

15 JUDGE WOODLOCK: It's within the purview and it's
16 within the purview of the trial court judge to narrow things.
17 And trial court judges tend to narrow things that they think
18 that the lawyers aren't doing a really good job at doing that.
19 So now I'm asking you how are you going to do your really good
20 job.

21 MR. BROWNE: They would explain documents put before
22 them. For example, there are things that we contend are
23 complaints. If it is a complaint, it triggers certain
24 practices, certain duties the company should have done, for
25 example, investigate, open up what's called a CAPA corrective

1 preventive action and take remedial steps to control the risk.
2 So there is a dispute, a factual dispute that the jury will
3 resolve as to whether or not the company had to do certain
4 things and their failure to do it caused the injuries at issue.

5 What they're doing is explaining. For example, there
6 are e-mails concerning adverse events. Are they adverse events
7 that are related to the product, or are they just adverse
8 events that have nothing to do with this case? For example,
9 the memos. Defendants represent that these memos that we've
10 been talking about that identify the safety risk and link it to
11 the knowledge deficit, to the confusion in the labeling, to the
12 confusion with the machine settings, they contend that's about
13 the practice of medicine that has nothing to do with the
14 product at issue. They have an expert who says that.

15 Our experts would explain, "What's being discussed
16 here is called a user error. This is a human factors issue.
17 This is product-related." When you have confusion about the
18 labeling, and you go into a clinic after someone died, and you
19 say, "Hey, do you know that GranuFlo has 8 acetate," the clinic
20 people have no idea --

21 JUDGE WOODLOCK: Is this specific causation then?
22 Isn't it going to specific causation? What you're saying is
23 this poor person suffered this injury because they didn't pay
24 attention to labeling, and the labeling should have illustrated
25 that. That's related to the specific person. That is the

1 specific administration.

2 MR. BROWNE: No, your Honor. They will not be getting
3 into whether or not a particular patient died because of some
4 failure. Instead, what they're doing is saying these incidents
5 are safety signals. These are things that show that there was
6 a problem. It's notice evidence. These are things that show
7 there was a problem with the product. It wasn't just the
8 cardiac event. It was also the labeling deficiency and the
9 machine interface deficiency. That's what those e-mails show.

10 JUDGE WOODLOCK: If it's free-floating breach of
11 negligence, that's one thing -- demonstration of negligence.
12 There's not going to have to be a lot of testimony about that.
13 And the way it becomes relevant is whether or not that
14 free-floating negligence has been reified in a particular case.
15 So letting these people kind of spill on and on and on about
16 shortcomings in industry standards or compliance with FDA I'm
17 not sure advances that. I share -- I mean, in some ways -- not
18 in some ways -- I entirely share Judge Kirpalani's view that,
19 you know, the trial judge is going to exercise control over
20 this. Fair warning on it.

21 MR. BROWNE: That's entirely appropriate, your Honor.
22 And the reality is it's not in our best interest to put these
23 people on the stand to drone on and on. That's why these
24 decisions are best left for at trial when there is context and
25 you see how it is coming in. For example, in Judge Kirpalani's

1 first trial, it's a timed trial. So we're not going to be able
2 to put these people on and tell a story and go through hundreds
3 of documents and do what's being suggested here.

4 JUDGE WOODLOCK: Or the time gets reduced in the
5 second trial, which is mine.

6 MR. BROWNE: That's fine. Also, if we do, I'm sure
7 Judge Kirpalani will cut us off. That's certainly -- that's
8 why these types of things are best addressed --

9 JUDGE WOODLOCK: They may be, but a little forewarning
10 about this might be helpful. They have anxious concerns. So
11 should you.

12 MR. BROWNE: Understood, your Honor.

13 JUDGE WOODLOCK: And the idea that something like this
14 is going to get wafted in front of more than one jury is
15 something that you should think about.

16 MR. MELSHEIMER: Your Honor, just so we're clear, my
17 objection is not boredom.

18 JUDGE WOODLOCK: No. Mine is, but that's --

19 MR. MELSHEIMER: Right. My objection is not, "You're
20 boring the jury." It's not just that they're going to do this
21 for hours. What they're going to try to do with this is
22 they're going to try to make scientific conclusions or medical
23 conclusions that, "Hey, when this person died, you should have
24 reported it because of GranuFlo." Well, none of these people
25 with all their alphabet degrees can say one word about that and

1 they should not do that. But that's the kind of example that
2 they're talking about with this narration.

3 So I don't know that we can get much farther on this
4 today, but it's not just a matter of hundreds of documents and
5 boring. It's about extending their expertise beyond what is
6 allowed, offering causation opinions.

7 And finally, I'll just end with this quote from this
8 *Boston Scientific* case, that this kind of testimony should come
9 in directly through the documents, through the percipient
10 witnesses and not through an expert publishing and narrating
11 the documents. With that I'll conclude.

12 JUDGE KIRPALANI: Can I just ask you for clarification
13 because I kind of missed the point at the beginning. The red
14 boxes on page 3, those are the things we are discussing now,
15 and the others you're going to be talking about with the other
16 side?

17 MR. MELSHEIMER: Your Honor, I believe the red boxes
18 are the ones that I tried to cover today. Item C, the state of
19 mind evidence, I think we've agreed that there's not going to
20 be a swami come in and talk about state of mind of anyone. I
21 think this adverse reporting issue has been resolved, and I
22 believe this issue with respect to Dr. Samaras's readability
23 analysis have been resolved as well. If they aren't resolved,
24 they'll be presented in connection with the motion in limine.

25 JUDGE KIRPALANI: Mr. Browne, is that a fair summary?

1 MR. BROWNE: Your Honor, I would like to speak to help
2 the Court with respect to the legal opinions portion of things.
3 I think I can help set a framework and help guide where the
4 line may be drawn.

5 JUDGE KIRPALANI: Okay.

6 MR. BROWNE: With respect to narratives, I think there
7 is a clear understanding of that issue. I do not believe that
8 testimony about adverse event reporting is clear. We are not
9 -- and that's one thing that I think may not be -- may not have
10 been addressed. State of mind as well.

11 JUDGE KIRPALANI: He didn't say it had been worked
12 out. He said --

13 MR. MELSHEIMER: It was proper subject for a motion in
14 limine, your Honor, at this point.

15 MR. BROWNE: Sure, if that's moot, then that -- then
16 may I just address the legal opinions?

17 JUDGE KIRPALANI: Of course.

18 MR. BROWNE: As the Court picked up, this is a case
19 that involves very complicated matters. This is about a
20 medical device company that for over a decade had certain
21 information and was expected to act on that information.

22 There are two issues that are presented, as the Court
23 honed in on. There's the issue of instructing on the law. And
24 as we discuss in our papers, we are not doing that. We are not
25 crossing the line. We are not going to come in and talk about

1 the Food and Drug Cosmetic Act. We're not going to come in and
2 say the product was misbranded. However, when you talk about
3 where the line is with respect to industry standards and use of
4 regulations, there is a line of things that are out. And I
5 think Judge Kirpalani nailed it right on the head when he said,
6 "You can't say things like, 'They were negligent,'" and we're
7 not doing that. And so our experts are walking the line
8 perfectly there.

9 But they have cast a wide net that I think is
10 overbroad, and so we just want to make clear that we do not
11 agree on those particular issues that the experts should not be
12 able to come in and identify what industry standards were and
13 whether or not they satisfy those standards. I think what that
14 really comes down to, if I heard argument on that correctly,
15 was semantics again and use of certain words. If I understood
16 correctly use of the words "violated" or "breached," if those
17 are things we can't phrase it that way, then I think that's
18 fine. We'd be able to comply with that and not have them
19 express it that way. But if they're instead trying to sweep
20 over the use of industry standards, then I think that's
21 something we need to explore a little more.

22 JUDGE WOODLOCK: Not to get into semantics too deeply,
23 but, "did not comply," "failed to comply," is that okay?

24 MR. BROWNE: I think, your Honor, that the case law is
25 split on this. Some courts don't allow that. That's akin to,

1 "They violated FDA regulations."

2 JUDGE WOODLOCK: That's just it. So we understand
3 what it is you plan to do, what you think you can do. You
4 understand, I think, the reservations that we have. So what
5 are you going to do? You don't say "breach," you don't say
6 "violate." Let's assume that for a moment. If you don't do
7 that, what are you going to say?

8 MR. BROWNE: If we can't use those phrases, then we
9 would do it the way your Honor suggested. And it's the same
10 thing with state of mind. You would ask, "Was there evidence
11 of X?" "Was there evidence of them doing the things that are
12 described in that industry standard?" And they can talk about
13 what they saw and what they did not see, but they just wouldn't
14 phrase it as, "They breached the standard of care," or "They
15 violated 21 CFR 803.3."

16 JUDGE KIRPALANI: You took a left turn there with the
17 state of mind. I didn't understand how that fit into the
18 discussion.

19 MR. BROWNE: I think that they're similar in the sense
20 that, just like what I heard the Court say, we're not going to
21 be able to get up and say, "They knew." "They intended." But
22 the expert -- and you pointed to this yesterday, Judge
23 Woodlock, the expert would be able to say instead, "Was there
24 evidence of risks," something like that. That's phrased
25 differently. That is not saying what is in anybody's mind.

1 That's not what anybody understood. Rather, that is what is in
2 the record. And that doesn't cross over the line into state of
3 mind because you're not using -- it's not being framed in that
4 way.

5 And so I basically linked the two things together.
6 You can't say -- what I'm hearing from the Court is you can't
7 say, "You violated a CFR," or "You knew." That's over the
8 line. But instead you can talk about whether or not there is
9 certain evidence or what they observed in the record.

10 JUDGE KIRPALANI: Well, if you are defining a discrete
11 record that they are dealing with and you ask them, "Did you
12 find any instance or evidence that Fresenius did X or did not
13 do X," then they could refer to documents, presumably. But you
14 used the example of risk. I mean, I would think if the letters
15 r-i-s-k appear in the document that they could respond. If
16 you're talking about risk in general, I'm a little hard-pressed
17 to understand how these people are qualified to make that --
18 that's the back door again to me. But I do think in general
19 you ought to be able to ask these experts if they reviewed a
20 set of documents or records and whether there was evidence of X
21 or evidence of not X. Of course, you know, the devil is in the
22 details there in what is the exact question.

23 MR. BROWNE: And you have it exactly right. It's the
24 latter, the way you just described it, Judge Kirpalani. They
25 would be using it in the way you just described. There's no

1 speculation. There's no inferences. These records, as you
2 stated earlier, state for themselves, and they're just
3 explaining the significance of them in terms of industry
4 standards and industry practice. Exactly the way you've put
5 it, Judge Kirpalani, is how it would be done and come in.

6 MR. MELSHEIMER: I'll just note that that's not the
7 way the reports read. So the fact that he's saying that,
8 that's great. But the reports read very much like people
9 trying to do things. And again, I'm really flagging this
10 because I think it's going to come up again and again. This is
11 not super interesting stuff, okay? This is made interesting by
12 efforts to say things like, "evidence of risk."

13 Well, how in the world is a biomedical engineer or
14 physics person going to say that this was evidence of risk of
15 GranuFlo? They're not going to be able to say that. They're
16 not qualified to do that, but that's what they're going to
17 repeatedly, respectfully, attempt to do with these witnesses,
18 and that's why we brought this motion to the Courts' attention.

19 JUDGE WOODLOCK: To be to be continued.

20 JUDGE KIRPALANI: Okay. So we haven't talked -- if
21 we're done talking about the plaintiffs' experts, we haven't
22 talked about Mr. Gibbs and the plaintiffs' motion. So in terms
23 of timing, Judge Woodlock, do you have a preference?

24 JUDGE WOODLOCK: No. I follow the pack.

25 JUDGE KIRPALANI: How long do you anticipate this

1 issue? It seems like a pretty narrow issue, at least as
2 defined in the papers.

3 MR. BROWNE: I think the motion is pretty surgical. I
4 would anticipate maybe 15 to 20 minutes to just walk through.
5 And I think what I've done in the PowerPoint, which I'll
6 provide to you, is to just frame the argument in a much more
7 clear way and also to distinguish some of the issues.

8 JUDGE WOODLOCK: My only concern is other people's
9 lunch.

10 JUDGE KIRPALANI: Maybe we should --

11 JUDGE WOODLOCK: The surgery you describe is cardiac
12 surgery, I think.

13 JUDGE KIRPALANI: Maybe we should take a short lunch
14 break then, half an hour. Is that sufficient for everybody?

15 MR. MELSHEIMER: I'll simply note a lot of us got
16 lunch, your Honors, but maybe the other side did not get lunch.

17 JUDGE KIRPALANI: Did you bring some for everyone?

18 MR. MELSHEIMER: Your Honor, we were going to bring
19 some for your Honors, but I was told that was inappropriate.

20 MR. KETTERER: Your Honor, I think we're ready, but
21 the court staff, though, I don't know. That's the other issue.

22 JUDGE KIRPALANI: Why don't we resume at 2:00. That's
23 50 minutes. We'll be out of here pretty quickly.

24 MR. MELSHEIMER: Perfectly fine.

25 (Recess taken 1:10 p.m. to 2:10 p.m.)

1 MR. BROWNE: Good afternoon, your Honors. Justin
2 Browne on behalf of the plaintiffs.

3 JUDGE KIRPALANI: Yes, Mr. Browne.

4 MR. BROWNE: I'm going to be very brief and just
5 highlight a couple of points with respect to our motion
6 concerning the opinions of Mr. Gibbs as it relates to design
7 controls. Mr. Gibbs' opinion is that design controls did not
8 apply to GranuFlo and NaturaLyte. His basis for that in part
9 was relying on a 2007 510(k) summary document. When he was
10 presented with that same document that he relied upon, he could
11 not replicate his methodology. He could not find within the
12 document support for the opinion that he intends to render
13 before the jury. Therefore, his methodology is inherently
14 unreliable.

15 A second reason for excluding Mr. Gibbs' design
16 control opinion is that part of his basis is that design
17 controls in his opinion do not apply to manufacturing process.
18 Suspecting that might be ipse dixit, I asked what authority we
19 could look at to test that opinion, and so he identified a
20 couple of different authorities, the regulations, the preamble
21 to the regulations and FDA guidance.

22 And so then I went to each of these authorities. For
23 example, I went to the FDA design controls guidance, and
24 expressly in the document it says the opposite of what his
25 opinion is, which is, "Design control applies to all changes to

1 the device or manufacturing process design, including those
2 long after a device has been introduced to the market."
3 Similarly, using his authorities, I went to the preamble of the
4 QSR, Quality Systems Regulation, and it says, "Design output
5 includes, manufacturing process, the specifications for the
6 manufacturing process."

7 So this is another example of, "It is because he says
8 it is," when he had no basis for it. We looked at the
9 authorities he said were authorities, and they completely
10 contradicted him. This is not a battle of the experts. This
11 is not a difference of opinion about the meaning of words on a
12 page. They're the complete opposite of what he said.

13 So the third basis I think that we should highlight
14 here is related to packaging and labeling. So he was unaware
15 that the packaging and labeling even changed, and he had no
16 idea based on his review of the four-page 510(k) summary. I
17 asked if he thought that labeling was a change to the design
18 because, as he conceded, if so, design controls would apply.
19 And he said no, it usually is not, and he manufactured this new
20 standard. He said because the physical manifestation has not
21 changed.

22 So again, I asked where we would look to test this
23 opinion, this theory. And again, he directed us to the
24 regulation and to the QSR. So I went to the regulation, 21 CFR
25 820.3, and I looked at the definition of design output, which

1 is part of design controls. It's right in the standard. And
2 it expressly says, "Design outputs includes packaging and
3 labeling," again, the complete opposite unequivocally of what
4 his opinion is.

5 He also said we could look at the preamble, and so we
6 did. And the preamble says, "Design output includes the device
7 labeling and packaging." So I asked again if we can look at
8 the guidance document, and we find the same result undermining
9 the reliability of his opinion because, again, it says,
10 "Packaging and labeling are components of the design."

11 Now, faced with all of this and the definition of a
12 medical device and a product found in the same regulations, I
13 asked then, "So a change to the label is a change to the
14 device, isn't it, sir?" And he said, "It is a change to the
15 device in the broadest sense." I asked again, "A change to the
16 packaging is a change to the device, isn't it?" And he said,
17 "Again, in the broadest sense of what constitutes the device."
18 So here again he has given an opinion about something he didn't
19 know anything about, and it was completely, unequivocally
20 contradicted by the very authorities that he said we can look
21 at to test his opinion.

22 This is exactly what the gatekeeping role of the Court
23 is intended for, to keep out this type of testimony. So
24 respectfully, we would request that Mr. Gibbs' opinions be
25 limited such that he cannot opine about design controls at

1 trial. Thank you, your Honor.

2 JUDGE KIRPALANI: Mr. Melsheimer.

3 MR. MELSHEIMER: May it please the Court?

4 Respectfully, I think that this is precisely the sort of thing
5 you cross-examine an expert on. There's no question he's
6 qualified. They don't question his qualifications.

7 JUDGE WOODLOCK: If he doesn't know what he's talking
8 about, it does kind of undermine it a bit. Here is somebody
9 who says one thing and then says another, I mean, in the
10 broadest sense, I guess says another.

11 JUDGE KIRPALANI: How is he left with a basis for the
12 opinion?

13 MR. MELSHEIMER: Your Honor, there is an expert debate
14 about when the design change takes place.

15 JUDGE WOODLOCK: But if he points to particular
16 documents and says, "I rely on this," and you look at the
17 documents and they say precisely the opposite --

18 MR. MELSHEIMER: Respectfully, your Honor, I don't
19 think that they say precisely the opposite. I think the
20 experts are debating. For example, one of the things we're
21 debating about here is whether or not a change in the
22 manufacturing process for GranuFlo or NaturaLyte --

23 JUDGE WOODLOCK: Let's just stop with this. Does the
24 CFR say that packaging is part of design?

25 MR. MELSHEIMER: I need to pull it up, your Honor, and

1 look at it for sure.

2 JUDGE WOODLOCK: Good thing you're not testifying as
3 the expert.

4 MR. MELSHEIMER: Well, I wouldn't put myself up as one
5 either.

6 JUDGE WOODLOCK: He didn't have any problem doing
7 that.

8 MR. MELSHEIMER: Well, your Honor, I think that his
9 interpretation of the regulation is that it doesn't require a
10 design reporting change given what happened with GranuFlo. He
11 says two things. He says that the products never changed and
12 therefore it's grandfathered in under these older regulations,
13 and he says the manufacturing change doesn't qualify as a
14 design change in his interpretation of the regulations, and
15 then he also says that the change to the label is not, quote,
16 "a design change."

17 JUDGE KIRPALANI: So who carries his side of the
18 debate other than his ipse dixit?

19 MR. MELSHEIMER: Well, one of the things he relies
20 upon is his interpretation of the regulation. The other thing
21 he relies upon is the fact --

22 JUDGE WOODLOCK: Well, if somebody comes in with an
23 absurd -- let's just hypothesize this as absurd. Maybe I'm not
24 hypothesizing. Am I supposed to accept that? Or am I supposed
25 to say, "Look, you don't get to say that." You can come in and

1 say, "I interpret the Constitution in a particular way." Well,
2 maybe you can, but there is some baseline for interpretation.
3 It's not a matter of negotiation or dispute between experts.
4 It's, there's the language.

5 MR. MELSHEIMER: Your Honor, he is offered as a
6 rebuttal expert. One of the things that Ms. Pence did was she
7 stated that the GranuFlo and NaturaLyte products were identical
8 throughout the course of their life. He took that, that's one
9 of the things he took and said, "Well, if that's true, if the
10 products were identical, then under my interpretation of the
11 regulations, they were not governed by these design change
12 requirements because they never changed." Certainly they can
13 argue about whether or not a manufacturing change means the
14 product is no longer identical, but part of what he's relying
15 on is Dr. Pence's assertion in her report, which he's
16 rebutting, that the products were identical throughout their
17 life.

18 JUDGE WOODLOCK: Let me take the narrowest one,
19 packaging. Is this really in a dispute about interpretation?
20 It couldn't be clearer.

21 MR. MELSHEIMER: Well, that's what he's saying, your
22 Honor. That's why if you listen to that, if I heard the
23 testimony correctly, he's saying in the broadest sense it could
24 be seen as a design change, but he didn't see it that way
25 because the product itself is not changing.

1 JUDGE WOODLOCK: How can he not see it that way in
2 light of the regulation? I mean in the broadest, narrowest,
3 whatever sense. You take the regulation and you look at it,
4 and it doesn't admit of that interpretation, does it?

5 MR. MELSHEIMER: Mr. Gibbs will argue that it does,
6 your Honor.

7 JUDGE WOODLOCK: Well, apart from Mr. Gibbs, who in
8 America would say that -- who else in America would say that
9 that interpretation applies?

10 MR. MELSHEIMER: Well, I think he would point to Dr.
11 Pence.

12 JUDGE WOODLOCK: That's Dr. Gibbs --

13 MR. MELSHEIMER: Mr. Gibbs. I don't want to promote
14 him.

15 JUDGE WOODLOCK: -- Mr. Gibbs is on the rise at least
16 as far as I know. You have one guy who says this doesn't mean
17 what it says or actually says, "There's no basis for it. I
18 relied on the CFR." He's pointed to the CFR, and the CFR
19 doesn't say it.

20 MR. MELSHEIMER: His interpretation of the CFR is a
21 product that doesn't undergo the changes -- that is identical
22 throughout its market life does not have to be subject to these
23 changes, to these design control requirements.

24 JUDGE WOODLOCK: Even packaging change? We'll all
25 agree the packaging change was undertaken here, right?

1 MR. MELSHEIMER: Correct. That's why his answer was,
2 "Well, in the broadest sense, yes." I don't -- obviously, I
3 sense your Honor's frustration on that. I don't think it's
4 that unusual for two experts to disagree about what is in the
5 CFR and what it means. He says, "Well, you need to look at --
6 the broad substance of it hadn't changed." Their expert says,
7 "No. Well, the packaging, that's important, that changed." So
8 it's a debate about what that means. I mean, it's a trivial
9 debate in one sense. We're talking about -- I don't want to
10 talk my way out of this motion, but we're talking about one
11 sentence in his report is what this motion is directed to.

12 JUDGE WOODLOCK: So why shouldn't that one sentence no
13 longer be in his report?

14 MR. MELSHEIMER: Well, your Honor, because I think
15 that he's entitled to -- with his expertise and his
16 qualifications, he's entitled -- let me get back to my motion
17 for a minute. This is part of the problem is you have people
18 interpreting the regulations differently. So we're going down
19 that road. This is a fellow --

20 JUDGE WOODLOCK: This is the argument in the broadest
21 possible sense. Now I want to narrow it. Why should that not
22 be cut out? Let's assume he gets on the stand and he states
23 what he stated in his report, and we just say, "Cut that out."
24 Why shouldn't that be done? You can talk -- and we will, I'm
25 sure, in the course of motions in limine -- about what the

1 broadest possible sense of interpretation would be, but this
2 doesn't seem to admit an alternative interpretation, this
3 particular language.

4 MR. MELSHEIMER: I believe, your Honor, that we've
5 briefed this, that sentence could be excised from his report,
6 and he would still have the opinions that he has that would be
7 meaningful, not about that one issue but about the other issues
8 that he's offered. So we've proposed that or offered that one
9 sentence being struck. I think, again, I'm hearing what you're
10 saying, but the fact is the notion that two experts would
11 disagree about the interpretation of a regulation is not that
12 surprising to me, and I don't think that's a subject of a
13 *Daubert* motion.

14 JUDGE KIRPALANI: Let me back it up a bit. You said
15 he's being offered in rebuttal to Pence, who said, "GranuFlo
16 and NaturaLyte never changed. Therefore the design controls
17 are not implicated." Isn't Pence wrong? Doesn't the cross
18 that Mr. Browne did of Mr. Gibbs prove that the premise is not
19 correct?

20 MR. MELSHEIMER: Well, I suppose, your Honor, I mean,
21 even a stopped clock has the right time twice a day. She might
22 be right --

23 JUDGE WOODLOCK: But that clock does not get to
24 testify as an expert. And that's the problem with this. I
25 mean, yes, you know, a stopped clock is right twice a day, but

1 that doesn't answer it. The question is whether or not there
2 are opinions that someone says are based on something that are
3 not based on it at all should be permitted in the court.
4 That's all.

5 MR. MELSHEIMER: I will simply say, your Honor, that
6 this is an opinion based on an interpretation of law. So
7 that's really what we're debating. It's one or two sentences
8 in the report. The direction I'm getting from the Court is get
9 rid of those sentences, and that's what we'll do.

10 JUDGE WOODLOCK: Seems prudent. That was the surgery
11 that you wanted to have performed?

12 MR. BROWNE: Yes, your Honor. But just so it's clear,
13 the sentences -- there's no opinion then on this issue. He has
14 lots of other opinions. But if he's not offering an opinion on
15 design controls at trial, then yes, that would be appropriate,
16 your Honor.

17 JUDGE KIRPALANI: So the opinion is that design
18 controls did not apply to anything that Fresenius did, correct?

19 MR. BROWNE: Right.

20 JUDGE KIRPALANI: That's what his opinion is saying --

21 MR. BROWNE: He would not be able to testify at trial
22 that design controls did not apply, that's correct.

23 MR. MELSHEIMER: Let me just say this. If Dr. Pence
24 is -- if the testimony is elicited that the products were
25 identical, as a guidance I'm getting is that he can't say,

1 "Well, you know what? If they're identical, then this
2 grandfathering thing applies." Because that's really -- that's
3 part of where he's getting this. It's not just his
4 interpretation. It's her statement that the products are
5 identical.

6 JUDGE WOODLOCK: I guess it's a nanosurgery to get to
7 the question of notice in the packaging. That's the one that
8 I'm most concerned about, just saying it's outside the realm,
9 the packaging. There may be points of interpretation or
10 different views on some of this other stuff but not that.
11 Can't say that it wasn't subject to design control. I want to
12 be sure, apart from the admirable tenacity, that we're not
13 fighting about something -- a misunderstanding about it.

14 MR. MELSHEIMER: I don't think we're fighting about a
15 misunderstanding, your Honor. I think that we can excise the
16 offending sentences. I just think that if she's got an opinion
17 that the products were identical, he ought to be able to
18 respond to whatever the implications are for the regulations.

19 JUDGE WOODLOCK: So there's a grandfathering
20 permission. Do you have a problem with that?

21 MR. BROWNE: No, your Honor, we do not dispute that.

22 JUDGE KIRPALANI: So is anybody contending that design
23 controls were triggered by any action of Fresenius?

24 MR. BROWNE: Yes. And Dr. Pence's opinion is not that
25 design controls did not apply or that the products were

1 identical. And similarly -- so this idea that he's rebutting
2 Dr. Pence and they have the same opinion, that is not what's at
3 issue.

4 In fact, his express testimony as to what he relied
5 upon was what defense counsel told him in the 510(k) summary,
6 not anything about Dr. Pence. That's his testimony under oath.
7 He looked at things. They say the complete opposite of what he
8 says. It's as simple as the Court has understood it to be.

9 JUDGE KIRPALANI: Anything further?

10 MR. MELSHEIMER: We've probably argued more about
11 these two sentences than we've argued about some other things,
12 so your Honor, I'm yielding to the wisdom of the Court on
13 excising these sentences from the report.

14 JUDGE WOODLOCK: I can't tell you how gratifying that
15 is, but the way in which this probably plays out is if you
16 think you get to get him in through Pence because Pence says
17 something, you probably have to approach the sidebar to do it
18 ahead of time so that, you know, the ragged edges of the
19 surgery can be mended together.

20 MR. MELSHEIMER: Wouldn't want to open a wound on
21 that, your Honor. We won't do so.

22 JUDGE KIRPALANI: Okay.

23 JUDGE WOODLOCK: And to all a good night.

24 JUDGE KIRPALANI: I guess. So tomorrow we have three
25 motions, and I'm going to suggest we start at 9:15 just because

1 I have a court reporter coming over here and this is foreign
2 land to her. So it might take her a while to get in and get
3 set up. So 9:15. Will Jarrett be here to open things?

4 JUDGE WOODLOCK: Jarrett will be here.

5 MR. KIRPALANI: Okay. Great. I appreciate that. See
6 you tomorrow morning.

7 (WHEREUPON, the proceedings adjourned at 2:27 p.m.)

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above-entitled matter.

Dated this 21st day of October, 2015.

/s/ Brenda Hancock

Brenda Hancock, RMR, CRR
Official Court Reporter

/s/ Kelly Mortellite

Kelly Mortellite, RMR, CRR
Official Court Reporter