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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS)	
GRANUFLO/NATURALYTE DIALYSATE)	
PRODUCTS LIABILITY LITIGATION)	No. 1:13-md-02428-DPW
-----)	
FLORELLA DIAL, Personal)	
Representative of The)	
Estate of Carley Dial,)	
Plaintiff,)	
vs.)	
)	No. 1:14-cv-11101-DPW
FRESENIUS MEDICAL CARE)	
HOLDINGS, INC., et al,)	
)	
Defendants.)	
_____)	

BEFORE: THE HONORABLE DOUGLAS P. WOODLOCK

DAUBERT AND MOTIONS HEARING
John Joseph Moakley United States Courthouse
Courtroom No. 1
One Courthouse Way
Boston, MA 02210
Friday, February 5, 2016
9:55 a.m.

Brenda K. Hancock, RMR, CRR
Official Court Reporter
John Joseph Moakley United States Courthouse
One Courthouse Way
Boston, MA 02210
(617) 439-3214

1 APPEARANCES:

2 ON BEHALF OF THE PLAINTIFF:

3 JANET JENNER & SUGGS, LLC
4 By: Brian D. Ketterer, Esq.
5 Justin A. Browne, Esq.
6 1777 Reisterstown Road
7 Suite 165
8 Baltimore, Maryland 21208

9 KREINDLER & KREINDLER
10 By: Anthony D. Tarricone, Esq.
11 Christina Graziano, Esq.
12 277 Dartmouth Street
13 Boston, MA 02116

14 GOLOMB & HONIK
15 By: Ruben Honik, Esq.
16 1515 Market Street
17 Suite 1100
18 Philadelphia, PA 19102

19 ON BEHALF OF THE DEFENDANTS:

20 COLLORA LLP
21 By: William H. Kettlewell, Esq.
22 Maria R. Durant, Esq.
23 100 High Street
24 20th Floor
25 Boston, Massachusetts 02110

DOWD BENNETT LLP
By: James F. Bennett, Esq.
7733 Forsyth Boulevard, St.
Suite 1410
St. Louis, Missouri 63105

ALSO PRESENT: Ronald L. Castle, Esq., Fresenius

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1 (The following proceedings were held in open court
2 before the Honorable Douglas P. Woodlock, United States
3 District Judge, United States District Court, District of
4 Massachusetts, at the John J. Moakley United States Courthouse,
5 One Courthouse Way, Courtroom 1, Boston, Massachusetts, on
6 Friday, February 2, 2016):

7 THE CLERK: All rise.

8 (The Honorable Court entered the courtroom at 9:55 a.m.)

9 THE CLERK: This is Civil Action 14-11101, Florella
10 Dial v. Fresenius Medical Care Holdings, Inc., et al. Court is
11 in session. You may be seated.

12 THE COURT: Well, thank you for showing up. A couple
13 of things at the outset. I understand from the parties that
14 neither Freeman, who was the subject of Motion No. 63 nor
15 Waxman, the subject of Motion No. 60 is going to be offered as
16 an expert in the case. Is that right?

17 MR. KETTERER: That's right, your Honor.

18 MR. DENNING: That's correct.

19 THE COURT: So, we are going to find those motions to
20 be moot.

21 Second, I had hoped to have Mr. McAlear, who is the
22 Jury Clerk here today, but it was not possible, and so we will
23 have a session on Tuesday to talk about jury matters.

24 I have your questionnaire. As a grandparent, I feel
25 very strongly about the importance of being a grandparent, but

1 do not expect stuff like that to show up on a questionnaire.
2 Well, I see it on a questionnaire. Do not expect it to stay on
3 a questionnaire. And similarly the kind of temperature taking
4 regarding experiences and opinions, I am not doing anything
5 like that in a questionnaire. So, I will mark it up, we will
6 have some idea of what the questionnaire is going to look like.
7 I do not intrude into jurors' private concerns. I expect them
8 to follow the instructions. The instructions are that they
9 should be disinterested, and anybody who says they cannot be
10 then we will explore further, but we do not take their
11 temperature about questions like, "Does there need to be a
12 limit on jury awards?" That is what gives lawyer-conducted
13 voir dire a bad name, and it is one of the reasons why the
14 Federal Court will not be following the practice of the state
15 court, I suspect, with respect to lawyer-conducted voir dire,
16 at least this Federal Court will not be. Lawyers manage to
17 demonstrate why it is that partisans are not the proper people
18 to be conducting the jury inquiry, and this is an exhibit in
19 that regard.

20 Next, I do want to raise this just so you can be
21 thinking about it. With respect to the application of North
22 Carolina law, here is my tentative thought, but it needs to be
23 informed by your view, which is, my preliminary review of North
24 Carolina law and Massachusetts law indicates that for purposes
25 other than cap the instruction will be the same, so substantive

1 instruction on what the jury has to find, or should be. I do
2 not think there are really any meaningful differences, and so
3 what I would propose to do is not instruct the jury with
4 respect to a cap, to then, if I determine that the cap is
5 appropriate, that Massachusetts law in this regard would apply
6 its own punitive-damage approach, then we will have the basis
7 for a reconfiguration of any jury verdict that involves
8 punitive damages.

9 The overarching interest that I have is, as I have
10 indicated I think on a couple of occasions, is that, to the
11 best of my ability I will try to fashion a verdict slip that
12 will make it possible for me on post-trial motions and for the
13 Court of Appeals to reconfigure in light of the law that the
14 Court applies. This is a classic example of it. If the jury
15 comes up with, and these are all ifs, but if the jury comes up
16 with punitive damages and the punitive damages are above the
17 Massachusetts cap, then depending on whether Massachusetts law
18 or North Carolina, the North Carolina cap, excuse me,
19 irrespective of whether Massachusetts law or North Carolina law
20 applies, the legal analysis can dispose of the issue, either,
21 as I say, in post-trial motions or in appellate proceedings.
22 But I say that without fully marinating myself in North
23 Carolina barbecue sauce in the law. You probably know it
24 better, or are going to, and so you ought to think about that.
25 I know it is a little farther down on the list of joint

1 proposed agenda items.

2 So, with that, let's turn to the issues of excluding
3 Borkan and Schwartzbard, and, more specifically, assuming that
4 I am not going to do it in gross, is there something in
5 specific that at this point you want to press as to limitations
6 on their testimony?

7 MR. DENNING: Good morning, your Honor. Roger Denning
8 on behalf of Fresenius. I have a slide deck, if I could hand
9 up a copy for the Court?

10 THE COURT: Sure.

11 (Document provided to the Court)

12 THE COURT: It is a long slide deck. Can we maybe hit
13 the highlights?

14 MR. DENNING: Of course, your Honor. Will do.

15 So, one thing I think is important to note at the
16 outset is that both Dr. Borkan and Dr. Schwartzbard were
17 general causation experts in this case. They started off
18 preparing general causation reports and examining the issue of
19 whether they think it's possible for GranuFlo or NaturaLyte to
20 start this chain of events that the plaintiffs say end up with
21 sudden cardiac arrest. Here we are talking about them as
22 specific causation experts and specifically whether Mr. Dial
23 suffered this chain of events that they say can lead to a
24 sudden cardiac arrest. What they have had to do in this case
25 is try to shoehorn the facts of Dial into this pre-existing

1 theory that they came up with before, before they were
2 considering Mr. Dial's specific medical history.

3 THE COURT: Apart from the argument, save it for the
4 jury, the question is whether or not there is sufficient
5 support here for the positions they take to permit a jury to
6 decide this, not whether or not you are going to have fun with
7 them on cross-examination, but whether or not there is enough
8 to get before the jury.

9 MR. DENNING: So, your Honor, I would say by ignoring
10 so much of the medical history from Mr. Dial and specifically
11 the events that happened in the months leading up to his
12 death --

13 THE COURT: So, they ignore it, you say. Maybe
14 another way of saying it is that they do not attach the weight
15 that you attach to it. The question for me is whether I throw
16 their testimony out on the basis that they do not seem to have
17 the same valences that you do.

18 MR. DENNING: Well, in this particular instance there
19 are two facts that are most critical to that. One is that this
20 was a NaturaLyte case, not a GranuFlo case. This is a 4
21 acetate, not 8.

22 THE COURT: And we will get to it when we get to the
23 motion *in limine* here. There is a little bit of studied
24 confusion on the part of both parties on this issue. He
25 received both NaturaLyte and GranuFlo, right?

1 MR. DENNING: He received GranuFlo from a period of
2 Summer of '09 to August of 2010.

3 THE COURT: I take that as a "Yes" answer to the
4 precise question I put to you?

5 MR. DENNING: It is, yes.

6 THE COURT: I prefer that you would answer the precise
7 question that I put to you.

8 MR. DENNING: He did for a period of time, yes, your
9 Honor.

10 THE COURT: Now, second, Dr. Buchanan had prescribed
11 GranuFlo, right?

12 MR. DENNING: He had.

13 THE COURT: And NaturaLyte?

14 MR. DENNING: He had.

15 THE COURT: This is the nature of the medical
16 treatment that was given to Mr. Dial, and I cannot imagine that
17 I am going to keep the travel of the medical treatment out.
18 Now, does that mean it is transformed in the nature of the
19 case? Probably not. On the other hand, I do not know why I
20 keep it out or keep it out for purposes of the experts
21 testifying.

22 MR. DENNING: When you say "keep it out," do you mean
23 that he was prescribed GranuFlo?

24 THE COURT: Yes.

25 MR. DENNING: Because we don't think -- the fact that

1 he received an 8 acetate product for over a year, and this was
2 only a year and a half before he died --

3 THE COURT: What are you going to say it is that was
4 the 8 acetate product? If it were a criminal case we would
5 call it "FNU LNU," "First Name Unknown, Last Name Unknown."
6 The "FNU LNU product," is that what you want to refer to it as?

7 MR. DENNING: I'm happy to refer to it as "8 acetate."
8 I think we could also refer to it as --

9 THE COURT: It is your product, it is called
10 "GranuFlo." It ties in, so we are going to use that term.

11 MR. DENNING: I think that's fine, your Honor, and our
12 Motion *in Limine* 1, I believe, on GranuFlo is not really
13 related to the fact that this product exists. It's related
14 more specifically to the documentation and arguments.

15 THE COURT: So, they make reference to this. They
16 have some theory that somehow there is some toxicity, I guess,
17 that is probably the wrong word, in prior administrations of
18 this.

19 MR. DENNING: I think there's no argument from the
20 plaintiff's experts that GranuFlo, which was last given to him
21 a year and a half, August to February, a year and a half before
22 he died, that that is somehow implicated in his death. I don't
23 think they are making that argument, and their theory wouldn't
24 support it.

25 THE COURT: So, it is a question of parsing a bit what

1 GranuFlo does and what NaturaLyte does or did to Mr. Dial. But
2 I think I understand their argument to be that there is this
3 slow but steady buildup in which GranuFlo provided some role,
4 and it should have been identified. I mean, I guess that is
5 what they are saying. And the issue is not for me to decide it
6 but for the jury to decide it.

7 MR. DENNING: That may be what they're saying. The
8 facts are directly opposite to that, and I understand that your
9 Honor thinks that might be something for cross-examination.
10 But I think here, I mean, the facts are so contrary to
11 something like that, that there's no way that should even get
12 in front of the jury.

13 There is a Slide 8 in this slide deck, and,
14 Mr. Sakimae, maybe you can pull up Slide 8 on the display.
15 This shows every predialysis serum bicarbonate lab value for
16 Mr. Dial over the course of his almost four years of
17 hemodialysis treatments. In the middle section there, from
18 July '09 to August 2010 is when he was on GranuFlo. After that
19 he was on NaturaLyte alone. What this shows is that Mr. Dial's
20 predialysis --

21 THE COURT: Just so I am marking this up, August 10
22 2009 to?

23 MR. DENNING: I'm sorry. July of 2009 to August 2010.

24 THE COURT: But just on, is it the y-axis, the dates
25 show August 10, 2009, they do not show July?

1 MR. DENNING: That's right. It would be right
2 between -- the way this graph is made I think the last number,
3 so the 9 in 2009, if you go straight up from that, that's the
4 Dial --

5 THE COURT: But it does not have a "July 2009."

6 MR. DENNING: It doesn't have a July 2009, but I
7 believe that would be the 21, the lowest value in that section
8 of the chart.

9 THE COURT: So, those are just someone decided to do
10 it bimonthly and they do not correlate with the actual
11 administration of the dialysis?

12 MR. DENNING: I think the data points are monthly. I
13 think the axis label on the bottom, because I think Excel
14 wanted to make it legible, it just defaulted to showing every
15 other month.

16 THE COURT: Will there be a Daubert motion with
17 respect to Excel?

18 MR. DENNING: I don't think so, your Honor.

19 THE COURT: Well, before this gets before any jury --

20 MR. DENNING: Okay.

21 THE COURT: -- it had better be accurate.

22 MR. DENNING: Of course. It is accurate, your Honor.
23 The axis just doesn't show every month, but the data is
24 accurate.

25 THE COURT: I feel like I am involved in a

1 Presidential debate. It is accurate, except that it is not?
2 It does not show the actual data point. I am not fooling
3 around about this stuff. If you want to have something like
4 this put before a jury, or a judge, it had better be accurate,
5 and saying that Excel has a mind of its own does not do it.

6 MR. DENNING: I understand, your Honor.

7 THE COURT: So, somewhere between 6/10/2009 and
8 8/10/2009 there is a data point that is called "July," right?

9 MR. DENNING: That's correct.

10 THE COURT: And that is a GranuFlo data point?

11 MR. DENNING: That is correct, your Honor.

12 THE COURT: And then when does it end?

13 MR. DENNING: In August of 2010.

14 THE COURT: We do have a data point there. It is, I
15 guess, the Excel equivalent of 10,000 monkeys at 10,000
16 typewriters sooner or later write the *Bible*; is that right?

17 MR. DENNING: You've got that one right.

18 THE COURT: So, we have got this period of GranuFlo.
19 You do not see it, right? You do not see this rise or this
20 continual development?

21 MR. DENNING: That's right. And, in fact, there is a
22 value of 27 during that GranuFlo time period, and then it drops
23 down the next month to 22. There was no change in prescription
24 during that time, no change in acid concentrate during that
25 time.

1 THE COURT: If I use a kind of laymen's toxicity
2 approach that it builds up and builds up and then it starts to
3 demonstrate it, why do I have to exclude this testimony by
4 these witnesses?

5 MR. DENNING: My point, your Honor, was, what I was
6 trying to get at --

7 THE COURT: The point is that this is terrific
8 cross-examination, but the question is how do I exclude the
9 testimony of this witness?

10 MR. DENNING: The testimony of the witness regarding
11 the NaturaLyte acetate product is what I think your Honor
12 should exclude, because every other -- almost every other acid
13 concentrate product on the market has 4 acetate, like
14 NaturaLyte. It's been on the market since 1981. This is
15 something that he uses in his own practice on a daily basis for
16 his own patients.

17 THE COURT: Then he is going to be very uncomfortable
18 on the witness stand, but that does not mean that he gets
19 knocked off. I want to see something that says that this is
20 just beyond science, not that it is not very good science, but
21 that it is beyond science.

22 MR. DENNING: I understand, your Honor.

23 THE COURT: And I will not even say "not very good
24 science," but science that is subject to impeachment by what I
25 will anticipate will be very effective cross-examination.

1 MR. DENNING: I understand, your Honor. The second
2 point, and I expect your Honor will feel the same, is the time
3 lag between his treatment and his death, which was a ten-hour
4 time lag, and we believe, according to their theory of this
5 rapid shift, that that would have had to have happened either
6 in the chair or very shortly after the treatment, not ten hours
7 after.

8 THE COURT: How long is the window?

9 MR. DENNING: So, in plaintiff's brief they concede
10 that it takes -- within two hours after the dialysis session
11 all the acetate has been converted to bicarbonate.

12 THE COURT: No, but how long is the window for
13 causation, that is, causing the effect on the patient that led
14 to the patient's death, not the metabolic changes or whatever
15 the changes are of the substance within the body?

16 MR. DENNING: So, to put an hour limit on it, nobody
17 knows, but Dr. Borkan consistently said it's a rapid
18 electrolyte shift; this is something that happens quickly.

19 THE COURT: The electrolyte shift and the actual death
20 are not coincident, are they? Is that what we have to say as a
21 matter of science?

22 MR. DENNING: That's what they've said, that the
23 electrolyte shift, the potassium growing intracellular causes
24 this ventricular fibrillation.

25 THE COURT: It does. I hope the plaintiffs personally

1 are not present here. Is that right, Mr. Tarricone? Because I
2 want to be perhaps more pungent to make my point than I would
3 if they were.

4 So, there is a death rattle. What rules that out?
5 There is the effect or the impact of the change, let's say it
6 is two hours, and by then it stops, but it does its damage,
7 kills him eight hours later. Now, is there something that says
8 nobody on God's green Earth would ever say that, or is it, as
9 you indicated more generally, nobody knows?

10 MR. DENNING: Nobody knows how long after that can
11 happen, but the fact that it would happen two hours after and
12 they wouldn't die until eight hours after that is inconsistent
13 with all of the plaintiff's theory in the case.

14 THE COURT: All right. But you know the examination
15 that I would give you, about three hours.

16 MR. DENNING: Nobody knows to that precision, none of
17 the plaintiff's experts know either.

18 THE COURT: But we are not talking about 25 days, and
19 so it is in the realm, I suppose, or at least someone like this
20 can make that statement subject to cross-examination. I guess
21 I am just -- well, you see the trend. So, does the plaintiff
22 who are up next for this. I think I am adjured by the First
23 Circuit to be latitudinarian in this, and unless somebody can
24 show me that they would have their ticket taken away, I guess
25 that is overstating it, but that anybody who held such opinions

1 would be drummed out of the fraternity, I don't know how I make
2 that determination under present circumstances. I am not a
3 factfinder.

4 MR. DENNING: I understand, your Honor. I'll save the
5 rest for cross-examination at trial.

6 THE COURT: All right. So, with respect to, then,
7 Motion No. 65, which is to Exclude the Testimony of Borkan and
8 Schwartzbard, that is denied, without, obviously, my taking a
9 position one way or the other on it, but it is a matter that
10 gets presented to the jury. So, now we go to --

11 MR. DENNING: Thank you, your Honor.

12 THE COURT: Now we go to Duffy.

13 MR. KETTERER: Good morning, your Honor.

14 THE COURT: You know the drill.

15 MR. KETTERER: I do.

16 THE COURT: So, direct yourself to things that you
17 think you legitimately can get kept out.

18 MR. KETTERER: I will, your Honor. The difference
19 between what we just discussed with Drs. Borkan and
20 Schwartzbard as opposed to Dr. Duffy, as I know that you have
21 reviewed in the papers, is the methodology which is of the
22 concern and the target of the motion, and that's where I would
23 confine most of my argument.

24 THE COURT: Well, let's talk about his opinions, the
25 particular opinions that you really want to deal with with

1 respect to Duffy.

2 MR. KETTERER: Well, your Honor, the methodological --
3 I do want to go to the specific opinions, and one of the things
4 that I would say is any of his rebuttal opinions, even though
5 that's a broad category, I think have sort of an egregious
6 spotlight on them because of things that are inconsistent, and
7 I know that your Honor's question that was just directed to
8 defense counsel was, "Well, listen, isn't that just
9 cross-examination, some of these flaws or inconsistencies or
10 things that you would point out?"

11 One of the differences, though, with Dr. Duffy is that
12 Dr. Duffy actually has issues where he says he did one thing,
13 and that's actually not evident in the way that it was
14 reviewed. So, for instance, he didn't know about the existence
15 of two reports, he didn't know whether or not there were
16 certain materials contained in the reports he was supposedly
17 rebutting. So, he's giving testimony, and then when he's at
18 his deposition, as you will note in our briefing, he is saying
19 the opposite of what actually appears in his report.

20 Now, the reason why that's a methodological flaw is
21 that the foundation or the ability to give that testimony isn't
22 just an inconsistency about an opinion, a medical opinion,
23 let's say. So, for instance, to say, "Well, you said here that
24 the cause of the incident or the injury is X, and here you say
25 it's Y, how do you reconcile those two things?", the difference

1 is, if the materials that you actually review, if the things
2 that you actually use to form the opinions, that is actually
3 the express issues which I believe that the Court ought to
4 explore in the Daubert context. So, for instance, it is not
5 simply the very opinion which is at issue. It is the flaw in
6 the manner in which they actually arrive at that opinion.

7 THE COURT: Well, let me just take it as I think you
8 have expressed it. It was sloppy, or he said one thing on one
9 occasion, something else on another occasion that he didn't
10 spend enough time looking at the documents, all of that.

11 MR. KETTERER: I think that that speaks more --
12 there's more depth to it, your Honor, than that, and I
13 understand what you're saying, which is that, well, because I
14 can hear the question coming out, which is going to be, "Well,
15 why don't you just cross him on that, that it was a sloppily
16 done report and it was a sloppily done issue?" And I think
17 that when we look at things that way, that you absolutely could
18 cross-examine, and I fully intend to, or someone will fully
19 intend to, some counsel will intend to cross-examine this
20 particular witness on this issue should your Honor deny this
21 motion.

22 But in Dr. Duffy's case the methodology, the very
23 issues which Daubert asks us to explore are is it reliable, the
24 manner in which they put the opinions together, is it just a
25 rubber stamp, is it *ipse dixit*, is it just saying these things

1 without any support? And if the report is done in such a
2 fashion there's nothing wrong with a lawyer having a
3 contribution to the report, there's nothing wrong with a lawyer
4 even drafting some of the report, but the opinions of the
5 expert must be the expert's opinions, and that's the problem
6 when you read through Dr. Duffy's testimony. His testimony at
7 the deposition belies the fact that it's not his testimony. He
8 doesn't actually have foundation.

9 THE COURT: Oh, no. It is testimony. You just say
10 that there is inadequate foundation for his testimony. He
11 still embraces what his scrivener or scribe said for him. I
12 think he will find the reference to "scribe" something that he
13 will have an opportunity to explain in some detail at the
14 trial. But I am not sure that I should knock him out for that.
15 He could have someone else write everything, as long as he
16 embraces it, and apparently he embraced it.

17 MR. KETTERER: That's true insofar as, your Honor -- I
18 agree with it insofar as you can embrace it, but the
19 methodology still has to be sound to the opinions to which you
20 embrace.

21 THE COURT: Well, but let's see where it is that it is
22 so fundamental that I say he just cannot testify as a witness.
23 If I hear "*ipse dixit*" again I will be sad.

24 MR. KETTERER: I don't want to make you sad.

25 THE COURT: That is just the kind of way people clear

1 their throat about Daubert matters. It is clear that the
2 plaintiff's people were more rigorous in reciting the *Baltimore*
3 *Catechism* of differential diagnosis, but it is catechismic. I
4 am really down to does he know enough, have enough information
5 and enough training to be able to express the opinion. And you
6 can ask him about what "differential diagnosis" means and did
7 he do it, and I suspect you will learn that he was a rose by
8 another name, that, in fact, he did it.

9 So, what is it that I should say could cause me to
10 keep him out of this case?

11 MR. KETTERER: So, let me go back to what -- your
12 Honor asked a very specific question of me right up front,
13 which was, "Tell me the opinion you want me to strike," and I
14 said the rebuttal opinion. So, let me go to Page 11, for a
15 second, and tell you why that's critical.

16 THE COURT: Page 11?

17 MR. KETTERER: Page 11, I'm sorry, of our initial
18 brief, of the plaintiff's Memorandum in Support.

19 THE COURT: Yes.

20 MR. KETTERER: And the issue, your Honor, is that the
21 reason I was using as an example the review of the actual
22 report is here is an example where Dr. Duffy does not seem to
23 have been aware of or actually reviewed the foundational
24 reports of Dr. Borkan and Schwartz, so how can you offer an
25 opinion about something where it's not necessarily certain, or

1 it seems that he did not review the actual underlying reports
2 of Dr. Borkan and Schwartzbard and file a rebuttal report
3 thereto? That's an example where I'm talking about the
4 specific kind of methodological flaw that's involved.

5 THE COURT: Let's pause with that. So, what's the
6 answer to that?

7 MR. DENNING: Your Honor, may I hand up a slide deck
8 that has a slide with the answer to that?

9 THE COURT: Sure.

10 MR. DENNING: Thank you.

11 (Document provided to the Court)

12 MR. DENNING: And, Mr. Sakimae, if we could pull up
13 Slide 12.

14 And, your Honor, if you want to turn to Slide 12.

15 THE COURT: All right.

16 MR. DENNING: So, what Dr. Duffy was doing in his
17 rebuttal report was responding to the opening case-specific
18 reports of Dr. Schwartzbard and Dr. Borkan. On this page you
19 can see all of the general causation aspects that Dr. Borkan
20 and Dr. Schwartzbard put in their case-specific report. They
21 had general causation sections, particularly in Dr. Borkan's
22 case-specific report.

23 THE COURT: What do I do with his statement that is
24 recited at Page 12 of the plaintiff's Memorandum, "I was not
25 aware that there were two reports"?

1 MR. DENNING: He wasn't, your Honor. He wasn't aware
2 that they had filed general causation reports. What happened
3 is, we sent all of the reports, including general causation
4 reports, to Dr. Duffy. He was unable to open them. They
5 became corrupted. Something happened. He said, "Can you
6 please send them back to us?" We sent him back only the
7 case-specific ones inadvertently, so all he read were the
8 case-specific reports, and he testified to that in his
9 deposition: "I reviewed only the case-specific reports from
10 Dr. Schwartzbard and Dr. Borkan." And that's accurate.

11 But he didn't understand that when he reports a
12 general causation, that meant a different report. He thought
13 it was these general-causation aspects of the case-specific
14 reports, the things that I list on Slide 12 before us: the
15 "Causes of Sudden Cardiac Arrest and Myocardial Ischemia," the
16 "CPA in Dialysis Patients," the "Acetate or Di-Acetate
17 Conversion to Bicarbonate," those sections of Dr. Borkan's
18 report that had nothing to do with Mr. Dial but were just
19 addressing in general this causation theory.

20 THE COURT: So, he did not read the general causation
21 reports.

22 MR. DENNING: He did not read their general causation
23 reports. He read their specific causation reports, and he is a
24 specific causation expert.

25 THE COURT: Well, yes, I suppose, but he might be

1 passing familiar with general causation, he purports to be, and
2 one reading his report might come to the conclusion that he
3 actually read the general causation reports as opposed to that
4 he did not.

5 MR. DENNING: That's true, and he corrected that in
6 his deposition when he was asked, and that's when we became
7 aware.

8 THE COURT: If I may just for a second?

9 MR. DENNING: Of course.

10 THE COURT: So, this comes down to a question of
11 whether or not, however he characterizes what he actually read,
12 what he actually read is sufficient to have a foundation.

13 MR. KETTERER: It depends on --

14 THE COURT: And why isn't it? It is not very good.
15 It is kind of any time you have to have more than a five-word
16 sentence to explain what you didn't do or you did do, you have
17 some problems, and he has some problems. But those are
18 problems for cross-examination, unless someone just reading
19 those reports could not reasonably have a basis for an opinion
20 with respect to the rebuttal report, in the rebuttal report.

21 MR. KETTERER: Well, your Honor, I think that my
22 response along those lines would be, first of all, obviously I
23 think that's a credibility question, but you would say that's
24 for cross-examination.

25 THE COURT: Isn't it?

1 MR. KETTERER: And to some degree, yes. I don't want
2 to fence and draw this too far out, because I think that your
3 Honor's position is very clear on this from the standpoint of
4 viewing it. I think that there is certainly an argument to be
5 made in regards to that impacts the methodology, right?

6 Credibility is, of course, an issue that is determined on
7 cross-examination to some degree. It can be determined there.

8 THE COURT: Let us assume someone for whom this
9 kerfuffle over what he read, what he didn't read, what was
10 corrupted, when it was sent to him by the attorneys, all of
11 that, let's just assume that he was someone who actually just
12 read the specific causation reports, and now we know that
13 that's what the case was, and drew an opinion on that basis.
14 What's wrong with that?

15 MR. KETTERER: I don't think that the way that your
16 Honor has posed the question in that limited frame is
17 necessarily a problem.

18 THE COURT: Well, expand the frame. Although, the
19 great photographer, I guess it was Stieglitz, used to say that
20 the way to make a photograph is to have a broad frame and then
21 squeeze it and squeeze it and squeeze it until you have got the
22 essence. I have tried to capture the essence, but perhaps you
23 can provide the context for me to evaluate the essence.

24 MR. KETTERER: Just a little bit. And the context is,
25 is that general causation opinions are to some degree what

1 inform the case-specific opinions, that background and that
2 backdrop, and if you file a report, a rebuttal report rebutting
3 the expert's general causation opinions, the plaintiff's point
4 is, well, he shouldn't be allowed to come in and talk about any
5 general causation opinions that Dr. Schwartzbard or Dr. Borkan
6 have with respect to it or general causation things that they
7 have talked about.

8 THE COURT: But what if those are, in fact, used for
9 purposes of specific causation? This suggestion that general
10 causation and specific causation are hermetically sealed and
11 independent does not strike me as compelling. There are things
12 that provide general background, and there are things that are
13 specific, but to get to the specific you have to know something
14 about the general.

15 MR. KETTERER: It's the whole frame.

16 THE COURT: So, what is the problem with him using and
17 responding to the general causation discussions and the
18 specific causation reports?

19 MR. KETTERER: Because that's not really the way the
20 reports are written. The reports are written in the sense of
21 you may draw upon some information that you have done in your
22 general causation report, and I would agree that if it appears
23 in the specific causation report, not just as a concept but the
24 actual detail of the discussion, he's rebutting not just the
25 concept but supposedly the detail that he alleged that

1 Dr. Schwartzbard or Dr. Borkan are using to arrive at their
2 case-specific opinions, and he is looking -- they're not giving
3 a full-blown analysis of their general causation opinions.
4 What it is, is they are explaining that their reference of how
5 they know or why they believe, I should say, that Mr. Dial's
6 event is caused by the NaturaLyte in this particular case or
7 the excess bicarbonate is based on their understanding of the
8 generalized science and the background, which they've already
9 opined about in their general causation reports.

10 Now, the problem is -- I agree with your Honor that it
11 is all woven together. That's my objection to allowing him to
12 testify in rebuttal to any of the opinions, because it is all
13 commingled. You can't just separate it out and say, well, he
14 referenced some general causation opinions, that because he
15 says he reviewed -- I don't know why you would say you reviewed
16 reports you didn't review, but in your written report why you
17 would do that.

18 THE COURT: Perhaps he will have an answer for you.

19 MR. KETTERER: I'm quite certain, your Honor.

20 But that interplay, though, how can those opinions be
21 methodologically reliable, even the case-specific opinions, if
22 it's all tied up together? And they are, to some degree.

23 THE COURT: I'm not sure that that makes any sense to
24 me. They are all functioning. Let me step back. Part of what
25 I will be suggesting to the parties is there is going to be an

1 order of proof here that is critical to the way the case comes
2 in, less a problem on this issue than on other issues.

3 But presumably the general causation experts testify.
4 Someone who can speak to specific causation will be exposed, I
5 assume, either sitting in the courtroom or reading the
6 transcript, unless the parties have some other plans for it.
7 So, they are going to know here is what people are saying.

8 MR. KETTERER: That's true.

9 THE COURT: And within the limits of their expertise
10 they can respond to that for purposes of specific causation
11 discussions. Now, if Dr. Duffy took on major issues concerning
12 general causation, maybe I would feel differently, but I don't
13 think that's the case.

14 MR. KETTERER: Okay.

15 THE COURT: What appears to be the case is he is
16 applying understandings of general causation to specific
17 circumstances.

18 MR. KETTERER: I don't think that I could add
19 something further to that particular discussion, your Honor,
20 and I don't want to continue to belabor the --

21 THE COURT: I appreciate that, and I will not have the
22 Clerk's notes report that you said "uncle."

23 But what other opinions are we really dealing with
24 here?

25 MR. KETTERER: Well, when you say "what other

1 opinions" --

2 THE COURT: Do you realistically think, in light of
3 the way in which I'm approaching this -- I do not mean to
4 forestall a rematch on the question of "uncle."

5 MR. KETTERER: Yeah, I know.

6 THE COURT: Experts, particularly when faced with
7 strong lawyers, as they are here, experts will find a vigorous
8 challenge, but I do not say I am calling the match, unless
9 there is something specific here that says that this guy has no
10 idea what is going on.

11 MR. KETTERER: And, again, your Honor, this would
12 inform the kind of frame which we're looking at, which you have
13 said that this Court doesn't view it the same way. To me the
14 thing that I have tried to express is that our concern is that
15 the methodological flaw into how the report is built, how it's
16 reviewed, whether or not there's ample foundation to give any
17 of the opinions, because -- and I won't say "*ipse dixit*" as my
18 argument -- but if there's not enough support, right -- when we
19 talked about this in the context of when we talked about the
20 modeling, right, was there enough evidence underpinning the
21 modeling from this sort of historical analysis, right? And did
22 the experts come in and actually have, not just the fact that
23 modeling is accepted, but was this modeling reliable,
24 sufficient to get past Daubert?

25 In fact, you had asked me, "Well, am I just here to

1 sit as a bump on a log," except I think you used a different
2 word.

3 THE COURT: I think the horticultural expression was
4 "potted palm."

5 MR. KETTERER: "Potted plant." And I said, "No," and
6 I think that that's the right answer, that the Court is not
7 there to simply act as a potted plant. So, the second step or
8 the depth in the analysis is, is questioning to some degree, if
9 it becomes obvious on its face that the expert who has actually
10 undertaken the analysis hasn't performed with any rigor or
11 can't opine sufficiently, and how do we determine whether
12 someone has opined or researched or formed their opinions with
13 any rigor? What's the methodology?

14 THE COURT: What is the methodological problem that we
15 are dealing with here? He is presented with -- somebody else
16 writes it for him, but he embraces it, says, "Yeah, I agree."
17 Then he has a lifetime of preparation, a Kumho kind of
18 qualifications, and he addresses with specificity various kinds
19 of aspects of this. What I am trying to get at is where I can
20 find he has failed to be within the competitive range of those
21 who offer opinions in this area? I guess maybe that is a way
22 of saying it, that he is just so far out of the competitive
23 range that one can say this is not going to see the light of
24 day, at least in front of the jury.

25 MR. KETTERER: I think that's an aspect of the Daubert

1 analysis, your Honor. That's the qualifications part of the
2 analysis. And I don't think that we --

3 THE COURT: It is both. I mean it as both.

4 MR. KETTERER: Okay.

5 THE COURT: It may sound like qualifications alone.
6 But just to get a sense that one could say, "I disagree," in
7 which case he testifies, or that's saying that the moon is made
8 of green cheese, in which case I exclude him. Now, somewhere
9 in there is some methodological problem, and I want to
10 understand precisely what that is, apart from the usual stuff
11 of you let the lawyers write it.

12 MR. KETTERER: Well, I also think that the reliability
13 or the basis by which we allow experts to testify before juries
14 is based on, the reason we ask these questions about
15 methodology and qualifications is to not allow completely and
16 wholly unreliable testimony to reach the jurors.

17 THE COURT: But he is not completely and wholly
18 unreliable. When I started it was before Daubert, and the
19 general view was let them cross-examine, and the parade of
20 humanity that used to come into the Courts under the banner
21 "Expert" was astonishing. Then Daubert came in and there was a
22 greater rigor, increased recognition on the part of the
23 District Judges that they should police, guard, act as
24 gatekeepers, maitre d's, whatever you want to call it, and
25 there has been a little bit of a loosening, and the loosening

1 has been I think because at a certain point there is, once one
2 gets into the competitive range, both in terms of
3 qualifications and in terms of methods of approach, that is
4 something for the people who are scientists to deal with.

5 Now, that does not mean that you do not look at things
6 very carefully. I do. We are all waiting for the specific
7 cause -- or maybe not everyone -- but I am kind of waiting for
8 the specific causation opinion in Millward. I think I know how
9 to take apart a case and try to deal with this, and I think
10 that I dealt with it there consistent with Millward I, which
11 was the general causation case that Judge O'Toole had.

12 But there is more flex in the joints now, and once we
13 get to people who are in the -- I keep using "competitive
14 range," which may be my *ipse dixit*, the shorthand, and I would
15 like to look at something specific that tells me that he
16 doesn't believe in atoms.

17 MR. KETTERER: Right.

18 THE COURT: That is too farfetched, but something that
19 says that this is the Dr. Igor Paul, you would not know him, of
20 experts who, having had at one point an affiliation with MIT,
21 became an expert in everything and was used in everything, and
22 then we said to the jury, "You decide what you want to do."
23 That is not this guy. The snippets I have read of it suggest
24 that I am going to be entertained by interesting
25 cross-examination, but that is not the grounds for knocking

1 somebody out.

2 MR. KETTERER: So, again, not to belabor the point,
3 your Honor, and I really don't want to, and I will just sum up
4 by saying it this way: I think everything you stated,
5 obviously, is a correct summation of the current law,
6 particularly in the First Circuit. I think that the way that
7 Millward analyzes and, as you said, loosens sort of things up a
8 little bit is accurate, and obviously I think that that is a
9 fair view of the law and the Daubert analysis.

10 That being said, I think that to analyze or to
11 understand it simply as that, if they don't say something that
12 is so far afield or so contradictory then they automatically
13 come in, is certainly one way to view it.

14 THE COURT: That is, of course, not what I am saying,
15 but you are absolutely right. Someone should not come in that
16 way.

17 MR. KETTERER: Right.

18 THE COURT: But that is not this.

19 MR. KETTERER: So, then the question is along that
20 spectrum where does this particular expert or any expert that
21 we have been talking about fall? And there are other reasons I
22 think that the Court has in terms of its analysis about why
23 certain evidence should or shouldn't come in or might or might
24 not be allowed, and that may depend not just on the expert or
25 the analysis, but also the type of evidence that it is that we

1 are discussing. So, I think that all of those things are
2 subtleties along that spectrum, and so it's hard to say.

3 In the context of this particular expert what I have
4 heard the Court say is, "Listen, unless you are pointing to
5 something very specific," and you said this with respect to to
6 the defendants and the plaintiffs, "Unless you are pointing to
7 something very specific that would completely knock this guy
8 out as rejected by the majority of the scientific community,
9 then it's ripe for cross-examination." If that's the Court's
10 analysis and position, then what I would say is, other than the
11 arguments I have already made with respect to the rebuttal and
12 with respect to our view of the methodology and why that's a
13 critical aspect to look at, there isn't something I would point
14 to to say this answers the Court's concern directly on that
15 particular point from that particular point of view. My
16 argument and the argument that I would make for the record is
17 and continues to be that, when we look at methodology,
18 methodology implies and imports and I think the Court does and
19 should look to some degree at what is the reliability not in
20 just a pure judgment call but in a scientific way of what is it
21 that they are doing. If you have someone else write the entire
22 report, you can't just say, "Well, I agree with those opinions
23 and that's enough methodology to be scientifically reliable."
24 Our view would be is that there needs to be some more rigor to
25 the opinions.

1 If you started a litigation you had never heard of
2 before, right, and the plaintiffs came in with science, and I
3 drafted the entire report, and I hired some expert from UCLA,
4 and they come in and they say, "Well, I agree with everything
5 that's here," I think that you probably, or maybe not, but I
6 think there would be trouble in accepting that kind of
7 broad-based opinion that seems to come from nowhere, really.
8 "What's the specific literature that you're citing? What's the
9 epidemiology? In a case-specific context what exactly are you
10 pointing to? Whose reports have you reviewed? How do you
11 contradict the nature of the --"

12 THE COURT: But I do not see this as, Dr. Duffy as
13 being without that kind of support. There may be aspects of it
14 that he did not think about as rigorously as he should have.
15 That will be brought out. But I cannot find that this is
16 someone who just stamped their name on somebody else's report,
17 that he is prepared to defend with explanation what the reasons
18 and the grounds were for his opinions.

19 MR. KETTERER: And, again, your Honor, I'm just going
20 to go through this one example.

21 THE COURT: One of my colleagues used to say, "Give me
22 your best one."

23 MR. KETTERER: Of course.

24 THE COURT: So, this is your best one?

25 MR. KETTERER: This is the one that I think is the

1 most illustrative. How's that, your Honor?

2 THE COURT: Okay.

3 MR. KETTERER: And if you look at Page 7, and I am
4 just going to read the last paragraph --

5 THE COURT: 7?

6 MR. KETTERER: -- of the Plaintiff's Memorandum, it
7 says, "Notwithstanding his 30 years of experience treating
8 patients and reviewing the literature, Dr. Duffy could not cite
9 to even one published medical source addressing the adverse
10 effects of alkalosis." Now, this is, of course, the very issue
11 in the case, your Honor. Parentheses, quote, "I read many
12 papers over the years and I cannot cite the name or the article
13 or the causes of cardiac arrhythmias in hemodialysis patients."
14 And you see both of those citations. They are noted in the
15 footnotes, your Honor.

16 And I guess my point would be, again, and I understand
17 the Court's view, and I don't want to, again, belabor that
18 point, but that's a point where he is saying, okay, let's look
19 at the actual issue. Now you are looking at the methodological
20 concern, which is, "Did you look at any literature, do you know
21 of any literature, did you cite any literature that you can
22 point to that supports your opinions?" That's a methodological
23 concern. That's not just, "Well, you embrace everything that's
24 said." That means that what you did in forming your opinions
25 doesn't actually have foundation if you don't know what the

1 foundation is.

2 THE COURT: Well, what it does say, I guess, and I
3 will want to hear from the defendant about this, what it does
4 say is that he presents as having 30 years of experience with
5 actual patients in the principles of hemodialysis, but he
6 cannot cite to particular sources, academic sources, or at
7 least medical sources.

8 Now, that is not great, that is not impressive. The
9 question is whether or not it excludes him, and if he had been
10 a dermatologist for 30 years I probably would feel differently,
11 but that is not the case. And so, the practical impact of
12 being a doctor in a particular specialty gets some Kumho
13 infusion here. I guess that is what it comes down to.

14 Assuming, as I do, I tried to read this stuff
15 carefully, that this is not read out of context, it is not
16 going to sound so great in front of the jury. But does it get
17 him thrown out? I don't know. I don't think so.

18 MR. KETTERER: So, again, your Honor, I understand the
19 view of the Court, and I guess what I would say is that, having
20 argued Daubert in a number of different jurisdictions and in a
21 number of different types of cases, when I listen and think
22 about how should plaintiffs address in their reports what is
23 adequate evidence to put before the Court to prove general and
24 specific causation, and the arguments I've heard over the years
25 from the defendants, not these defendants, but defendants in

1 general and the critiques that Courts, not your Court, but
2 Courts in general have made about deficiencies in Daubert
3 analyses, the underpinnings of those critiques are you can't
4 just roll in an expert and say, "Well, they're a specialist in
5 this particular field," whatever that field is, "and I want
6 them to opine about this particular issue," and then they give
7 their opinion, and then the Court says, "Well, wait a minute,
8 wait a minute. That's great that they had this kind of
9 experience for 20 years, 30 years," whatever it is, "and they
10 are a leading researcher in the field, but we have to know or
11 understand what the basis of those opinions are." The basis of
12 those opinions must extend beyond just simply, "I have the
13 experience," and one of the reasons for that is how do I know
14 what the reliability -- how do I know the source, how do I know
15 the reliability of that information? Because you gave an
16 example of an expert I'm not familiar with, but someone from
17 MIT who was basically opining about everything.

18 THE COURT: I am not sure MIT would say he is from
19 MIT, but affiliated with them.

20 MR. KETTERER: Affiliated with them. But if that
21 expert comes in and opines about everything under the sun, but
22 one of those things happens to be something he was a specialist
23 in, it isn't necessarily more credible or less credible; it's
24 simply we don't know. So, that type of testimony is the type
25 of testimony that Courts typically question.

1 THE COURT: There is no question that I question it.
2 The question is whether or not my questioning is going to lead
3 to its exclusion and exclusion on a motion *in limine*. Bear in
4 mind, I have said this before, just as contractors tell me that
5 the contract is the beginning of negotiations, my experience
6 with trials is the trial is the beginning of the legal
7 analysis. There are post-trial motions, then there are
8 appeals, and there are ways of sorting through this.

9 This much I am clear about, is, I am going to afford
10 the parties a fair opportunity to get their case in. If,
11 coming back and looking at this, I say it just was not enough,
12 then it gets excluded, a new trial or whatever, I am not sure
13 that that falls in this category yet.

14 I understand the point. I am not trying to cut you
15 off that much.

16 But what is the response?

17 MR. DENNING: Twofold response.

18 THE COURT: It is the lawyer who bills \$25,000 for a
19 consultation and says it's the 15 minutes and the lifetime of
20 preparation. That is what this is.

21 MR. DENNING: Yeah. So, two responses, your Honor.
22 First of all, it was a very pointed question that he was asked
23 in deposition, to recall off the top of his head the name of a
24 paper that he had read about alkalosis. He said, "Sitting
25 here, I can't remember the name of the paper."

1 The exact questioning is, he said, "As I have
2 explained, you know, my life has been devoted to taking care of
3 these. I have been reviewing this for many years. Did I cite
4 all those references over the 30 years that drove me to my
5 opinion? No."

6 And he was asked, "Well, what papers have you read on
7 the adverse effects of alkalosis?" "I've read many papers many
8 years ago. I do not know. I can't cite the exact paper or
9 reference for you." Then he was asked the question --

10 THE COURT: He says, "I cannot cite the name or the
11 article." The problem is he doesn't cite anything.

12 MR. DENNING: Well, the second response to this, your
13 Honor, is this is not the crux of his disagreement with
14 Drs. Borkan and Schwartzbard that alkalosis can have adverse
15 effects. He's saying Mr. Dial didn't have alkalosis. There
16 was no spike in his serum bicarbonate because of -- so, this
17 wasn't something that he said is a key differentiator and I
18 need to buttress this with all sorts of support. It's
19 something he fundamentally doesn't disagree with the
20 plaintiff's experts. Alkalosis can have adverse effects.
21 Sure.

22 THE COURT: Experts get pressed in deposition and so
23 on, and sometimes they get bloodied a bit, but I do not think
24 it is terminal for this guy. So, I am going to deny the Motion
25 to Exclude Dr. Duffy. That is Motion No. 58.

1 Airway's jury was deliberating, and I don't know how many of
2 you remember Judge Keeton's courtroom. Obviously, those from
3 out of town don't, but maybe Mr. Kettlewell does and
4 Mr. Tarricone. But it was right in that pink room, that was
5 the courtroom, and then right next to it was this barely more
6 than a partition, and so we were arguing and the people on the
7 other side were a bunch of bankers from New York who had never
8 seen a jury, to my knowledge, and were a little uncomfortable
9 with the idea that juries might decide things, and while we
10 were arguing there was a loud bang, and it appears that the
11 jurors were throwing chairs at each other in the course of the
12 deliberations in the World Airways case. That convinced, I
13 think, the lawyers for the banks that they never wanted to have
14 a jury in any case, and they all went to arbitration
15 thereafter, I am sure, for the rest of their lives.

16 In any event, I don't think the World Airways cases or
17 the airline cases govern this. I do think that to make
18 distinctions between punitive damages and the general
19 applicability of the law, I want to think about this some more.
20 Obviously, I will think about it in terms of instructions, but
21 is there anything really different, apart from the cap that you
22 know of now? It is not a pop quiz, but apart from the cap that
23 distinguishes North Carolina law and Massachusetts law on
24 punitives?

25 MR. DENNING: I think the only other difference, your

1 Honor, and I don't think it's going to end up being relevant in
2 this case, is North Carolina has a statutory scheme toward the
3 forbid strict liability claims. I don't think that's going to
4 be relevant in this case. That's the only other difference.

5 THE COURT: Right. But as to punitive damages, I do
6 not see it as -- I will charge them with a kind of plain
7 vanilla punitive damage charge, I would assume, and I will hear
8 from you in just a second, and I do not assume a prejudice to
9 the defendant to being exposed to a jury determination with
10 respect to punitive damages that may exceed the cap, that I
11 just put the cap back on there if that determination is made.
12 Am I correct about that? You would rather not like them
13 thinking about telephone numbers, but that is the concern.

14 MR. DENNING: That sounds right. The only wrinkle, if
15 I may, your Honor on that --

16 THE COURT: Sure.

17 MR. DENNING: -- is issues like the company's net
18 worth, which I don't think is relevant for any issue other than
19 punitive damages. It might be an interesting twist. I know
20 that in the Ogburn case, and just because it's what we did
21 before, Judge Kirpalani did not allow that evidence in and
22 said, "Okay, if they come back then we will introduce a few
23 documents and send the jury back to deliberate on the
24 punitives."

25 THE COURT: Right.

1 MR. DENNING: Just for reference.

2 THE COURT: That model, which is a model that I have
3 used in similar kinds of cases, seems to me to be the right
4 thing. I don't think there would be very much else other than,
5 "Here is what they got on this." Punitive damages have their
6 own problems, but they are still part of the law. I have no
7 difficulty saying to a jury, "We just have one further question
8 in light of your analysis," and it would be the same jury
9 there.

10 MR. DENNING: Okay. Understood, your Honor. And the
11 punitive damages instruction, then, would be given to the jury
12 before that second phase, I guess?

13 THE COURT: Yes. That's my general view of what I
14 would be doing rather than raising -- maybe this is too cute by
15 half -- I would not knowingly lie to the jury that they were
16 all done when the first verdict was returned, but simply say,
17 "We have got some questions, and the first of these questions
18 is," they may not remember that I said, "The first of these
19 questions is," and then send them back. Now, there is
20 frequently a problem, or potential problem, with disappointed
21 jurors who return a verdict and then aren't that happy about
22 having to do it again, but I will try to take the sting out of
23 it. They do their duty, in my experience.

24 MR. DENNING: I understand, your Honor. Thank you.

25 THE COURT: Did you have something you wanted to add?

1 MR. HONIK: I did, your Honor. Good morning. Allow
2 me to introduce myself. This is the first time appearing
3 before you. I'm Rubin Honik from Golomb & Honik in
4 Philadelphia. I'm a member of the trial team for the
5 plaintiffs.

6 Your Honor, I read with great care and listened with
7 great care this morning to your general approach to how to
8 handle punitive damages, and to a person on our team we agree
9 with your approach. But I hasten to point out that, unlike the
10 situation in Lastorka in which all the parties agree that
11 Massachusetts law and Mississippi law on the availability of
12 punitive damages was identical, and but for the presence of a
13 cap there was otherwise no difference, there are material
14 differences here between North Carolina and Massachusetts, and
15 although it's entirely --

16 THE COURT: What are they? Just give me a sense of
17 them.

18 MR. HONIK: I will tell you precisely what they are,
19 your Honor. Under Massachusetts law, as you well know,
20 malicious, willful, wanton or reckless conduct or gross
21 negligence will suffice as a basis to apply punitive damages.
22 By contrast, in North Carolina only a finding of fraud, malice,
23 willful or wanton conduct will suffice for punitive damages.
24 So, the concept of reckless conduct or gross negligence present
25 and available here in Massachusetts is not in North Carolina.

1 THE COURT: Well, what you are saying, or the import
2 of what you are saying is to force me to make the decision with
3 respect to whether North Carolina law and Massachusetts law
4 applies to punitive damages before I charge the jury.

5 I am resistant to that to the degree that I can
6 properly be resistant to it, because, as I stated earlier, I do
7 not want a retrial if I am wrong one way or the other. That is
8 why I suggested a plain vanilla instruction with respect to
9 punitive damages, if it ever gets to that. Now, are there
10 meaningful distinctions that are expressed by those adjectives?
11 Well, the Courts have said so. I am not sure that they are
12 visible to the non-lawyer eye when they are instructed on it.
13 I would encourage the parties to think long and hard about
14 that, because if what you have done by saying you have got to
15 do it this way or that way because you have got to make the
16 decision about Massachusetts law versus North Carolina law is
17 raise the specter that if I'm wrong about it -- I will try not
18 to be wrong -- but if I'm wrong you get a new trial on
19 everything, even if you could have gotten a judgment on
20 punitive damages the first time out.

21 So, maybe it is important to tease those distinctions
22 out and to rely on those distinctions in some treatise-like
23 sense. On the other hand, it certainly has the potential for
24 delaying gratification if the distinctions are drawn in a
25 different way than you suggest. If I heard it correctly, and I

1 have not, as I said, studied North Carolina law, it really
2 turns on recklessness. If you think you have got a case that
3 does not include all of those -- that a jury could find does
4 not include all of those other bad things but does include
5 recklessness, I suppose it is worth rolling the dice on it.
6 But rolling the dice, as I am sure you understand, means
7 increases some costs for what might be an illusory benefit.

8 So, I simply raise that. We are going to have to deal
9 with it for instruction purposes. If the parties are going to
10 press that issue, I, of course, will make the determination
11 that I have to. As I have indicated before, I try to make the
12 distinctions if I have to, but if I do not, then try to do it
13 in a way that means that we have got a factfinding that the
14 jury does, and then we have got a judge on post trial and three
15 judges on appeal who can sort through the factfinding and then
16 slice and dice to get a judgment that is both factually
17 supportable and legally correct.

18 MR. HONIK: Respectfully, your Honor, I think there is
19 one other implication of how the Court may end up on this
20 issue --

21 THE COURT: Okay.

22 MR. HONIK: -- and that is, candidly, in trial
23 preparation and here's why: The concepts of recklessness and
24 gross negligence revolve around degrees of care. The very word
25 "negligence" is the absence of due care under a set of

1 circumstances. So, gross negligence, and this is well spelled
2 out certainly in Massachusetts law is --

3 THE COURT: Which I will not be applying it here for
4 those purposes, that is to say, unless you tell me that I only
5 do that for purposes of punitive damages.

6 MR. HONIK: Well, that's what I'm addressing. This
7 only applies to punitive damages. We have reached an
8 understanding as between counsel that North Carolina law
9 applies in all other respects.

10 THE COURT: Okay.

11 MR. HONIK: They have filed the motion, we have
12 withdrawn our objection, and that's where we are on that issue.

13 But with respect to punitive damages, consider if you
14 will, our preparation for trial. We truly think that there is
15 evidence in this case, quite a bit of evidence, which on a
16 degree-of-care axis may point to the defendant having been
17 grossly negligent.

18 THE COURT: But how is it going to make a difference?
19 So, you put Buchanan on the stand, you knock him around a bit,
20 you talk about what they did report or did not report,
21 understanding that I will have something to say on that, but at
22 the end of the day, first you get the core North Carolina
23 judgment, which may not have gross negligence and recklessness
24 in it specifically, but I do not know what different evidence
25 you are going to be introducing.

1 MR. HONIK: Your Honor, if we were theoretically to
2 receive guidance from you, from the Court, at the outset that
3 you will be permitted, if the evidence supports it, to
4 demonstrate gross negligence, the preparation for that case is
5 markedly different.

6 THE COURT: How? Just tell me how. I am not being
7 confrontational.

8 MR. HONIK: Because the concepts of willful, wanton
9 conduct borders on demonstrating intent.

10 THE COURT: But those are all things in the air. I
11 feel like Joe Friday, "Facts, ma'am." That is what you are
12 doing for the trial. So, you are introducing evidence that
13 provides the basis for facts? I do not know what different
14 examination you are going to be doing of the defendant's
15 witnesses if you ultimately think you are going to get a
16 willfulness instruction or a gross negligence instruction than
17 you would from a regular negligence instruction.

18 MR. HONIK: Your Honor, Mr. Tarricone at some point, I
19 assume, is going to stand up in front of the jury with an
20 opening, and I know for me, as a trial lawyer, I would want to
21 know --

22 THE COURT: There was agreement that there were two
23 distinctions here, two different jury verdicts. There is the
24 case in chief, the basic case. Then there is going to be an
25 opportunity to offer additional evidence and argue to the jury

1 with respect to punitive damages.

2 Now, I do not think that, apart from the question of
3 what is this company worth, what can they absorb in punitive
4 damages, that is really what that evidence is about, there is
5 going to be any new evidence.

6 MR. HONIK: I agree with that, your Honor.

7 THE COURT: So, what is trial preparation here?
8 Mr. Tarricone gets up and addresses the jury and tells them
9 about the case that the plaintiff has, and then we have a
10 verdict which may be like Ogburn or may be different, and if it
11 is different then there will be a little bit more testimony or
12 maybe just some documents introduced, and then Mr. Tarricone,
13 or whoever, a reasonable facsimile, if there were one, gets up
14 and says, "By the way, this was not just negligence. That is
15 why we asked you about before. This was willful, this was
16 reckless, this was," whatever the magic words are. But I do
17 not see that that changes trial preparation.

18 MR. HONIK: And that may be correct, your Honor, if,
19 in fact, there is an opportunity to address the jury in the
20 second phase --

21 THE COURT: There would be.

22 MR. HONIK: -- and say, "The negligence we
23 demonstrated to you was gross negligence, and here's why." If
24 that's the case I accept the concept of --

25 THE COURT: I think that is the way I conceive it.

1 But this, then, goes back to this question of so what are we
2 going to be charging the jury on if we get to that? Are we
3 going to use the adjectives that the Courts in North Carolina
4 use or the adjectives that Courts in Massachusetts use? That
5 is an issue. And on that, I am to some degree agnostic. If
6 pressed to it, I will make whatever decision I have to make
7 about which law applies, recognizing that there is the
8 potential that I will have chosen the wrong one.

9 Let me use an example. I once had a case involving
10 insurance coverage for pollution, and it was governed by either
11 Maine law or -- actually, North Carolina law, I think it was --
12 and the question was coverage and then I think interest
13 payments. The only law that I had was a construction of Maine
14 law by the Federal District Court in New Hampshire and North
15 Carolina law by the Appellate Court in North Carolina. I said
16 to the lawyers at that time, "I find that the New Hampshire
17 Court got it right for purposes of Maine law, and I find that
18 the North Carolina Appellate Court got it right for purposes of
19 the interest."

20 In the interim, the Supreme Court of North Carolina
21 reversed the Appellate Court, and the Maine law Court took a
22 different position from the New Hampshire Court. And so, I was
23 put in the position and the parties were put in the position of
24 successfully arguing a conflict-of-law case that had the effect
25 of adversely affecting their interests here.

1 I think you should be careful about adversely
2 affecting your interest in making those choices. That is the
3 sole suggestion I make. But this, I think, will be fodder for
4 further discussion.

5 MR. HONIK: Thank you, your Honor. As long as we have
6 an opportunity at some point to press that gross negligence is
7 a standard --

8 THE COURT: Right. Let me just ask this. I want to
9 take a break in just a second, but let me just ask this: I
10 have not even looked at it. Do we have schedules for jury
11 instructions and verdict slips?

12 MR. BENNETT: Your Honor, that was one of the things I
13 was just going to bring up. We have been trying to comply with
14 your standing order, and so we wanted to know when you wanted
15 that, and that's why we wanted choice of law discussed today so
16 we knew what to do. We were thinking that you would want a
17 verdict slip of some form, and we are going to submit that to
18 you at the time that you want it.

19 THE COURT: So, we'll talk about it. Do you know
20 enough about what the questions of choice of law is? I am
21 going to be applying Massachusetts law for the substance of the
22 case --

23 MR. BENNETT: North Carolina.

24 THE COURT: -- excuse me -- North Carolina law for the
25 substance of the case, Massachusetts choice of law to apply

1 North Carolina law, and then I am going to be thinking long and
2 hard, and so are you, about what the punitive damages is on it.

3 MR. BENNETT: Right. And so, what we were thinking,
4 and we would take whatever guidance you give, of course, is it
5 would be essentially the questions that you would be asking,
6 and that would be the submission from us to you, and so it
7 would just be three or four questions of what we think the
8 verdict slip should look like.

9 THE COURT: Right.

10 MR. BENNETT: Thank you, your Honor. We can do that
11 whenever you direct, because we have been working on it in
12 anticipation.

13 THE COURT: So, we will talk about it. I want to take
14 a break now and come back in, say, 20 minutes or so.

15 MR. BENNETT: Thank you.

16 THE CLERK: All rise.

17 (The Honorable Court exited the courtroom at 11:18 a.m.)

18 (Recess taken)

19 THE CLERK: All rise. Court is back in session. You
20 may be seated.

21 THE COURT: Well, I apologize for taking your time,
22 but there was a meeting that I had to have.

23 That, then, takes us, I think, to the motions *in*
24 *limine*. We have talked a bit about the GranuFlo/NaturaLyte
25 problem. I am now focusing on Fresenius's Motion *in Limine*

1 No. 1, and I guess it is all going to depend on the character
2 of the introduction. As I indicated earlier, I do not see
3 myself masking the name "GranuFlo" or the fact that GranuFlo
4 was prescribed and, in fact, used for a period of time in what
5 may turn out to be a revised chalk that shows the chronology of
6 it. But to say this is a GranuFlo case is to be quite
7 inaccurate, and I don't want the GranuFlo stuff to overwhelm
8 everything else in the case.

9 So, let me understand from the plaintiff what you
10 think you are going to be doing with this.

11 MR. KETTERER: Your Honor, let me just make sure I
12 understand, that I have heard the Court correctly. The Court's
13 concern is, obviously, that this is not a specific -- a case
14 where the plaintiff received GranuFlo. While some of the
15 treatments involve GranuFlo, an implication that GranuFlo is
16 somehow the focus or feature of this trial would be in the
17 Court's view inappropriate, and that is not the intention nor
18 the intent of the plaintiff in terms of how the evidence should
19 come in, nor how the evidence will actually be presented. The
20 reality is, and I think that this is generally true
21 thematically about how I generally view motions *in limine* when
22 I argue them, which is, you said it earlier, the facts are the
23 facts. The fact is when GranuFlo is part of the history, if
24 it's appearing as part of a memo, if it's appearing as part of
25 a document --

1 THE COURT: Well, let me put it in a different way --

2 MR. KETTERER: Sure.

3 THE COURT: -- because it is anticipating something
4 that we are going to talk about, which is the Hakim memo, which
5 I am a little unsettled by in terms of responses to or the
6 motions *in limine* that have been raised. Yes, facts are facts.
7 On the other hand, when they become a stalking horse for some
8 other extraneous, potentially misleading and, in any event,
9 inadmissible matters, then if the parties do not take it in
10 their own hands I will, either by instructions, cautionary
11 instructions, sharply phrased responses to objections.

12 GranuFlo, I suppose, carries its own baggage. I do
13 not want that baggage to be deposited in this court in this
14 case. And so, while I don't want to be, and as I have
15 indicated, I do not want to create some false illusion about
16 some product with an unknown name, I do not see this as a
17 GranuFlo case really at all, and problems of, perhaps, notice
18 or related matters for GranuFlo are unlikely to get in.

19 MR. KETTERER: One of the issues, unfortunately, your
20 Honor, as your Honor, who is far more experienced, knows, is
21 that the motions *in limine* sometimes, without seeing the
22 evidence or actually seeing the documents, makes it difficult
23 to talk about it in the abstract, but let's talk about it from
24 a specific context of some examples of how this may play out.

25 THE COURT: All right.

1 MR. KETTERER: So, for instance, the issue of memos
2 that include both NaturaLyte and GranuFlo as topic matters I
3 think would be fair game, given the fact that it covers both
4 products, and so the things that the memos that are the subject
5 matter of either or any document that addresses both products
6 specifically I think then is fair in the sense that it's not
7 compartmentalized.

8 THE COURT: Maybe, but let's step back a bit.

9 MR. KETTERER: Sure.

10 THE COURT: Because reading the other motions *in*
11 *limine* there is a suggestion, which I reject, that simply
12 because something is admissible for purposes of business
13 records or as an admission of a plaintiff, documentary
14 admission of a plaintiff, or is used for a medical treatment,
15 that it just walks in all by itself without the judge excluding
16 it. No. It is going to have to be tied to relevance to this
17 case, and it is cabined by Rule 403, which I view as robust in
18 dealing with those kinds of issues that can be distracting for
19 the jury.

20 So, let's take what triggered my observation. Let's
21 take memos. I will have to look long and hard at some of these
22 memos, but the mere fact that somebody issued a memo does not
23 get that memo in. If it is offered for the idea that there was
24 a memo, offered for the idea that there was a particular kind
25 of notice, it probably can come in by way of narrative: "Did

1 you receive notice? I show you a document dated November 2011.
2 Did you see that? Were you aware of it? You see that it says
3 that this is an issue that ought to be addressed?" I would
4 probably let that come in. Not likely to let the Hakim memo
5 come in as such, nor the conclusions of it, and to the degree
6 that somebody starts suggesting that those conclusions are
7 science, I will disabuse the jury of that.

8 So, you are absolutely right. I think maybe you were
9 not here the last time, but I gave kind of my schtick about
10 what motions *in limine* are.

11 MR. KETTERER: I read the transcript.

12 THE COURT: I think of them as tone poems, Zen koans.
13 They are efforts to give the parties some idea of how the case
14 is going to unfold. If you want something you are going to
15 have to offer it, and I am going to have to reject it, but
16 nobody wants to spend a lot of time doing that. You make your
17 record, and whatever the record is the record is.

18 But I want to tell you as clearly as I can that I am
19 not going to let the case go by aromas wafting through the
20 courtroom that emanate from something that is not at the core
21 of the case.

22 MR. KETTERER: I certainly appreciate the Court's
23 position, and I think that co-counsel do as well, your Honor.
24 I certainly understand the idea of wanting to confine and sort
25 of streamline and make sure that relevant evidence is what is

1 coming in. I guess the only way to really go through it is to
2 then look at the documents as they are going to come in.

3 That being said, I know that you, because we have
4 talked about this at length, about the Hakim memo, whether or
5 not coming in, or not coming in, however that works, and I
6 understand that this Court's position has been certainly issues
7 with some of the conclusions and some of the things. I have a
8 feeling that we are going to be talking about some of the way
9 the Court looks at that in the next motion *in limine*.

10 With that said, I won't jump ahead, but I certainly
11 have a view on that as well.

12 THE COURT: But you started down a road that I made
13 you pause on with my observations of where you are going.

14 MR. KETTERER: Sure.

15 THE COURT: But let's take a particular document, a
16 document you know they are going to raise an objection to that
17 falls in this GranuFlo rubric. Give me an example so we can
18 maybe talk it through in terms of a particular document.

19 MR. KETTERER: Well, your Honor, actually, in looking
20 through the documents yesterday and sort of talking out -- the
21 objection, as I understood it, is documents that pertain
22 specifically to GranuFlo, or let's say there is an email, and
23 the email is an email from Ray Hakim to Mike Lazarus, and the
24 only thing in the email that is referenced there is concerns
25 with GranuFlo. Now, there's nothing in there that references

1 NaturaLyte. There's nothing that references a concept which,
2 although we dispute is at issue, this issue of total buffer --
3 it may reference total buffer, but the focus of that email is
4 GranuFlo. It's not our intention, it's not the plaintiff's
5 intention to introduce something which is squarely only on the
6 issue of GranuFlo.

7 Let me give you a different example, though. Let's
8 say, though, let's take the example of the memorandum.

9 THE COURT: The memorandum meaning --

10 MR. KETTERER: No, not *the* memorandum, a historical
11 memorandum, one from, let's say, 2009.

12 THE COURT: I think of the Hakim memorandum as being
13 kind of like the *Dead Sea Scrolls*.

14 (Laughter)

15 MR. KETTERER: Well, let's not think about it that
16 way, your Honor. Let's hypothetically pretend that the
17 plaintiffs, unless the defendant is going to bring it as an
18 issue or make it an issue, that the plaintiffs are not
19 introducing the Hakim memo or are not even seeking to introduce
20 the Hakim memo, because we have heard what your Honor has had
21 to say.

22 Now, that being said, let's talk about a different
23 memo, and that memo references both GranuFlo and NaturaLyte.
24 Let's say it's another document that references the calculation
25 of total buffer, adding 4 for NaturaLyte, adding 8 for

1 GranuFlo. Now, that's the kind of document that I don't know
2 that there's still a dispute about, but I don't think is,
3 assuming it's relevant under all the other Court's
4 considerations, that it's relevant to the information and the
5 theories of liability or causation, because it could be
6 either -- many of these memos are not just strictly liability
7 documents or notice documents, but they also have elements or
8 data points or things that are laden within them. So, the
9 question is if it references both things or a concept that is
10 at the core, forget whether it would be at the core of a
11 GranuFlo or a NaturaLyte case, it's at the core of this case,
12 at the core of the case that we have before your Honor, then I
13 believe that's the kind of document that the plaintiffs are
14 seeking to admit, and we don't want it excluded or redacted
15 just because it says the words "GranuFlo" on it.

16 THE COURT: So, let me respond. I think this is
17 something that I am going to have to see in specific before,
18 and my rulings are only meaningful in terms of the specific
19 proffers. I have a resistance to lots of documents, choking
20 the jury with documents, and so unless it is something of some
21 totemic value, my general sense is you can get it in through
22 asking a witness about the substance of the document, but the
23 document does not come in. That is a kind of general view. It
24 depends on the seriousness of the document itself, but at some
25 point I am a guardian of the force of name.

1 The second is not to distract the jury from things
2 that are important, relevant and material to this case, and so
3 things that introduce or suggest some other kinds of misconduct
4 or bad action I am going to be resistant to, other than the
5 core of this case, did the NaturaLyte cause the death here, and
6 are the defendants responsible for that? I do not know what
7 more I can say in response to that, to the motion *in limine*
8 here, than that, unless I have got particular documents in the
9 context of a particular --

10 MR. KETTERER: I agree with that, but one thing I
11 wanted to raise, and unfortunately I was not able to be here, I
12 believe it was at Wednesday's hearing, and I know that there
13 was a subject matter that came up with respect to there had
14 been an emergency motion, and then there was a question, and I
15 know that I didn't have an opportunity to read the transcript,
16 but I know that you had discussed, there was some discussion
17 about the OK, 1K, and I think your Honor's position had been
18 that you were afraid that was going to be a distraction, there
19 was a motion *in limine* on it, and rather than take up the
20 Court's time now, I am happy to discuss as an example
21 of something that is --

22 (Sound from the gallery)

23 THE COURT: Let me make a point. Every dog gets one
24 bite. That was the bite. If electronics which apparently the
25 teams think are going to transform this courtroom into a

1 Best Buy start to distract, as that just did, then the
2 individual who has that piece of electronics will pay a fine of
3 \$500 and will be ejected from the courtroom and will not be
4 permitted to be in the courtroom again.

5 Now, whose was it?

6 VOICE FROM THE GALLERY: Your Honor, it was mine. I
7 apologize.

8 THE COURT: And who are you?

9 VOICE FROM THE GALLERY: My name is William
10 Maller (ph).

11 THE COURT: Who are you with?

12 VOICE FROM THE GALLERY: I'm not interested directly
13 in the case. I'm just observing on behalf of another party.

14 THE COURT: What other party?

15 VOICE FROM THE GALLERY: An insurance company.

16 THE COURT: Let me reiterate what I just said.

17 Anybody who interrupts the Court with that kind of inattention
18 to the electronics that they bear on their body is going to
19 bear a scar, and that scar is the \$500, and you will not be
20 permitted to be in the courtroom, and I will then address the
21 question whether or not the party that you represent can appear
22 in the courtroom, because they have sent somebody who is
23 unfamiliar with their obligations to make sure that there are
24 no distractions in the courtroom. I have not asked you what
25 insurance company, but I will the next time.

1 VOICE FROM THE GALLERY: I understand, your Honor. I
2 apologize, your Honor. It won't happen again.

3 THE COURT: All right. So, I want every one of the
4 parties here, and I assume that every one of the parties and
5 representatives of parties and people who are here understand
6 that, because this is directed to the parties in the case,
7 their counsel and all persons who act in concert with them. I
8 do not want to see or, more accurately hear, that kind of thing
9 again. So, I think I have been clear. Fair notice. But that
10 was the one bite. I assume everybody understands that now.

11 MR. KETTERER: Certainly, your Honor.

12 THE COURT: Let's go back.

13 MR. KETTERER: Your Honor, just on reference to the OK
14 or 1K that was at issue, and I understand that the Court's
15 position, just getting back to where we were on the track of
16 the point that I wanted to make was simply that there is a
17 motion *in limine* on it, and I would like to be heard on that at
18 the time.

19 THE COURT: Oh, yes, we will get to the specifics of
20 that one.

21 MR. KETTERER: Okay.

22 THE COURT: It is not listed as one of the ones on
23 today.

24 MR. KETTERER: I understand.

25 THE COURT: I offered some preliminary views on it,

1 but the preliminary views were offered for purposes of trying
2 to give the parties some idea of how I am likely to be dealing
3 with this.

4 MR. KETTERER: That's what I wanted to understand in
5 the context of this conversation as well, is that, obviously,
6 there are some documents that need to be seen and need to be
7 seen in context. It only made me think of it because I know
8 that this issue had been addressed, and I wanted to put in at
9 least our position as to why it fit into the context and not
10 just based on that argument we made with respect to the
11 GranuFlo.

12 THE COURT: Right.

13 MR. KETTERER: So, I understand your Honor's ruling or
14 your Honor's position on this, that you will need to see the
15 documents. I think I've at least, to some degree, previewed
16 the way the plaintiffs view introducing those kinds of
17 documents, that it's not our intention to be distracting, that
18 the documents that we're offering, we will try to be judicious
19 about what it is that's offered. I think we have heard the
20 Court very clearly that your Honor would like the documents to
21 be, for important reasons --

22 THE COURT: No bigger than a bread box worth of
23 documents.

24 MR. KETTERER: We are working on that. So, then the
25 issue is, your Honor, then seeing the actual documents as they

1 come in.

2 THE COURT: Right.

3 So, let me understand from defendants what is an
4 example, what is the issue?

5 MR. BENNETT: Certainly. At the highest level, our
6 issue was a document that says, "Why doesn't GranuFlo have a
7 label on it that says in big, bold letters '8.'" It sounds
8 like they're not going to try to do that, because it's only
9 GranuFlo. Then the issue comes to memos who have their, we
10 would view their character as something that the plaintiffs
11 would want to paint in a negative light to us, based on the
12 fact that it's GranuFlo.

13 Let's take, as a specific example, some of the
14 historical memos on the subject that do talk about NaturaLyte
15 and do talk about GranuFlo, talk about GranuFlo having extra 8,
16 people not understanding that, things like that. What we would
17 take from the Court is the approach -- ask that the approach be
18 taken that the witness who is sponsoring that document testify
19 as to the contents of the documents that are relevant and
20 probative for this NaturaLyte case. That's in evidence in that
21 manner. The content of the document is not in dispute, so
22 there's no need for a best evidence objection or anything like
23 that. And so, I think that with the Court's statement that
24 it's a NaturaLyte case, the plaintiffs trying to navigate that
25 as well, us objecting at the appropriate time and a general

1 approach of having witnesses actually testify about what they
2 had notice of or what they read and what they understood that
3 is actually relevant to this case, we can make this work in
4 that manner.

5 THE COURT: I am unballasted by particular documents,
6 so it is a little difficult to deal with this, but let's take a
7 document that has both GranuFlo and NaturaLyte -- I already
8 made it a hermaphrodite by doing that -- that has both in
9 there, and it provides notice of people out in the field just
10 do not understand this. You have told them about this and they
11 do not understand, and it involves both of them. Are you
12 saying it just involves NaturaLyte for that purpose?

13 MR. BENNETT: I would say that on a document like
14 that, or one of our communications, where we say, "Hey, we did
15 give notice," and it talks about both, I would think that that
16 would be a matter where the document could be received into
17 evidence subject to any appropriate instruction or explanation
18 by counsel in closing on the appropriate use of the document in
19 this particular case.

20 THE COURT: Well, I will do the instructing.

21 MR. BENNETT: I understand that. Of course.

22 THE COURT: While I, of course, appreciate the
23 willingness of counsel to help the jury by their own
24 instructions to them, I will be the one doing the instructing.
25 One of the things I would like to see is what a cautionary

1 instruction looks like in this area to kind of cabin this
2 somewhat.

3 MR. BENNETT: Understood. When I said "instruction,"
4 I meant from you and argument from me.

5 THE COURT: And you understand what I meant.

6 MR. BENNETT: I certainly do.

7 THE COURT: So, we both have an understanding of our
8 respective roles.

9 MR. KETTERER: One thing I would just add onto this,
10 your Honor, just the discussion broadly is, as I'm listening to
11 Mr. Bennett sort of elucidate what their position is now is
12 that understanding -- and you will have heard the opening so
13 that these documents will be further contextualized.

14 THE COURT: See, let me just tell you something. One
15 of the reasons that I do spend a fair amount of time, even at
16 this very high level of generality in talking about motions *in*
17 *limine*, is to identify those things that I am going to warn the
18 parties off of for purposes of opening statement. It may be
19 that the evidence comes in at a later point, but there will be
20 certain kinds of third-rail issues, and I do not want you
21 lighting the jury up or electrifying them until you know and I
22 know that this train is going to run on that track.

23 MR. KETTERER: I appreciate that. I guess my point is
24 a little bit different than that. There's definitely a view or
25 a theory, especially from a scientific view, of how the case

1 works, and I think that informs the Court's view in terms of
2 ruling on documents, or I think it will, and so, it's not -- I
3 understand the Court's message is, "Hey, listen, these are the
4 boundary lines, don't go into opening and go outside the
5 boundary lines," but that's different than what is your theory
6 of the case. Let's say it's a NaturaLyte case, right? There
7 is a theory of, however you view the case or however the
8 plaintiffs are going to argue, this is why NaturaLyte caused or
9 how the plaintiffs argue NaturaLyte caused the injury. This is
10 why NaturaLyte is, in fact, liable. So, when the documents are
11 viewed there is a context then to why that document may be
12 significant.

13 And that's all I'm saying, is that that's the reason
14 why, even arguing in a vacuum, if we were to look at a specific
15 document, without the attendant actual theory of how the case
16 is being prosecuted, I think that it loses some of the context.
17 I do think that there are boundaries of things that are clearly
18 off limits when you talk about your view of how the November
19 2011 memo or the Hakim memo, to use the colloquialism, might
20 get used. That's a boundary line that's guidance for opening,
21 and that's a very broad category of document. I think that
22 these are finer sort of things, and that's why I'm sort of
23 posturing it this way.

24 THE COURT: Well, the short of it is I cannot act on
25 this motion *in limine* at this point. I think two things: One,

1 as I have indicated, opening is very important to me that
2 people do not bring to the attention of jurors things that do
3 not have a likelihood of going to the jury, or at least I want
4 to think about in the context that you have described, and the
5 second is to give you some sense of how I feel about this. But
6 this is a matter of feeling, rather than dealing with
7 particular matters. I think the way it is going to play out or
8 become reified for the parties' purposes is, as you reduce the
9 number of documents to a bread box, you identify those things
10 that are of concern to the parties, and then we will talk about
11 them before opening. The first question to ask each other is
12 whether this is going to come in in an opening. If there is a
13 likelihood of an objection, I do not want the objection made in
14 the presence of the jury. I want it to be avoided in the
15 presence of the jury, because another of my crotchets and
16 conceits is I do not like sidebars. We take stuff up before
17 trial, we take stuff up at the break, we take stuff up at the
18 end of the case. So, give me a heads-up of, "Here are the
19 things that might happen today," and I will give you some
20 instruction on that. But I know, as you all know, you do not
21 have a preserved objection until you make a proffer and I rule
22 on it, and so the way in which we are going to do that is I
23 think by narrowing the issues first in the development of your
24 exhibit lists and so on and then is this something to come in
25 in opening statement, and I urge both parties to recognize that

1 the opening statement is a broad statement of their views, not
2 the opportunity to put chalk on your shoes by getting close to
3 the lines of the game.

4 MR. KETTERER: May I ask a question, your Honor?

5 THE COURT: Sure.

6 MR. KETTERER: So, although I will not be doing the
7 opening statement here, but one of my concerns I do want to
8 address so that we do have a context to discuss it is that the
9 understanding that I have just now on openings is that they
10 should obviously -- they should not be argumentative, and you
11 don't want to have an objection, obviously. That's something
12 that is hard to anticipate.

13 THE COURT: Well, let me be clear on this, because
14 some people are surprised the first time they try a case here.
15 If somebody has got an objection to the opening, they make it
16 contemporaneously. If they do not make it contemporaneously,
17 they have waived it, as far as I am concerned.

18 MR. KETTERER: Okay.

19 THE COURT: But then they have to be concerned,
20 obviously, in making an objection that I am going to say, "Oh,
21 that's fair," and losing credibility with the jury. So, there
22 are opportunities and dangers for everyone in that. But if you
23 want to preserve an objection to an opening, you have got to
24 make the objection.

25 MR. KETTERER: That's what I wanted to clarify, your

1 Honor, is because you don't want the objections made in front
2 of the jury, and, of course, we are not going to announce what
3 they are. But, obviously, I held back at the state court trial
4 in making objections. I kind of regret doing that at the
5 opening statement.

6 THE COURT: Well, there is a different approach. I am
7 not familiar with Judge Kirpalani's approach to this, but I
8 think for Massachusetts lawyers who come here I am sometimes
9 surprised, and they are frequently disappointed, when they tell
10 me at the sidebar after the opening statement, "I have all
11 these objections," and I say, "You just waived them," and they
12 say, "Well, we didn't make them," and I say, "You make my
13 point; you didn't make them." So, that's true in the
14 Massachusetts state courts too. But I just want you to have
15 fair warning of what my approach is on this.

16 MR. KETTERER: I understand that, and I appreciate
17 that, and that's why I wanted to make sure that if there is
18 something we feel objectionable, we make it contemporaneous.

19 THE COURT: I am not saying you cannot make
20 objections. You should make objections if something happens.
21 I would like to avoid objections if my ruling ahead of time can
22 avoid objections and saying we will get to it at a certain
23 point and you do not need it in your opening statement, that
24 sort of thing. And I want to avoid taking the jury's time
25 looking at the back of my robes over here at the sidebar, and I

1 will become increasingly inhospitable when someone says, "May I
2 approach the sidebar?", because we should have worked this out
3 ahead of time, or at least worked out how we are going to work
4 it out and when we are going to work it out ahead of time that
5 does not involve sidebars.

6 So, with respect to this question of GranuFlo, I think
7 I have given the broadest possible information to the parties
8 with respect to this motion to indicate that there is a great
9 deal of ambiguity in it. I am going to say it is allowed in
10 part and denied in part in accordance with the instructions
11 that I have just given here, and then we will deal with
12 specifics on it.

13 Now, the question of the adverse event reporting,
14 which is Motion No. 94, I guess I really do not understand from
15 the defendants how we avoid, at least in the particulars of
16 this case, asking questions about, "Did you make a report of
17 this?", let's say to Dr. Buchanan, just using him as the kind
18 of anthropomorphized defendant in this case.

19 MR. BENNETT: I believe that asking Dr. Buchanan, "Did
20 you make a report of this?", is fair game if it is actually
21 some foundation for the idea that there are some possibility
22 that there should have been a report, and I understand that's
23 the plaintiff's theory that they presented.

24 THE COURT: But isn't there that, even if it is not --
25 if I do not have to dust up on my FDA law, isn't there part of

1 this that ongoing a corporation would have a responsibility,
2 whether or not it is a public safety responsibly, but
3 responsibility or at least would have a practice of keeping
4 people posted on the experiences with their product or
5 associated with their product or contemporaneous with their
6 product, however we want to talk about it?

7 MR. BENNETT: Certainly there is, and we have what's
8 called a "Medical Device Reporting Policy" that is triggered at
9 certain levels if someone has reason to think that a product
10 contributed to a death. Our view of why that isn't relevant in
11 this case, especially as to a long discussion about policies,
12 other instances and other things like that is that, in a case
13 where the patient was on NaturaLyte, where the patient arrested
14 at 9:17 after leaving at 10:44 that day, and where he left
15 dialysis with regular rate and rhythm and a normal pulse and
16 with no complaints, that it would not be supported to go into
17 what we would view in this case as a diversion of all of the
18 details of FDA reporting requirements, how we handle it in
19 other cases.

20 THE COURT: Let's use this one as an example, this
21 event. Again, using Dr. Buchanan as the talking head for these
22 kinds of things, the plaintiff asks him in cross, or however he
23 is put on, that they ask him, "Did you report it?" And he
24 says, "No," and then they ask him is he aware of the policy,
25 company policy, and he either says, "No," or, "Yes," but he

1 probably would say, "Yes, I am, but this did not fall within
2 it, at least as I understand what I am reading of this
3 material." Now, it seems to me that the policy gets in to some
4 degree so that you understand what he is saying no to, that he
5 did not think it was applicable here. It seems to me relevant
6 to ask that. It seems to me that, again, not knowing exactly
7 what the thrust and parry is going to consist of, that he can
8 be rehabilitated on redirect or friendly cross by saying, "Why
9 didn't you?", and then he says something -- maybe you will even
10 write it for him -- like what you just said here, which seems
11 to be the way these witnesses are prepared. Have we crossed
12 the line there yet?

13 MR. BENNETT: No.

14 THE COURT: So, this is more an issue about, "And did
15 you do it in other cases? Is it done by the company in other
16 cases? Is it done by the company in response to FDA
17 responsibilities?", that sort of thing.

18 MR. BENNETT: That sort of thing, and then an FDA
19 expert is talking about it, what's the company's procedure, if
20 a complaint had been made, how should it have been handled and
21 have a whole case about or a whole lot of witnesses about other
22 instances unrelated to Mr. Dial.

23 THE COURT: All right. So, let's start with the basic
24 foundation there, which is, yes, you get to ask him did he
25 report it, and you get to bring out company policy with respect

1 to that. What else do you want?

2 MR. BROWNE: Your Honor, Justin Browne on behalf of
3 the plaintiff. Your Honor, we're talking about specifically
4 Dr. Buchanan and the idea that perhaps we can only limit it to
5 his role in reporting and ignore the corporate responsibilities
6 pursuant to industry standards.

7 THE COURT: Yes, I understand that. That is why I am
8 asking you. So, what else do you want? What are you going to
9 do, put on a corporate representative to say, "This is our
10 reporting protocol, we did not have it until late, we did not
11 use it that much, sometimes people did not do it," all of that
12 stuff? Is that what you are thinking about?

13 MR. BROWNE: Your Honor, what we would show through
14 the testimony is that for many, many years, before Mr. Dial's
15 death, the company was investigating adverse events that are
16 substantially similar to his event, and, therefore, they had
17 notice of the issues directly being litigated in this court.

18 THE COURT: What does that mean? First, who is the
19 witness who is going to testify, witness or witnesses, and,
20 second, how are they going to be -- I realize you spoke in
21 shorthand, but what are they going to say? They are going to
22 say, "We were investigating deaths involving someone who had
23 many years of dialysis without a problem whose death occurred
24 10 hours after the administration?" Is it going to be that
25 they were investigating things that are essentially the same

1 factual underpinnings as this one?

2 MR. BROWNE: Yes, your Honor. There's two parts to
3 that. We're talking about the medical aspect of it, the
4 temporality, for example.

5 THE COURT: No, no. I asked about the witnesses who
6 are going to testify and what they are going to say.

7 MR. BROWNE: Okay. The witnesses, they have been
8 referred to broadly in this court as the "regulatory experts."
9 That is one group of experts that would testify about this.
10 And what they would say, your Honor, is that the company had
11 safety signals, they had notice of ongoing problems with the
12 product. What are those problems? That the information that
13 was disseminated that they are going to say was sufficient to
14 discharge their duty to warn, we are going to be able to show
15 they had notice that, no, in fact, it wasn't, they weren't
16 communicating the right information, they were not
17 communicating the information effectively, and they were not
18 making sure, they were not validating that that information was
19 actually being followed, and, as a result he was injured.

20 THE COURT: How do I access precisely what your FDA
21 experts are going to say? Because, as I understand it, what
22 you are saying is, "We want to deal with the corporate policy
23 more broadly through the lens of these FDA experts." Are there
24 reports that I should be looking at or should have looked at
25 before I came down here, that kind of thing? What is it that

1 is going to show me what the universe is of what you want to
2 offer?

3 MR. BROWNE: There are emails wherein there are
4 nurses, and I'm sure you're familiar with them, Ms. Baker and
5 Ms. McIntyre, who were investigating incidents of
6 cardiopulmonary arrest with high bicarbonate --

7 THE COURT: Here is the problem with them as witnesses
8 or the documents that they generated speaking for themselves,
9 is, you are getting into a question of other bad acts maybe,
10 and I am not -- I do not want to get into the specifics of
11 *Federal Rules of Evidence* dealing with other bad acts -- but
12 the idea that I am going to try other incidents, which I am
13 not. But I want to understand how this testimony is going to
14 be elicited, from whom, and it is probably not going to be
15 through the individual, unless you can tie it to something that
16 is very close to this event, it is not going to be from those
17 nurses as to, "I wrote before. I wrote an email when somebody
18 died, and they died and we learned about it," that kind of
19 thing. That is not likely to be something that I am going to
20 permit, because it simply is too wide-ranging and not
21 sufficiently cabined.

22 So, is there another form that this testimony or this
23 initiative, evidentiary initiative, is taking? You said "FDA
24 experts." What are they going to say, that they reviewed all
25 of this stuff?

1 MR. BROWNE: Yes, your Honor.

2 THE COURT: So, that brings me back to this question
3 of where do I access what they would say and what it is that I
4 would be looking at?

5 MR. BROWNE: Well, their reports cover this, your
6 Honor. They go into great detail about this.

7 THE COURT: So, I should look at the reports with a
8 view toward deciding these larger issues that come up at least
9 under the heading "FDA Motions" in the agenda that was proposed
10 here?

11 MR. BROWNE: So, your Honor, part of our case is
12 Fresenius should have warned, they should have disseminated
13 information, they should have changed the label, the labeling,
14 and they should have changed the manner in which they did that,
15 not just change the label but how they communicated the
16 information to the doctors so that they would have changed
17 their prescribing practices.

18 THE COURT: I understand that theory. I am just
19 trying to understand how the testimony, how the evidence is
20 going to be adduced in support of that theory.

21 MR. BROWNE: So, for example, you are familiar with
22 the PSO, the Patient Safety Organization. Shortly before this
23 man's death there was a presentation of adverse events that are
24 similar to the one at issue in this case where they identified
25 all those years of prior memos and all the other efforts to

1 warn did not work, they were inaccurate.

2 THE COURT: You say that they are just like this. I
3 looked at that, not as carefully as I should, but I will, but I
4 could not say that they were just like this. I could not say
5 that there was a similarity sufficient here, and that is what I
6 am trying to figure out, where I find something that I can say
7 that there was sufficient notice of the likelihood that such an
8 adverse event would take place with respect to someone who was
9 in the position of Mr. Dial, and it's not just a generalized,
10 "There are problems out there somewhere."

11 MR. BROWNE: Yes, your Honor. The central issue
12 relevant here in this case is high bicarbonate. Those prior
13 events involved --

14 THE COURT: Well, there is high bicarbonate, and there
15 is high bicarbonate. I think that I will be hospitable only if
16 there is more rigor to the concept of high bicarbonate so that
17 I can understand fully how this is getting in. Because this is
18 not an FDA case, and, while frequently standards that are
19 applied by regulatory agencies are part of a plaintiff's case
20 is generally, in my experience, when we have got something that
21 is sufficiently clear that there is not really a dispute about
22 what the regulatory standard is. Here there is some dispute.

23 MR. BROWNE: Yes, your Honor. The adverse events, for
24 example, in the document that I have referred to involve cases
25 where the total buffer, the total amount of bicarbonate

1 delivered to the individual, was above 40. That's exactly this
2 case. That's precisely this case. Additionally --

3 THE COURT: But that is the dimension of generality
4 that you would rely on, total buffer over 40 -- what is the
5 metric again?

6 MR. BENNETT: Milliequivalents per litre.

7 THE COURT: Milliequivalents, yes.

8 MR. TARRICONE: Your Honor, let me just address one
9 point, and then Mr. Browne will continue.

10 THE COURT: Sure.

11 MR. TARRICONE: So, Baker and McIntyre are
12 investigating adverse events, hundreds of them, over a period
13 of several years, and then in 2010 -- and they have been
14 communicating their concerns with appropriate people. In 2010,
15 in preparation for a presentation to the PSO they identify
16 seven cases, and they put them in a PowerPoint for the
17 presentation, and these seven cases -- and the focus is what is
18 the association of high bicarbonate in cardiopulmonary arrest?
19 Are there modifiable risk factors associated with the
20 administration of dialysis that implicate the high bicarbonate,
21 and is there some modification that can be made to reduce this
22 risk? And they focus specifically on high bicarbonate as being
23 a modifiable risk factor.

24 THE COURT: And is high bicarbonate defined as over
25 40?

1 MR. TARRICONE: High bicarbonate is --

2 THE COURT: No, in this presentation.

3 MR. TARRICONE: Yes, it is. So, the seven cases have
4 total available bicarbonate, that is, the prescription of the
5 bicarb either plus 4 or plus 8, depending on whether it's
6 NaturaLyte or GranuFlo, and the total range of these seven
7 cases is 42 to 48. Mr. Dial had 44. He got the highest amount
8 that could be set into the machine, 40 plus 4, 44. So, he's
9 right in the middle of this grouping. So, they took that to
10 Mr. --

11 THE COURT: He is in the second quartile, I think.

12 MR. TARRICONE: Yes. Yes, your Honor.

13 THE COURT: Not to get too specific.

14 MR. TARRICONE: So, they take this data to Mr. Lacson,
15 who is the company's epidemiologist, Chief Epidemiologist, and
16 he does a study of the first quarter patient data for
17 Fresenius, for a large segment of the Fresenius clinics, and he
18 arrives at some conclusions that, again, the association of
19 high bicarbonate with cardiopulmonary arrest. He, then, to
20 test that -- and there's further reporting to the PSO. To test
21 that, he then waits for the entire year to be finished, then he
22 tests the entire 2010 to see if the data in the study shows the
23 same as the first quarter, and he does that in March of 2010.
24 He finishes, in March of 2011 he finishes that, and he puts
25 that information together in various graphs, and he finds a

1 very significant increased risk of cardiopulmonary arrest for a
2 certain segment of the patient population. That segment is
3 patients whose bicarbonate are above 26 -- 26 and above is
4 statistically significant -- as well as down in the low range,
5 below I think 18, statistically significant increased risk of
6 cardiopulmonary arrest, and that patients whose bicarb is 28 or
7 higher have a vastly increased relative risk, increased
8 relative risk of cardiopulmonary arrest.

9 And then he does one thing further. He looks at,
10 okay, we have high bicarbonate. What about low potassium? Low
11 potassium is what causes the arrhythmic event, the cardiac
12 arrhythmia. It's not the bicarbonate, it's the potassium. The
13 bicarb affects the potassium. The higher the bicarb, the more
14 it can drive the potassium down. The potassium is the
15 electrolyte that affects the functioning of the heart, which is
16 an electrically operated pump, if you will.

17 So, he then looks at, okay, well, what about
18 patients -- he determines from the data, now the entire 2010,
19 that patients with bicarb of 28, and we are talking about
20 predialysis serum bicarb, the monthly labs that are done, with
21 28 or above and potassium below 4 are at vastly significant
22 increased risk, and this is where -- and there are charts that
23 he prepares that show this.

24 Mr. Dial, bringing it back to this case, his
25 predialysis serum bicarb taken 10 days before he died was 28,

1 and his predialysis potassium was 3.7. He was in the highest
2 risk category, 28 bicarb and 3.7 potassium. And then we can
3 look forward from there what happened. But going back, the
4 work that Ms. Baker and McIntyre were doing was focusing
5 specifically on the modifiable risk. What's the modifiable
6 risk? It's potassium and bicarbonate and how we get the right
7 balance to minimize the risk to a certain segment of the
8 patient population.

9 THE COURT: Let me turn this back a bit having to do
10 with order of proof. I assume that these studies are not
11 studies that I would consider to be adequate science. They are
12 speculative. I do not mean it in a diminishing way or a
13 derogating way, but speculative, provocative, with a view
14 toward identifying what problems could be out there, but, as
15 with the Hakim memorandum and its conclusions, not something I
16 am likely to let come in as such.

17 So, then the question becomes what kind of notice and
18 why should that notice come in? Not the document itself, not
19 whatever associations, whether fully validated or not by
20 science exists, but whether these concerns should be brought to
21 the attention of the jury. How do they get to the attention of
22 the jury? Well, first, that there is a showing sufficient for
23 a finder of fact to find that these associations exist. You
24 think you can do that with your general causation experts and
25 your specific causation experts. Okay, so they come in.

1 Second, this notice issue it seems to me is dependent
2 on my understanding more fully what legs those experts, the
3 real science experts, have.

4 Third, I am not sure that there is a need for the
5 particular kinds of memos that go back and forth, because they
6 would be confusing, confusing in the same way as the Hakim
7 memo, that it takes on the mantle of science when it does not
8 really have it, but it is provided, it has got underlying bases
9 that can properly be brought to the attention of the jury.
10 Now, what does that mean as I think this through? That you get
11 the foundation, as I think you will, for your theory of it.
12 Whether the jury believes it or not is another matter, but you
13 get that in. And then you introduce evidence of some form that
14 says the company was aware of this before Mr. Dial died, aware
15 of the potential that their product was doing this because of
16 these pieces of data they had that were brought to the
17 attention of persons with some responsibility. I will, of
18 course, hear from the defendant on this, but I am not
19 uncomfortable with that, as I now understand it.

20 Then there is this question of the FDA stuff. I think
21 that is potentially going down the rabbit hole, to get into
22 that, and I am not sure that I fully understand where the
23 parties are in their back and forth on FDA stuff, having read
24 the motions *in limine* and associated papers for that.

25 But what more than what I have just outlined, putting

1 to one side FDA, do you think you are entitled to? That you
2 can say the Chief Medical Officer, whatever Mr. Lacson's name
3 is, said this? That, it seems to me, is saying he is an
4 expert, so you should rely on him, and I do not think he is.

5 MR. TARRICONE: No, your Honor. Let me see if I can
6 answer your question.

7 THE COURT: Sure.

8 MR. TARRICONE: First of all, Dr. Lacson, who is the
9 Chief Epidemiologist at the company, the reason they collect
10 the data is so they can look for trends. Why do they do that?
11 Because that's what is part of the industry standard for a
12 company that is selling a drug or product like this. They look
13 to see what effect it's having.

14 THE COURT: Just so you know what you are dealing with
15 or what I am thinking about at this time, let's assume that
16 they collect data -- this is a hypothetical, but it will
17 illustrate my concern -- he collects data, he is focused on
18 this, he is thinking epidemiologically, and he says the
19 association between a full moon and the death of the defendant
20 or death of people who take dialysis at that time is sufficient
21 for us to be concerned. Now, we come to trial, and that
22 association is not something I anticipate would be successful,
23 and so the underlying theory is thrown out. Now we have one in
24 which the jury is going to hear, I think, about the association
25 that they were concerned with. But I am not going to permit

1 the jury to be distracted by the idea that they were looking
2 into it to draw the conclusion that the association was valid.
3 It is only for purposes of notice, that they were concerned
4 about this --

5 MR. TARRICONE: Well, exactly, your Honor, and that's
6 what -- Mr. Browne is going to address what the industry
7 standard is on that, and that's what I was getting to. First
8 of all, though, this study was done by biostatisticians.
9 Dr. Lacson testified that it was done in a scientifically valid
10 manner. But, anyhow, the history that I gave you, Baker and
11 McIntyre beginning in 2007, '08, '09, '10, did some 750
12 investigations. Those two. There were other people in the
13 same position, based on those notebooks that we have been
14 talking about recently, which had some 1,000 to 1,200
15 incidents. They conducted 750 investigations focusing on CPA,
16 cardiopulmonary arrest, high bicarbonate, that, and then what
17 was going on when they went to the PSO. Let me just finish
18 this one thing, because I want to make sure I make this point.

19 THE COURT: All right.

20 MR. TARRICONE: The question, and we have one of our
21 expert witnesses who will be addressing this, is during that
22 process what is the obligation of a company to report? And we
23 are not just talking about FDA reporting. What are they
24 expected to do? And Mr. Browne is going to explain what the
25 industry standard is.

1 THE COURT: Report to whom?

2 MR. TARRICONE: Well, for starters, the clinical side
3 reporting to the product side of the company, because here we
4 have this company that is wearing two hats, if you will.

5 But I am going to ask Mr. Browne to address what that
6 industry standard is, because it's quite rigorous, and that's
7 what our expert is going to address, that these events --

8 THE COURT: Well, but, see -- I understand I will hear
9 from Mr. Brown. We will probably take a break too so you can
10 all eat. But here is I think where I am going on this, which
11 is, I am open to the idea, obviously open to the idea of
12 notice. I am not open to the idea that the notice provides a
13 backdoor for documentation that has not been vetted for
14 expertise purposes. So, drawing a line for that is going to be
15 fairly important to me.

16 Second, that there was an industry standard or
17 regulatory requirement is derivative of whether or not there
18 was notice given to the relevant people at the defendant. And
19 this goes to a larger question of causation. That they did not
20 tell the FDA is not, under anybody's theory here, the cause of
21 death to Mr. Dial. It is, in the worst-case analysis,
22 regulatory misfeasance -- or compliance misfeasance on the part
23 of the company.

24 And so I want to kind of parse through the relevant
25 uses of it. First, no backdoor of not fully vetted science;

1 number two, no ancillary trial over compliance; but, three,
2 permitting a fair opportunity to talk about notice that they
3 had, for giving you a fair opportunity to speak to notice that
4 they had. That is what I am focused on.

5 I will leave it at that, but the defendants are going
6 to have to respond to that too, which is, however rigorous or
7 not rigorous the various studies that were done, somebody was
8 culling information. The information can be narrowed,
9 Mr. Tarricone says it has been narrowed to things that are
10 parallel to the Dial circumstances, and to the degree that they
11 can, I am likely to let it in for notice purposes. You knew
12 that this was something to be looked at. Of course, there has
13 to be the foundation that the something to be looked at could
14 have caused the death, but I am assuming, as I do, that they
15 are going to be able to get that in. That is where I am going
16 on this thing but with constraints over it.

17 Now, I am sure you want to respond immediately, but I
18 am not going to let you, because it is 1:00, so we will come
19 back at 1:45 to continue this.

20 THE CLERK: All rise.

21 (The Honorable Court exited the courtroom at 1:00 p.m.)

22 (Lunch recess taken)

23 THE CLERK: All rise.

24 (The Honorable Court entered the courtroom at 1:47 p.m.)

25 THE CLERK: Court is back in session. You may be

1 seated.

2 THE COURT: So, maybe, Mr. Bennett, you want to --

3 MR. BENNETT: Yes. Thank you, your Honor. In
4 listening to the evidence that plaintiff was discussing, and in
5 listening to the Court's views, as I understand the order of
6 proof that you have just been discussing in the context of this
7 motion, I think we basically agree with it, which is, general
8 causation talks about whether high serum bicarbonate can result
9 in a high pH, which can result in alkalosis, which can result
10 in an arrhythmia-type event. Then they can attempt to try to
11 prove notice, and I think that's where we're getting into our
12 area of disagreement, and the plaintiffs have advanced three
13 specific pieces of evidence in this regard. The first is this
14 data that they say arose out of it. Make no mistake about it,
15 that data and those conclusions are the Hakim memo data and
16 conclusions. That's exactly what's in that memo.

17 THE COURT: Well, but I have said "data sí, memo no,"
18 I guess is what I have said.

19 MR. BENNETT: Right. And I don't think they have an
20 expert that took the underlying raw data, ran the data, put it
21 through a rigorous process, published something or did anything
22 with it, so I don't think they are going to try to use the
23 data. I think what they are trying to say is say, "I want to
24 take these graphs out of the Hakim memo," which I think would
25 be forbidden.

1 THE COURT: Well, let me put it a different way. They
2 put on a witness, maybe one of your people or something, and
3 they say, "Did you do anything? Did you get any notice, hear
4 anything about this, hear any of that stuff?" The witness
5 probably says, "Yes." "Did you do anything?" "No." Well,
6 whatever the witness is going to say.

7 MR. BENNETT: Right.

8 THE COURT: But then the notice fat is in the fire.

9 MR. BENNETT: Yeah, and I think the question --

10 THE COURT: Whether that means that there is going to
11 be some running of the data or that sort of thing, that's a
12 different issue.

13 MR. BENNETT: Or for us to go to the second piece of
14 evidence, whether it means that there is going to be a trial on
15 all these other incidents. They talked about seven incidents
16 that the Clinical Quality Managers had looked at. Those are
17 totally different circumstances. One of them is a 28-year-old.
18 Four of the incidents are the same patient who had three
19 successive heart attacks. They have unbelievably different
20 circumstances.

21 We have the actual case studies here, but when you
22 look at them you have nobody with a 28, which is what
23 Mr. Dial had. All of their serum bicarbonates were above 28.
24 One of them has diabetes, congestive heart failure, seizure
25 disorder.

1 THE COURT: But what does that mean? I am just trying
2 to understand how people will try their case, and in some ways
3 my understanding will presumably shape the way they do it. So
4 they put the person on and he says, "Yes, we had notice of
5 various events like that, but they were distinguishable
6 events," I guess. Is that a way that this putative person is
7 going to respond?

8 MR. BENNETT: I think that if they were allowed to get
9 into the details of the specifics, the person who looked at
10 those would say these are very distinguishable events. I think
11 that if the question is are we going to say that at the time
12 and before Mr. Dial died that we were aware that a patient with
13 high serum bicarbonate could have alkalosis, and that's a
14 marker for it, that if you have alkalosis, that can and is a
15 recognized risk factor for arrhythmia, and that patients on
16 dialysis with arrhythmias can, because of acid-base balance, go
17 into arrhythmia and have a cardiopulmonary arrest, I think we
18 are going to say that, not only did we know about that, we were
19 focused on it, we worked on it, and we did have notice of that.
20 If then it's going to go to, well, now let's talk about 300
21 specific cases where they think that that happened, that's
22 where I think we would have our objection.

23 THE COURT: Well, but let's stop at the general, what
24 I will call a concession, that you had notice of the potential
25 for this kind of problem at a high degree of generality. Then

1 the next question is, "What did you do about it?"

2 MR. BENNETT: Right.

3 THE COURT: And so, what are you going to say then?

4 MR. BENNETT: Our witnesses will come in and say that
5 starting in 2000 -- well, for purposes of this issue and this
6 doctor, we would say starting in 2000, 2002, 2005, 2008, 2009,
7 2010, 2011 we talked to all of our doctors. Dr. Buchanan is
8 going to get on the stand and say, "I received all these memos
9 and information that said that the general issue that I've said
10 we're on notice of is something that he knew about, and he was
11 informed about it from Fresenius, and he knew about it by
12 virtue of being a physician with tremendous experience." Our
13 people will say, knowing that you want to avoid alkalosis, and
14 knowing that you want to avoid a risk factor for arrhythmia, we
15 did communicate it out to the field.

16 THE COURT: All right. I think I understand your
17 position with respect to what I will call the two pieces of
18 information, that is, the idea that there was notice of some
19 sort at a high degree of generality, and then the question of
20 do you get into specific cases and try the specific other cases
21 that are purportedly suggestive. You said there were three
22 things.

23 MR. BENNETT: Yes, that's what they mentioned.

24 Mr. Tarricone talked about -- this specific PowerPoint is the
25 one he's talking about. I don't know if it would help you to

1 see it.

2 THE COURT: I will take a look at it.

3 MR. BENNETT: Thank you. I have a copy for you guys,
4 too.

5 (Document provided to the Court)

6 MR. BENNETT: I have tendered to the Court a
7 PowerPoint labeled "Acid/Base Concerns," which is the document
8 that Mr. Tarricone was describing in his presentation, and he
9 said that there were seven cases. If you turn to case one --

10 THE COURT: There are several adverse events, which
11 can be one poor devil having three events himself.

12 MR. BENNETT: Exactly. The first one actually had
13 four, but you're correct. The Case One is the first one. On
14 the bottom right corner you'll see a .0003 as the Bates label
15 for that.

16 THE COURT: Yes.

17 MR. BENNETT: So, you can see the differences between
18 Mr. Dial and these cases, the first one being in every single
19 one of these adverse events that happened on dialysis where the
20 electrolyte shifts are all happening not 10 and 11 hours
21 afterwards, but this is a patient who was 45, a different age,
22 different gender, multiple different comorbidities, including
23 congestive --

24 THE COURT: I do not mean to -- well, I guess I do
25 mean to foreshorten the discussion.

1 MR. BENNETT: Sure.

2 THE COURT: Just so I understand that they are
3 different from your perspective.

4 MR. BENNETT: Exactly.

5 THE COURT: Now, the third issue, though?

6 MR. BENNETT: The third issue is this FDA expert
7 issue, and I think we just totally agree with your observation
8 that, if we were being tried by the FDA for noncompliance,
9 maybe that would have some probative value, but in a situation
10 where our policies are coming in, which the Court has stated
11 the view that our policies come in, and our policies basically
12 say that what the FDA policy is, that there's no reason to get
13 into that whole sideshow of having people get up here and say,
14 "Here's what the law is on FDA, here's what they should have
15 done," and all of that we think is inadmissible. We do have a
16 motion *in limine* for Tuesday on that, but I think we were
17 viewing it the same way you were describing it, which is that
18 that's not necessary and tied to his death.

19 THE COURT: Well, I was anticipating these as being
20 today, but, in any event.

21 MR. BENNETT: We're ready to do them.

22 THE COURT: The motions were Fresenius's motion to
23 exclude testimony regarding FDA documents and communications
24 after the Hakim memo. I will have my understanding refined by
25 that.

1 So, Mr. Tarricone, or, Mr. Browne, back to this. They
2 say, "We got notice of problems." Why do we have to get more
3 deeply into it than that?

4 MR. BROWNE: Your Honor, the experts will explain per
5 industry standards and practices what a medical device company
6 is supposed to do when you have notice.

7 THE COURT: So what? They get notice and they say
8 they did not do anything. I really do not understand what this
9 is, unless someone says to me they got the kind of notice that
10 would have required them to do something differently in this
11 that would have benefited Mr. Dial.

12 MR. BROWNE: That's precisely it, your Honor. Defense
13 counsel just stood up and said they are going to proffer to the
14 jury that they sent out these memos. The import of this
15 evidence is that did not work. They should have and could have
16 done it differently.

17 THE COURT: So, now we are back to order of proof.
18 You put on your case however you get it in. You are going to
19 get it in that you got notice. You are over the bar in your
20 case in chief now. Then they come back and they have got some
21 sort of affirmative evidence, whatever it is, that is supposed
22 to mitigate that, they did all that one could reasonably think
23 is necessary, and at that point I can look at this more
24 carefully to understand what it is that I am going to let you
25 get into.

1 They may think differently about how they are going to
2 deal with this issue, but unless you have got something that
3 says they had notice and that notice would have generated this
4 action with respect to this product that would benefited have
5 Mr. Dial, I do not see it coming in in the case in chief.

6 MR. BROWNE: And that evidence, your Honor, is that
7 the memos you sent did not communicate the information that was
8 necessary for this doctor to --

9 THE COURT: But, see, you have not gotten these memos
10 that they sent in yet. Your case in chief has got them saying,
11 "We got notice." Maybe you are going to introduce these memos,
12 or think you are. I do not think you are, not in your case in
13 chief, because I want to see this come in in an orderly fashion
14 that I can understand and shape for purposes of not distracting
15 the jury from other matters. So, the way I see it, as I said,
16 is you have got your case in chief. It looks to me like you
17 will be over the bar on general causation, over the bar on
18 specific causation, over the bar that they had notice of events
19 that could have given rise to the duty to do something else.
20 They will come back with some evidence of their own in their
21 case in chief, and then I will let you, to the degree that it
22 is relevant, get into it in your redirect case more deeply.
23 And that is probably how I am thinking about these FDA matters
24 as well. I just do not see how it is necessary for your case
25 in chief.

1 MR. BROWNE: For our case in chief it is a failure to
2 warn and inadequate warnings. We will show that they had
3 notice, as we have established, and that they didn't
4 communicate the information that was necessary for this doctor
5 to change his prescribing practices that were necessary to keep
6 Mr. Dial alive. Let me do it the other way. Had they done the
7 proper --

8 THE COURT: Let me ask you this. I am interrupting,
9 but it is my way of trying to keep track of at least the line
10 of inquiry that I am making. Are you going to put Dr. Buchanan
11 on yourself?

12 MR. TARRICONE: Which doctor?

13 THE COURT: Buchanan.

14 MR. TARRICONE: Buchanan? Yes, we are putting
15 Dr. Buchanan on.

16 THE COURT: So, that puts me in a somewhat different
17 setting. I will hear what he has to say.

18 MR. BENNETT: There is just an interesting procedural
19 issue, which is, he's only available on the date that I
20 mentioned. So, if the Court would permit -- I agree that we
21 would not object and would agree that they could rest their
22 case subject to him testifying, and they would put him on
23 first, but it would be on the 26th, if that's okay.

24 THE COURT: In any event, I think in your case
25 Buchanan is a necessity for this kind of issue, for

1 case-in-chief kind of thing, if you want to put him on. What I
2 do not want to do is have an extensive excursion into other
3 matters, and understanding what is justifiably extensive and
4 what is not is a matter that is going to take some time for me
5 to understand in the context of the evidence that is actually
6 submitted here.

7 MR. BROWNE: I understand that, your Honor, and it's
8 not going to be negligence in the air, and it's not going to be
9 a discussion, an elaborate discussion about technicalities that
10 have no connection to the case. That is not going to happen.
11 Instead, the expert is going to stand up and say, "What do
12 medical device companies do when they have this type of notice
13 information?" There are practices they're supposed to follow.
14 "Did you find evidence of Fresenius following those practices?"
15 "No, I did not."

16 THE COURT: And that comes, as far as I am concerned,
17 comes in after Buchanan.

18 MR. TARRICONE: Well, your Honor, we have a problem
19 now, because we have asked for Buchanan, and Mr. Bennett told
20 us we can't have him until their case.

21 THE COURT: Let me step back. First, I understand
22 that Dr. Buchanan is very concerned about his schedule. I am
23 concerned about mine, and so Dr. Buchanan may find that he has
24 got to appear. That is one way of dealing with it. Another
25 way of dealing with it is to say I will tell the jury we will

1 put on bits and pieces of the case in a way that causes the
2 minimum disruption to the parties. On that one, this is sauce
3 for the gander. You may have somebody out there who wants a
4 concession too in terms of timing and when they appear, and my
5 experience is when concessions are made everybody works
6 together. When they are not made, then we have a different
7 kind of tenor to the trial, and, if push comes to shove,
8 somebody who is within the scope of this Court's power, both
9 *de facto* and *de jure*, had better show up when people want them
10 to show up. Maybe we have jumped ahead to the testimony of
11 Dr. Buchanan and Mr. Powell, which is on the list here.

12 But to go back to this earlier point in my colloquy
13 with Mr. Browne, I will understand more fully and be able to
14 give you direction with respect to that evidence of other
15 people saying, "Here is the industry standard," and maybe the
16 FDA aspect of it too, only after I hear what it is that
17 Buchanan will say he did or did not do or received or did not
18 receive. Because if what happens is he received everything
19 that one could reasonably say the industry standard called for
20 or one could reasonably say FDA compliance would have expected,
21 then I do not see having testimony about industry standard or
22 FDA compliance. That is kind of the way I am looking at it

23 Go ahead.

24 MR. BROWNE: Yes, your Honor, and that is the dispute.
25 It's twofold. One is, they failed to communicate information

1 to him at all, and information that was communicated to him was
2 not communicated effectively, adequately. It was not given the
3 right way.

4 THE COURT: And that depends on this: First, Buchanan
5 saying. "Who knew? Never heard." That is one aspect of it.
6 But that is Buchanan. And the second part of it is some
7 approach to the idea of effectiveness. That is to say, I have
8 to hear from Buchanan about why it was not effective to deliver
9 this. Did they have to tie Buchanan down to a table and
10 whisper in his ear? All the things that would deal with
11 effectiveness are things that depend on him first, I think.

12 MR. TARRICONE: Well, the reporting requirement is not
13 just related to Dr. Buchanan. A prudent manufacturer has other
14 obligations to report, or clinical, the clinical side has an
15 obligation to report.

16 THE COURT: All that may be true, but it has to be
17 tied to the death of Dial. That is the point.

18 MR. TARRICONE: Well, it is.

19 THE COURT: Explain to me how it is tied to the death
20 of Dial.

21 MR. TARRICONE: Because it has to do with the dosing
22 of bicarbonate and patients getting too much bicarbonate.

23 THE COURT: What were they supposed to do? They were
24 supposed to tell the physician who was prescribing what the
25 tolerances were?

1 MR. TARRICONE: The risk of high bicarbonate in
2 certain patients, certain population -- certain patients among
3 the patient population -- and give adequate information so that
4 the dosages were appropriate for patients, which is part of the
5 instructions for use, which is industry standard. When we talk
6 about labeling, it's not just the label on the product. It's
7 instructions for use and so forth.

8 THE COURT: How am I going to know the deficiencies in
9 this case? Because it does turn on Buchanan on this, I think,
10 because he is the prescribing physician, he is the audience
11 that this kind of notice is supposed to be provided to. How am
12 I going to know what the deficiency was, or purported
13 deficiency was, until I hear what Buchanan says?

14 MR. TARRICONE: Well, that's part of the problem with
15 the order of proof, which we would like to have him in our case
16 near the beginning of the case. We will probably finish our
17 case on Wednesday or Thursday, and we can't have him until
18 Friday. Setting that aside -- let me give you a specific
19 example.

20 THE COURT: Well, no, let's not set it aside, because
21 we will get to this. So, things happen. Dr. Buchanan has to
22 be here on a different schedule.

23 MR. BENNETT: The way that this came about is I made a
24 schedule for him to come in our case. I hadn't been asked to
25 bring him for their case, and he set his practice schedule. I

1 will call him immediately and give the instruction of the
2 Court.

3 THE COURT: So, when do you want him, what day?
4 Because he may interrupt. I am not going to take him for --

5 MR. TARRICONE: The second day of trial, your Honor,
6 would be ideal.

7 THE COURT: That would be --

8 MR. TARRICONE: First week.

9 THE COURT: -- probably Friday, I would think, and he
10 was able to do Friday, the 26th, so now he is able to do
11 Friday, the 19th. I understand doctors are very busy.

12 MR. BENNETT: Sure. He is not an employee of ours, of
13 course, but I'll give him the instruction, and we will get him
14 here per your instruction, or I will be up here begging for
15 something reasonable that accomplishes the same goal.

16 THE COURT: Right. I do not think you want that. I
17 think you will find a way to make his heart and mind follow.

18 MR. BENNETT: Thank you.

19 THE COURT: So, we have got Buchanan coming in in your
20 case in chief, and I will hear what he has to say, but I do not
21 think I can realistically act on the motion *in limine* without
22 that information on it. You are in a position to say, I think,
23 in your opening statement -- I will hear what Mr. Bennett says
24 in response -- but you are in a position to say in your opening
25 statement, from what I know, you have a good-faith basis for

1 saying Buchanan never was adequately notified about what he
2 should do in this connection, and then we will see what that
3 means.

4 MR. TARRICONE: Exactly.

5 THE COURT: But we are not going to be, "And, by the
6 way, I want to introduce you to the Federal Drug Administration
7 and what they do -- "

8 MR. TARRICONE: We are not getting into the FDA.

9 THE COURT: -- or the experts, "You will hear from
10 this expert that," because I am not sure you are going to be
11 hearing from these experts until I know what Buchanan has to
12 say. I am not foreclosing it. I am just saying in opening
13 statement, an opening statement is a general opening statement
14 about, "You will hear that they knew about this and,
15 nevertheless, knew about problems of this sort at this
16 generality, but they nevertheless went forward and they did not
17 give adequate notice to Buchanan, or maybe he did not hear."
18 But, in any event, that is how I think I am going to punt the
19 issue until I have got adequate information to deal with this
20 motion *in limine*.

21 Apart from disappointment, is there a problem with
22 that approach?

23 MR. TARRICONE: I think I understand.

24 THE COURT: But is there something that I have not
25 touched on?

1 MR. TARRICONE: Well, one of our principal experts is,
2 we use the term "regulatory," but it's really not so much
3 regulatory as it is the industry standard on how a prudent
4 manufacturing company operates, and very little of it relates
5 to FDA reporting.

6 THE COURT: It may not, but here is the thing: If the
7 state of the evidence, even after you put him on the stand, is
8 that they gave notice -- I use "notice," I should not --
9 instruction that was consistent with industry standard and was
10 consistent with whatever the regulatory compliance obligations
11 are, then I do not think we have any evidence about industry
12 standard or regulatory compliance. It is there. They say that
13 here is what they suggested to people. Then you are into the
14 efficacy of the instruction that has been received. But I am
15 not sure industry standard tells us very much about efficacy of
16 instruction. It just says do it right.

17 MR. TARRICONE: Well, I'm not sure I agree with that,
18 your Honor. It's not just "do it right." It's also what are
19 the risks, what are the risk factors and --

20 THE COURT: Well, but that will come out in him, I
21 think. It is very risky to give bad prescriptions. This is an
22 invitation, as far as I am concerned, to get into ancillary
23 trials, and I am not doing that -- if I have to do it -- if it
24 has to be done, I will put it in the passive voice, if it has
25 to be done I will do it, or permit it to be done, but I am not

1 running into it right away until I have had this orderly
2 process that gets me there.

3 MR. TARRICONE: Our plan is to have a very tight case.
4 We are not going to have sideshows. That's not our intention.

5 THE COURT: And it is not that I am disregarding your
6 ability and willingness to do that, but I may have an even
7 tighter view of how the evidence comes in, I do, for both
8 sides.

9 MR. BROWNE: Your Honor, may I kind of proffer how I
10 think it would come in?

11 THE COURT: Sure.

12 MR. BROWNE: This is what you keep asking about. We
13 have to establish duty as part of our negligence case. They
14 should have done something. Our case is they should have
15 changed their labeling, and they should have communicated it in
16 a different way, instead of just emailing a memo or putting it
17 on a website.

18 So, the first question is what triggers the duty? Why
19 should they have done that? That's the notice evidence. The
20 notice evidence comes in through scientific experts, as we
21 talked about, general causation expert -- I'm trying to go
22 through the order of proof. Fresenius was aware of the risks,
23 here are the risks, they are meaningful. Then the industry
24 expert comes in and talks about risk management. When a
25 company is aware of risks it's supposed to take corrective and

1 preventive actions, such as changing the label or changing the
2 design, changing the machine interface, for example. And
3 that's what Fresenius should have done. They didn't do it
4 here.

5 I'm getting exactly to where you keep honing in on,
6 which is proximate cause. Then we have to show it would have
7 made a difference in this case. That's proximate causation,
8 failure to warn. That's where Dr. Buchanan comes in. Then he
9 comes in and says, "You know what? None of this matters to
10 me." Maybe the jury then finds we didn't satisfy proximate
11 causation, or he says, "Yes, that's meaningful information. I
12 would have changed my prescription if I would have had that
13 information." The jury then can look at that evidence and say,
14 "Yes, this was a failure to warn. They should have done
15 something different."

16 That would be, I think, one way that it could play
17 out. That would be the order of proof.

18 THE COURT: Sure. And I understand that and in both
19 cases I would not hear from the what I will call your general
20 experts in this area until after I heard from Buchanan,
21 Buchanan either saying, "It would not have made any difference
22 to me," and then you have experts who say, "Well, of course it
23 would. Here is what would have been required," so that I
24 understand what it is that was the failure on the part of the
25 person who was the audience for this notice.

1 It is not a matter of distorting your case. It is to
2 be sure that there is not put before the jury more than is
3 necessary for the jury to hear on this. That is the way I
4 think I want to go. We will, of course, hear by Tuesday that
5 Dr. Buchanan, of course, can be here, and he will, and then you
6 can think about the so-called experts, and I will too, of
7 course, in that context.

8 So, what I think I want to do with respect to Motion
9 No. 94 is simply again say allowed in part, denied in part in
10 accordance with the instructions that I have given, and we will
11 move the ball down the road on that.

12 Now to Hakim. No harm in asking for me to reconsider.
13 Denied. So, what are we going to do with the Hakim stuff? How
14 is it coming in? What are you going to use for what I call
15 "Hakim data"?

16 MR. KETTERER: Your Honor, this has been a subject of
17 debate, and, as I heard it today, I don't know that either
18 parties are clear. I know the defendants have their
19 interpretation, I know we have our interpretation, and, I'll be
20 honest, I'm kind of at a loss. And I do understand the
21 "denied" part, and before I say something dumb, like, moving to
22 reconsider the entire thought process, I mean, part of the
23 discussion we had this morning about Dr. Duffy was based on the
24 logical procession, which is, look, you can't just say, or I
25 said you can't just say you have 30 years of experience and

1 that's the reason why it's whatever, that's the basis of my
2 opinion, and you told me, "Well, that's kind of a question for
3 cross-examination, and I wouldn't rule out an opinion based on
4 that." So, we have had this whole discussion about the Hakim
5 data pretty much on the same basis.

6 THE COURT: Well, the difference is that one is
7 proffered as an expert, and I have been evaluating him as an
8 expert. Hakim is not going to show up here. Neither party has
9 offered him as an expert in this area. I cannot say that this
10 document -- I probably would say it is not -- that this
11 document is genuine expertise. Now, if you are going to say,
12 if part of your argument, I do not mean to trivialize it, but
13 part of your argument is so we will have a battle of 30-year
14 veterans in nephrology, I do not think that is quite right.

15 You will get a shot at Dr. Duffy, but you do not get
16 that shot through an incompletely vetted memorandum of some
17 other veteran in this area.

18 MR. KETTERER: And I guess this is the issue, and I
19 don't know how much, and I don't remember from the first
20 Daubert hearing, your Honor, exactly how the procession of this
21 kind of came in. But I think that that's sort of an unfair way
22 of characterizing the memo, because the essence of the memo
23 is -- well, first of all, Dr. Hakim was deposed for four days.
24 And you're right, he isn't being proffered as an expert. He is
25 being proffered as a fact witness. Nor is the memo being

1 offered as a piece of expert testimony in and of itself, which
2 was part of the basis for how I started, and I probably
3 shouldn't have started this way, but started the argument with
4 you about the fact that how do you make a Daubert motion over
5 this sort of separate piece of evidence when there isn't really
6 an expert testimony? You could challenge the way Dr. Waikar or
7 Dr. Fine or someone who is going to use the information in
8 their opinion on that or their methodology use in their
9 opinion, but excluding the actual Hakim memo on the basis of a
10 Daubert challenge procedurally to me was flawed because of the
11 -- let's put that aside for a second.

12 THE COURT: Let me flip that on the other side, which
13 is to say attempting directly or indirectly to introduce this
14 as expertise is flawed, and so it cannot become a document
15 which has the potential for suggesting to the jury that there
16 is the kind of expertise attached to it that is associated with
17 the Courts making a judgment about the admissibility of other
18 expert testimony.

19 So, to the degree it is useful, it is
20 gathered-together data, and that data can be used by experts
21 who are here to be examined for its supporting quality, but I
22 do not suppose, or maybe I am wrong about this, that your
23 expert is going to say, "We relied on the fact that Dr. Hakim
24 was being paid by the defendant --

25 MR. KETTERER: No.

1 THE COURT: "-- said this, which coincides with what
2 we think."

3 MR. KETTERER: No. But, see, this is the trouble that
4 I have about the -- I don't want to spend too much time
5 wrestling over the Hakim memo per se, although, just from this
6 intellectual standpoint, your Honor: When you think about it,
7 the challenge wasn't to any of those experts and their use of
8 the Hakim memo. I mean, it was sort of indirectly that he
9 can't rely on the Hakim memo because it's bad science, but
10 that's a factual call.

11 THE COURT: Well, it is and it is not. To the degree
12 that we are doing the legislative history of how we got to
13 where we are with Hakim, bear in mind that part of this is my
14 shaping the case --

15 MR. KETTERER: Okay.

16 THE COURT: -- and my concern with respect to making
17 sure that the jury is presented with real science that can be
18 challenged in their presence and not be distracted by the
19 existence of kind of, I will not call it "junk science," but
20 proto-science, and that is what the Hakim memo strikes me as
21 being. At best, interesting speculation about avenues of
22 examination on the basis of principles not fully tested.

23 MR. KETTERER: Okay. And I guess my point to your
24 Honor would be on that, that the idea of the conclusions, and
25 this informs the rest of our discussion about what we are

1 talking about with what is the underlying data, because the
2 defendant's claim is, well, wait a minute, all these graphs,
3 everything that appeared in the Hakim memo is also bad science
4 and, so, therefore, any other presentation which historically
5 ever touched upon the same data which appeared in the Hakim
6 memo is, therefore, problematic and should never be shown to
7 the jury. And my problem with that kind of analysis is that's
8 the kind of factual analysis -- saying that the Hakim
9 conclusions, that whatever conclusions he drew from whatever
10 the data was are flawed, and, therefore, appear in the memo and
11 you can't rule the memo out -- and, by the way, part of what I
12 have understood your critique to be of the Hakim memo is to
13 some degree a 403 concern of you basically have your guy out
14 there, the Chief Medical Officer of Fresenius. He rolls out --
15 by the way his name's not on the memo -- but the company rolls
16 out this memo. The memo says there's causation, essentially,
17 there's this big risk, and there's all these conclusions that
18 are attached as to what that data means, and that in front of
19 the jury is problematic, because it attaches all this power to
20 it which may or may not be true.

21 If that's the Court's position, I get it, and that's
22 what I thought I understood from the Daubert hearing.

23 THE COURT: I think you have accurately stated it.

24 MR. KETTERER: Okay.

25 THE COURT: So, the question, then, is what do I let

1 in? What do I let come before the jury?

2 MR. KETTERER: And that is the data and analyses which
3 are part and parcel, which were done historically through the
4 company. They are not attached to any conclusions in the sense
5 of, first of all, any expert can view the data compilation that
6 was done, the analyses, the charts, and they can interpret them
7 and that can be cross-examined: "Yeah, I think that that
8 relative risk is good." "Where did you get that -- they said
9 600 to 800. Did you get that data? Did you look at that
10 data?" That's all cross-examination.

11 THE COURT: And how is that being precluded here? Are
12 your people going to say, "I relied on this underlying data
13 from Hakim"?

14 MR. KETTERER: First of all, it's not from Hakim.
15 That's just it.

16 THE COURT: Well, I am just using him.

17 MR. KETTERER: The company.

18 THE COURT: He is the mailbox that this stuff was
19 mailed to.

20 MR. KETTERER: I don't know that it's the mailbox,
21 your Honor. That's the other problem.

22 THE COURT: In any event, whatever it is, "Did you
23 consider this data?"

24 MR. KETTERER: Yes.

25 THE COURT: "Yes, I did. It supported my view."

1 MR. KETTERER: Yes.

2 THE COURT: "Yes, it did." If they say that.

3 MR. KETTERER: Yes.

4 THE COURT: So, they have said it.

5 MR. KETTERER: Okay. If that's it, great, we're set.

6 That's part of it. And, by the way, that's not the entire
7 analysis.

8 THE COURT: So, let's pause right there.

9 Any problem with that, Ms. Brooks?

10 MS. BROOKS: Yes, a very big problem, your Honor.

11 What plaintiffs are doing, they are conflating data with
12 analysis.

13 THE COURT: I understand that. I understand that that
14 is where they are going, but what they are doing, the mixing
15 bowl for that is their expert.

16 MS. BROOKS: Yes, your Honor. Now, if their expert
17 wants to testify that that expert looked at the underlying data
18 which exists on an Excel spreadsheet and from that formed
19 opinions, the expert would be allowed to do that, had the
20 expert actually done that and did a report talking about it.

21 No experts did that. All of the plaintiff's experts, and we
22 attach their opinions to the appendix to the original Hakim
23 Daubert, all they did was pick up the Hakim memo, look at the
24 analysis which this Court found was, as Dr. Lacson who did the
25 analysis described, quick, dirty, preliminary, rough, not ready

1 for publication --

2 THE COURT: Let me just pause on this for a minute to
3 be sure that you both have joined issue on this. At the risk
4 of saying you are both right, you are both right, and so the
5 question is have your experts done that with the data as
6 opposed to saying, "I looked at this and I endorsed these
7 opinions"?

8 MR. KETTERER: First of all, it's like if you took
9 data.

10 THE COURT: Let me put it a different way, which I
11 might do, which is to say, okay, if your guys have done it they
12 get a chance to depose him on your nickel to see what that is
13 and see a report from you, timely, that incorporates that.
14 Have they?

15 MR. KETTERER: Your Honor, the answer is no, but let
16 me explain as to why. The "why" isn't that they picked up the
17 November 2011 memo and looked at this. First of all, these
18 things, the data and the analyses we want to use, there's
19 extensive depositions. They appear numerous times through
20 numerous documents. If you read a piece of medical literature
21 and it has figures in it, you can ask all of their experts who
22 prepared these reports, and they have all relied on those
23 figures, they have all relied on those analyses. That is the
24 data. That's the way it's done in the scientific community.

25 THE COURT: Well, no, not entirely.

1 MR. KETTERER: It's part of the information.

2 THE COURT: No, not entirely. So, now we are dealing
3 with something that we have to disaggregate, that is, what
4 underlies the Hakim memo or the materials of the Hakim memo
5 used for purposes of reaching its conclusions and the opinions
6 that are expressed.

7 Now, as I understand it, your people have never said,
8 "We looked at the underlying material here." Now, I am not
9 getting into the Excel spreadsheet yet. I may. But what they
10 have said is, "Hah, hah, Hakim."

11 MR. KETTERER: Not exactly. Well, then we have to
12 step back and go to the history of it, your Honor, because some
13 of the history of getting the data, the raw data --

14 THE COURT: No, we do not have to. We are where we
15 are. We are right here right now --

16 MR. KETTERER: Okay.

17 THE COURT: -- and I am dealing with the evidence that
18 is available to you. I will afford the opportunity for a
19 supplemental opinion that addresses precisely this issue, but I
20 do not think it has been teased out yet, and I will permit
21 cross-examination of these people so that I can understand
22 precisely where they fall between opinion and data. What I
23 have seen suggests to me, and it is what caused me to be
24 resistant, is the kind of treatment of the Hakim memo as kind
25 of a voucher, "See, even they thought that," and that is not

1 good enough.

2 MR. KETTERER: But this is where we disagree, your
3 Honor. This is the fundamental disagreement that, as
4 respectfully as I can put this to you, that we have with the
5 Court about your interpretation of the Hakim memo.

6 THE COURT: I am glad you put it respectfully.

7 MR. KETTERER: The idea that I think the Court has had
8 is that somehow all the experts and the Hakim memo was this
9 sloppily constructed thing that was just thrown out there, and
10 that's not the case. Mr. Tarricone got into some of it, but
11 the process by which it was done, and, although counsel loves
12 to reiterate the "quick and dirty" like 95 times every time
13 that the thing comes up --

14 THE COURT: Sort of like "*ipse dixit*."

15 MR. KETTERER: Yeah. But the issue is that the
16 testimony of Dr. Lacson, any supplemental motion, anything that
17 the experts looked at, the experts also looked at what
18 Dr. Lacson did, what was the analysis. One of the markers for
19 scientific rigor is did you see replication. This is not
20 one-off data; this is data that got replicated.

21 THE COURT: I just do not understand this fully. You
22 seem to be ships passing in the night without me around. If
23 they looked at data they can say, "Here was some data that I
24 looked at, here were a series of studies that I looked at."
25 Where that data came from might be fair game as well. Where it

1 was ultimately embedded is not.

2 MR. KETTERER: I'm not sure I understand, your Honor.

3 THE COURT: Ultimately embedded in the Hakim memo
4 providing the opinions.

5 MR. KETTERER: Well, let me make sure I understand
6 this. So, the data is collected all throughout -- I mean the
7 historical procedure is it is collected all throughout 2010.
8 Now, it appears, as counsel notes, in an Excel spreadsheet.
9 They've also been producing presentations and memos and charts
10 and graphs. All of that stuff is relied on. The experts got
11 all of that. Dr. Fine, he doesn't get just -- he gets the
12 spreadsheet, he gets the data, he gets the analyses, he gets
13 the conclusions.

14 THE COURT: See, the problem that is presented by all
15 of this, or teed up by this fragile, volatile accommodation
16 that is made in the expert rules over the idea that something
17 is not hearsay simply because an expert relies on it, it can be
18 looked into, that sort of thing. But what they can rely on, as
19 far as I am concerned, is the data itself. I keep saying this,
20 but maybe, in saying it, I am making it clearer for you and
21 perhaps make myself clearer.

22 If there is a cohort study that is relied on by Hakim,
23 the cohort study -- and relied on by your experts, your experts
24 say, "That was helpful," that's okay. But attaching it to the
25 -- I keep saying the "Hakim memo," or memos of that ilk which

1 have not themselves been tested by the customary mechanisms,
2 which I have indicated are quite latitudinarian of expertise is
3 not going to come in. They are not going to come in that way,
4 because they will be viewed by the jury for both purposes, and,
5 as a consequence, "both purposes" meaning both expertise and
6 data, and the consequence is they raise the potential for
7 misleading the jury and confusing the jury.

8 MR. KETTERER: And I totally understand the Court's
9 view on this, and I guess the ships passing in the night, is
10 defendants still obviously take the position that you don't get
11 to use those charts or graphs or whatever.

12 THE COURT: Well, but you say "charts or graphs," and
13 I think what I would like to know is maybe an example so that I
14 can understand what one shows the issue, what one would be
15 illustrative of the issue.

16 MR. KETTERER: Well, your Honor, I actually don't have
17 the exact one that I want to use, but this is enough of an
18 example. This isn't in the Hakim memo, but --

19 THE COURT: So, are we looking at the 2008 FMS Data
20 From 2009 Medical Director Report?

21 MR. KETTERER: Yes.

22 THE COURT: So, we take the headline off.

23 MR. KETTERER: Okay, fine. This is just an example
24 for your Honor.

25 THE COURT: Well, it had better be a good one, because

1 it is going to be the one that is going to persuade me or not.

2 MR. KETTERER: Well, it's the one I just happen to
3 have handy.

4 THE COURT: Really, this is not a kind of pop quiz.
5 If there is something better that you are going to be able to
6 bring to my attention, that's good.

7 MR. KETTERER: I think my point is, though --

8 THE COURT: Let me make my point, and then you will
9 make yours.

10 MR. KETTERER: Okay.

11 THE COURT: If what is involved here is somebody who
12 says, "There is data that has been brought together in this
13 fashion that I have looked at," and it loses the "From Medical
14 Director Report" and that sort of thing, and your person says,
15 "I rely on this, this is helpful to me," then, subject to
16 hearing more from Ms. Brooks, I am likely to let it come in.

17 MR. KETTERER: Okay.

18 THE COURT: Now, am I going to let that chart come in?
19 Probably not.

20 MR. KETTERER: Which chart?

21 THE COURT: I am using the chart that I just happen to
22 have up here, the Acid/Base Concerns circular. Am I going to
23 let the chart come in? It depends on how many charts there
24 are, that kind of thing.

25 MR. KETTERER: Right.

1 THE COURT: But if your guy says, "I looked at the
2 three-month average bicarbonate and looked at it in terms of
3 the percentage of patients and the hazard ratios disclosed in
4 materials that I received, the underlying data that I received
5 from the defendant or from FMS, and that, I believe, supports
6 and informed my opinion," then, yes, I would let that in.

7 MR. KETTERER: Okay.

8 THE COURT: But if someone says, "And the Medical
9 Director drew this conclusion," no.

10 MR. KETTERER: No, no, no, no. I understand that.
11 That part and the whatever, I totally get that. That's not in
12 question at all. And so I have understood what you have just
13 said, you would like to have this redacted off (indicating).

14 THE COURT: Well, if you think you are going to get it
15 in as such, I have some resistance to that, and that goes back
16 to this idea of whether or not sponsoring or relying upon a
17 document by an expert means that the underlying document not
18 only meets hearsay concerns, it also gets to be independently
19 marked as an exhibit for the jury. There I have some
20 resistance, and this resistance is the larger resistance I have
21 to what I keep saying, more than a bread box versus a
22 collection of documents. But you go up there and the guy says,
23 "You know, I looked at this, and I looked at the profile of the
24 data that was involved here," the kind of mix between
25 unadjusted and case mixed and cased-mix labs and whatever they

1 say --

2 MR. KETTERER: Sure.

3 THE COURT: -- if I think it is going to be helpful
4 for the jury to see, I might mark it as a chalk. If it is
5 really fundamental I might let it come in as a fundamental
6 document. But if he says, "I rely on this sort of thing,"
7 good, you can have it.

8 MR. KETTERER: Okay.

9 THE COURT: But it is not going to be this kind of, I
10 will call it "perverse voucher;" that is, Fresenius had people
11 who said things that were not tested scientifically. Fresenius
12 is now running away from what these people said. In any event,
13 I do not want the jury speculating as I have speculated
14 throughout of what is going on here? Is it office politics,
15 palace politics? What is going on? Because, while I like to
16 speculate, it is not material to the judgment in this case.
17 What is material to the judgment in this case is the data that
18 is relied upon for purposes of drawing conclusions and not that
19 you can, as I saw characterized as perverse vouching, say,
20 "Ah-hah, they said it, therefore, it is true." That is not
21 going to come in.

22 MR. KETTERER: I certainly understand that, your
23 Honor. I understand those are the rules of the Court. That's
24 not really my issue on this particular motion.

25 THE COURT: So, have I not answered your issue?

1 MR. KETTERER: You have.

2 THE COURT: So, Ms. Brooks, what is the problem with
3 what I have just said?

4 MS. BROOKS: Your Honor, as far as, once again, they
5 want to look at some data and say, "I looked at this data and I
6 relied on it in part in forming my opinion," we have no issue
7 with. What happens is the graphs they are talking about are
8 Figures 2 and 3 in the Hakim memo. Those graphs are not data.
9 Those graphs are representative of an analysis that was
10 conducted on data.

11 THE COURT: Maybe you could pass it up.

12 MS. BROOKS: Absolutely, your Honor. I know we had
13 multiple copies of the Hakim memo at one point.

14 THE COURT: And I am sure in this collection I have
15 got it back there, but I do not have it with me.

16 MS. BROOKS: And I apologize for my highlighting on
17 there, your Honor, but I drew a box around Figures 2 and 3,
18 which is, Figure 1, I believe, is just some bicarb data. We
19 have no issue with that. It appears in lots of documents. But
20 Figures 2 and 3, so what do they represent? They don't
21 represent data. They represent an analysis that Dr. Lacson
22 conducted, not Dr. Hakim, Dr. Lacson at the behest of Dr.
23 Hakim. It is this analysis that Dr. Lacson described as, I'm
24 sorry he did, at the time was quick and dirty, rough,
25 preliminary, et cetera.

1 THE COURT: Now, let me just take this a bit. So, we
2 take out relative risk of CP arrest, colon, bicarbonate. Then
3 we have got this chart, and their expert says, "I think that
4 this reinforces my view that there is an increased risk of
5 cardiac arrest, cardiopulmonary arrest, in data that is out
6 there, and so they say, "I looked at this and there were under
7 20, unadjusted," whatever are the specifics of the data that
8 are reflected in this chart, "and I relied on that." Okay, he
9 relied on that.

10 First, what is the problem with that? And, second,
11 why can't you simply say, "Are you aware that the author of
12 this says that this is just a quick and dirty approach?"

13 MS. BROOKS: The reason is, your Honor, that this
14 Court and Judge Kirpalani ruled in writing that they could not
15 rely on it. Those specific two, Figures 2 and 3, could not be
16 relied on because of the flawed methodology of the underlying
17 analysis.

18 THE COURT: It is done by derivation, for me anyway,
19 from the more fulsome Memorandum that was written by
20 Judge Kirpalani. So, I am looking at Page 12 of Judge
21 Kirpalani's decision, and what he appears to be talking about
22 and what I recall is the dissonance between the graph and the
23 conclusions, not that the graph was going to be kept out. Now,
24 am I missing something in his opinion?

25 MS. BROOKS: Yes, your Honor. He also goes on where

1 he's saying the conclusion about a 6 to 8 fold greater increase
2 or greater risk is not supported by the graph. He then goes
3 on, though, and says, "Fourth, even the plaintiff's experts
4 were unable to interpret Figures 2 referenced percentage of
5 patients because of the lack of data or information about
6 methodology -- "

7 THE COURT: Well, but I guess that comes back to this:
8 Of course I want to be focused on precisely the evolution of
9 this, but I am working on the assumption that they can testify
10 about this graph and what the various elements that they seek
11 to introduce are. You have properly called attention to the
12 finding that they were unable to interpret it. If they are
13 unable to interpret it, then of course it stays out here. But
14 that is a graph-by-graph kind of thing.

15 The point is that graphs, assuming that they have not
16 been incorporated or made into an argument like relative risk
17 or Medical Director Report, that sort of thing, they are simply
18 representations of data that can be interpreted. Now, if these
19 people -- if somebody says, "Did you look at this in Figure 2,"
20 and I have not gone back to look at the underlying stuff, and
21 the witness says, "Yeah, I relied on it," and then somebody
22 gets up and says, "You didn't rely on it, you couldn't even
23 read it, right?", and they can be impeached by their
24 deposition, well, it probably should not even be offered, but,
25 in any event, it is not going to be reliable. And if, in fact,

1 that happened, somebody tried to take the expert beyond what
2 the expert could support, I probably would say, "Ladies and
3 gentlemen, I am striking the reference to that testimony,
4 because it is clear that the witness is unable to interpret
5 it."

6 MS. BROOKS: Your Honor, the Court's Order actually
7 went farther and says on the next page, Page 13, the
8 conclusion: "In sum, the findings in the Hakim memo are
9 conclusory statements that are either not supported by data or
10 are contradicted by certain data of which Dr. Hakim was aware.
11 These findings are, therefore, not scientifically sound support
12 for the general causation argument and cannot be used to prove
13 general causation. Moreover, the plaintiff's experts cannot
14 rely on them."

15 THE COURT: So, let me pause with this, because we
16 have been dealing with a series of different things,
17 conclusions, data and findings, and what you are saying to me
18 is that this or such charts are findings?

19 MS. BROOKS: Correct, your Honor, they are. They are
20 analyses, they are not data.

21 THE COURT: So, I guess maybe we have to do it step by
22 step to deal with any one of these that you rely on. So, let's
23 use Figure 2. Is there any question that your experts said
24 they were unable to interpret Figure 2's reference to
25 percentage of patients?

1 MR. KETTERER: No. No, not as a broad-based statement
2 across all experts. There were some experts who were asked in
3 terms of a certain percentage on a certain spot in that
4 percentage, and I know the quote that they want to bring out,
5 that there was something in terms of the actual reading whether
6 they could see it, whether that was clear. Now, there was an
7 expert who testified that they had trouble reading it.

8 THE COURT: Was that an ocular problem or intellectual
9 problem?

10 MR. KETTERER: I think it's an ocular problem for
11 them, but I don't have that testimony right in front of me to
12 look at. But, even if it's from that expert, if that expert is
13 at issue and comes in and says, "Of course," that's an issue
14 that the Court can take up, if that particular expert shows up
15 and says, "I want to now interpret something I said I earlier
16 couldn't interpret."

17 But let me back up a step, because what they handed up
18 is the 2011 memo, I'm sure, and let's look at where those
19 graphs actually appear, because we don't have to use the 2011
20 memo to look at those graphs. And I can put that up on the
21 screen, your Honor. Let's just put up the first page and then
22 go to that one.

23 Because what I would like to do, your Honor, is the
24 2011 memo seems to be extremely controversial in terms of how
25 it is going to get used, all the things that are attached to it

1 and the conclusions. And, by the way, this issue, this
2 particular memo, they objected to these graphs because they
3 said it was underlying from the same Hakim memo, and Judge
4 Kirpalani did not out of hand say, "Oh, I've already ruled on
5 this in the Daubert." What he asked us to do was, he said, "I
6 am going to exclude these for now, these three graphs. Do not
7 use them. Brief the issue and come back to me." We made a
8 decision not to brief the issue, because we didn't need it in
9 that trial. All right? We had other evidence that was coming
10 in.

11 THE COURT: So, let me just pause on that. I try, as
12 you know, to coincide in the way in which I am approaching
13 things with Judge Kirpalani's, unless there is a good reason
14 not to. And so, I would like you, again, not a spot quiz, but
15 I would like you to identify where this matter came up before
16 Judge Kirpalani. I have the transcripts here.

17 MR. KETTERER: Okay. So, your Honor, you have got to
18 give me a minute to find them, but I can tell you the day.

19 THE COURT: We can go back to this on the second, but
20 I think we are making progress on this issue, which is to say,
21 if you have got an expert who has said that they relied on this
22 and they could read it and interpret it, and it is de-fanged of
23 argumentation and association with what I will call "Hakim
24 vouching --"

25 MR. KETTERER: I want to do this example, then, your

1 Honor, to show you what I mean by that.

2 THE COURT: All right.

3 MR. KETTERER: Here is the example. This is,
4 actually, how I believe it came up in context before Judge
5 Kirpalani. If it wasn't in this version, it was an earlier
6 version. This is a PowerPoint you were handed up. You were
7 handed a version of this, the April 2010 Acid/Base Concerns.
8 This is a later iteration that was presented to the PSO in
9 July, and this is the July 28th, 2010 version.

10 Now, all this text below, it might come in for some
11 other reason, this presentation, subject to your Honor's ruling
12 or whatever, but for the purposes of a witness like Dr. Fine,
13 that's not what we're offering this particular presentation
14 for.

15 So, can we go to the chart that I had? Okay.

16 So, this is the cardiopulmonary arrest. This is a
17 graph that was compiled. This is not Dr. Hakim's graph. This
18 is not inside the Hakim memo. This doesn't mention Dr. Hakim
19 as the medical officer.

20 THE COURT: Isn't it the same thing, though?

21 MR. KETTERER: It is the same figure that eventually
22 will appear. But this is actually my point, your Honor, about
23 the entire analysis that the Court has sort of viewed the Hakim
24 memo. So, the Hakim memo seems to -- the original
25 interpretation of the Hakim memo is, well, there's this memo

1 that's sort of this pronouncement, and where did it come from?
2 The reality is it has come from a long history and a long
3 progression.

4 THE COURT: Let me just maybe focus more. Maybe I
5 have to go back and forth between you and Ms. Brooks. I am not
6 so concerned about the provenance, that is, the document in
7 which the chart appears. If it is in the Hakim memo I don't
8 really care. If it is in the July 2010 PowerPoint, or whatever
9 this was, I don't care. What I care about is whether or not
10 your experts will say they relied upon the data reflected in,
11 maybe I will call this -- well, I will just call it a chart,
12 rather than calling it a finding.

13 MR. KETTERER: They will.

14 THE COURT: All right.

15 MR. KETTERER: That this is a document that --

16 THE COURT: Okay.

17 So, Ms. Brooks, so they say that. You do not think
18 that is a good approach, but so what?

19 MS. BROOKS: The "so what," your Honor, is that's in
20 direct violation of this Court's Daubert order.

21 THE COURT: I just don't think so, I just don't think
22 so. And I look, again -- and I will permit you both the
23 opportunity to do it. I have reserved the right that -- there
24 is a terrific opinion, I would have to pull it out, by Justice
25 Jackson that included all the various ways that judges have of

1 saying that they reconsidered, including, "I cannot imagine a
2 person of my mental capacity coming to this erroneous
3 conclusion." And I may do that. But I do not think I came to
4 an erroneous conclusion by embracing the decision of Judge
5 Kirpalani on this issue. I certainly did not understand myself
6 to be doing that, and I do not think he understood himself to
7 be doing that. I think we both understood that what we were
8 saying is don't look to the conclusions, and to the degree that
9 the findings are just "Conclusions Lite," don't look to the
10 findings, look to the underlying materials.

11 So, you have raised this issue of whether they are
12 really relying on this thing, or the data on this thing, and if
13 they are, if they say they are, and if the chart is tidied up,
14 redacted fairly to reflect what the data is and not to make an
15 argument or to provide backdoor introduction of what I have
16 referred to as the "vouching," I am likely to let it in.

17 MS. BROOKS: So, here is the problem with that, your
18 Honor: What plaintiffs are trying to do is get in through the
19 backdoor what they have not been allowed to get in through the
20 front door, specifically Figures 2 and 3 that appear in the
21 Hakim memo.

22 THE COURT: Let's stop talking about them as "Figures
23 2 and 3." Let's just simply talk about them as charts with
24 respect to risk of CP arrest.

25 MS. BROOKS: That's the problem, though. They're not.

1 And so, that's the whole issue, is that Figures 2 and 3 were
2 excluded by this Court very specifically. We specifically
3 moved for various opinions and Figures 2 and 3. That was our
4 motion before the Court, and we are trying to get it now. I
5 didn't know we were going to reargue this, your Honor. I would
6 have brought all the paperwork.

7 THE COURT: You will get to, and also based on further
8 discussion that we have had and a refined understanding that I
9 now have, I may reconsider, even if I think that embedded in
10 the prayer in the motion *in limine* is sufficient information to
11 alert me that I was not only ruling out 2 and 3, I was ruling
12 out the figure from the July 2010 Acid/Base Concerns memo,
13 because it is simply presented in another document. So, you
14 are absolutely right, Figure 2 is not going to come in, but
15 that does not mean that that graph and the underlying data is
16 not going to come in.

17 MS. BROOKS: So, if it's a different graph, your
18 Honor, we have no objection to that. For example, in the
19 document that we handed you, that's a different graph.

20 THE COURT: Let's take the one that Mr. Ketterer just
21 put up.

22 MS. BROOKS: Unfortunately, I don't have that.

23 MR. KETTERER: I only have it on the screen. I don't
24 have a hard copy myself.

25 THE COURT: Is it on the screen?

1 MR. TARRICONE: It's on the screen.

2 MS. BROOKS: So, this, I believe, is Figure 2 from the
3 Hakim memo.

4 THE COURT: No. It is the precursor to Figure 2. It
5 is not Figure 2.

6 MS. BROOKS: Well, I believe it is exactly Figure 2.
7 It is from the first quarter. Now, if I'm wrong, if it's not
8 Figure 2, then we have --

9 MR. KETTERER: I don't think that's your Honor's
10 point.

11 MS. BROOKS: Excuse me. I'm asking if I'm wrong, if
12 it's not Figure 2, your Honor, we don't have an issue with it.

13 THE COURT: It was replicated as Figure 2 in the Hakim
14 memorandum, but it had an earlier life as this graph in, thank
15 you very much, Acid/Base Concerns July 28th, 2010.

16 MS. BROOKS: And so, if what plaintiff is saying is
17 that it is -- if I might ask directly?

18 THE COURT: Sure.

19 MS. BROOKS: Counsel, is it the representation of the
20 first quarter analysis by Dr. Lacson?

21 MR. KETTERER: It probably is, because the data would
22 have to be.

23 But the point I think your Honor is making --

24 THE COURT: Wait a minute. Ms. Brooks has got the
25 floor on this.

1 MR. KETTERER: Sorry.

2 MS. BROOKS: Thank you, your Honor. So, if it is
3 simply, as you say, the precursor to Figure 2, then the
4 analysis has the same fundamentally flawed methodology that
5 Dr. Lacson testified about.

6 THE COURT: So, you get to cross-examine any witness
7 who relies on that, any expert who relies on that. But the
8 point is that calling a chart a "finding" and then saying that
9 Judge Kirpalani and I both knocked out all findings that are
10 associated with the Hakim report does not accurately state what
11 I think we meant then and certainly what I mean now.

12 And so, what I am saying is that, if there is an
13 expert who says that they looked at this chart, again, redacted
14 so it does not have matter to which a fair objection could be
15 taken, then have at him, say, "That's stupid." Well, you will
16 not say that, but, "Are you aware that a person who is involved
17 or looked at this said that this is quick and dirty?" The
18 problem is I am not sure I am going to even let that
19 impeachment work on this chart, because that brings in in a
20 different way the Hakim memo itself, and that was kind of a
21 wholesale characterization by Dr. Lacson.

22 Do I pronounce it correctly?

23 MS. BROOKS: Yes, it is Dr. Lacson, your Honor. Yes.

24 THE COURT: We are going to fight it out over the data
25 and any chart that fairly reflects the data.

1 MS. BROOKS: And so, here is the problem. If this
2 comes in and we are not allowed to attack the validity of what
3 is represented in this analysis, then it's the worst of all
4 roles in that the jury will be able to look at --

5 THE COURT: What do you mean the "validity"?

6 MS. BROOKS: The validity as in the underlying
7 methodology. Is it sound, is it repeatable, has it been peer
8 reviewed?

9 THE COURT: Well, what does that mean in terms of
10 cross-examination? Here are some reports of data, okay? It's
11 reports of data. You may not think it is complete, it is not
12 full, but it provides some information that was gathered in
13 some fashion.

14 MS. BROOKS: But, you see, your Honor, that's the
15 difference. It's not a report of data. Data would simply be
16 how many cardiopulmonary arrests did an individual suffer while
17 having dialysis. That's data. How many of those individuals
18 had predialysis serum bicarbs greater than 28? That's data.
19 How many had predialysis less than 21? That's data. What they
20 then did was perform an analysis on that data, and that's
21 what's represented here when you look at the odds ratio
22 estimates and the relative risk of cardiopulmonary -- it
23 disappeared. I'm sorry. Which is here.

24 Thank you, Mr. Sakimae.

25 Now, what happened is we showed this figure to every

1 one of plaintiff's experts to see whether they could even
2 interpret what is being shown in this figure.

3 And now, Mr. Sakimae, if you could put that up.

4 And here is what they said, your Honor. It's on the
5 screen. We showed it to Dr. Akar, this figure, and he said,
6 "Yeah, I can't tell what this percentage of patients refers
7 to." Dr. Borkan: "I don't know how to interpret that
8 information."

9 THE COURT: That's a different issue from the issue
10 that I'm dealing with now. So, let me just take this, because
11 I want to deal with Figure 2 and its precursors. If we took
12 out -- this is an unusual graph, in that it has x and y and
13 xxy.

14 MS. BROOKS: It has two y -- I think two things
15 represented on the y-axis, your Honor, which makes it more
16 confusing.

17 THE COURT: So, we take one of the ys out, the odds
18 ratio estimates. It's fair, isn't it, for purposes of the
19 x-axis and the y-axis?

20 MS. BROOKS: No, it's not.

21 THE COURT: Why?

22 MS. BROOKS: And here's why not: Again, because the
23 underlying methodology was flawed. When one does this kind of
24 a study to truly predict hazard ratios you have to do a case
25 matching, not a case mixing, so that you make sure, for

1 example, that someone who had a cardiopulmonary arrest versus
2 someone who didn't, you match them for gender, for age, for
3 dialysis vintage, et cetera.

4 THE COURT: So, why isn't that cross-examination?

5 MS. BROOKS: Because that goes directly to Daubert.
6 That is a faulty methodology that is not accepted in the field.

7 THE COURT: Not necessarily. I am trying to find a
8 nicer way of saying it, but you get in the weeds on some of
9 this stuff, on some of the data, and you say you cannot make
10 what you make out of it with just this data. Now, is that
11 sufficient to exclude the use of this data? No. By an expert
12 who says, "No, I used that." Now, you may have an expert,
13 probably do, who says, "Nobody would rely on this kind of
14 thing, because it does not do the differentiation that is
15 necessary," and to the degree that we get into that, then we
16 get into it. But I don't think that they are proscribed from
17 saying that they relied on it.

18 Now, this stuff about these people say what you report
19 on the figure, the finding that you put up I guess is Slide No.
20 33, that nobody is going to embrace this graph, well, that is a
21 nonstarter for this graph, but I think that this is reflective
22 of data which they can say they relied on, and you can
23 cross-examine them on it, and you can impeach them on it,
24 impeach their methodology on it. That is the kind of line that
25 I am trying to draw in this.

1 MS. BROOKS: Totally understood, then, your Honor.
2 So, if Figures 2 and 3 or their predecessors are coming in, and
3 the plaintiff's experts are allowed to rely on them as part of
4 their opinion, we have plenty of ammunition to deal with that,
5 and we certainly will.

6 THE COURT: That is the line that I am trying to draw
7 in this area, that I was trying to draw, I think Judge
8 Kirpalani was trying to draw in this area.

9 This can be off the record.

10 (Discussion held off the record)

11 THE COURT: I'm afraid that perhaps in our Memorandum,
12 or Judge Kirpalani's Memorandum, which I endorse, adopt,
13 embrace, that we may have used a No. 4 pencil. So, now we're
14 sharpening the point, and I think I have delineated the
15 usefulness of this, unless there is something more. I do want
16 to take a break at this point.

17 MS. BROOKS: Your Honor, that is actually very
18 helpful, then. So, what we list and Judge Kirpalani lists on
19 Page 6 of the opinion is all out, but Figures --

20 THE COURT: No, it is not out. It is not out. It has
21 received a refinement.

22 MS. BROOKS: I was about to say that that does not
23 include -- so, this does not actually list Figures 2 and 3, so
24 Figures 2 and 3 are in, but the --

25 THE COURT: Not as Figures 2 and 3.

1 MS. BROOKS: Okay.

2 THE COURT: As representations of data they are in,
3 and they happen to be incorporated in the Hakim memo, also
4 incorporated in the Acid/Base Concern --

5 MS. BROOKS: Understood.

6 THE COURT: But they are representations of data
7 itself. If they are false representations, that's another
8 thing. If they have got an extra chromosome, XXY, they are out
9 as well. That Y axis is not going to be included in it,
10 because nobody seems to understand it --

11 MS. BROOKS: Understood, your Honor.

12 THE COURT: -- or it is argumentative.

13 MS. BROOKS: That's very helpful. Thank you.

14 THE COURT: So, we will take a break.

15 THE CLERK: All rise.

16 (The Honorable Court exited the courtroom at 3:05 p.m.)

17 (Recess taken)

18 THE CLERK: All rise.

19 (The Honorable Court entered the courtroom at 3:15 p.m.)

20 THE CLERK: Court is back in session. You may be
21 seated.

22 THE COURT: Several things: One, I just noted that
23 the Clerk indicated to the staff that we are on reduced
24 staffing now. I want to honor that to some degree, so I may
25 bring this to a sharper conclusion for today.

1 I think you have the sense of what I am thinking on
2 matters that have to do with the data that found its way into
3 the Hakim memo and that sort of thing, my view with respect to
4 FDA matters, I have not ruled on this directly, we have not
5 actually dealt with it, and similarly material having to do
6 with the FDA's proceedings on March 29th, 2012. Maybe we will
7 take those up at the next occasion.

8 There was an opportunity to talk about the remaining
9 motions *in limine*. Is that simply the parties are talking
10 about and trying to refine their views on it; is that it?

11 MR. KETTERER: I think there is some discussion, but
12 there are some that are outstanding that still need resolution,
13 your Honor.

14 MR. BENNETT: I can report on which ones are agreed,
15 so you don't have to. Mr. Gotz is who I think -- some of the
16 other counsel may have been on the phone as well. First off,
17 on these FDA motions, your Honor, the two that are listed on
18 today's agenda have been, in fact, resolved by an agreement
19 that FDA actions after Mr. Dial's death are not going to be
20 brought up by either party.

21 THE COURT: So, I will treat them, that is -- let's
22 see my agenda here -- the Motion *in Limine* No. 6, which is
23 Motion No. 98 as moot, and Motion No. 87, which is the
24 plaintiff's Motion *in Limine* to Preclude All Evidence of FDA,
25 as moot.

1 MR. BENNETT: Yes.

2 MR. KETTERER: We agree. One just caveat, and I know
3 your Honor is aware, and I said this before Judge Kirpalani
4 before we started in that court. Of course, if we felt the
5 door was open for some reason, we would want to approach your
6 Honor about that. Subject to that, no.

7 THE COURT: But you have got a sense of what I want.

8 MR. KETTERER: I agree.

9 THE COURT: And I will emphasize another point, call
10 it rules of the road, which is, I hate surprises.

11 MR. KETTERER: Absolutely.

12 THE COURT: That is why I have gone on at length on
13 these things to get a sense of what is out there. But I am
14 kind of like an old dog that is over in the corner and is
15 sleeping quietly, and then it gets startled and it bites. So,
16 don't startle me, okay?

17 MR. KETTERER: Not the intention, your Honor. And
18 this is just in the opposite context, that if we heard
19 something that was a surprise to us, we would obviously want to
20 approach you.

21 THE COURT: Bring it up and we will have a discussion
22 about it.

23 So, that takes care of 98 and 87. Those are the two
24 FDA motions.

25 MR. BENNETT: Yes, your Honor. And I don't have the

1 docket numbers, but I have our numbers. So, Fresenius's Motion
2 *in Limine* No. 3 regarding alleged failure to communicate with
3 physicians at non-Fresenius-owned clinics has been agreed.

4 THE COURT: Has been agreed what?

5 MR. BENNETT: It's been agreed that the plaintiffs are
6 not going to introduce evidence that we didn't warn
7 non-Fresenius clinics.

8 THE COURT: So, that is allowed with the agreement of
9 the plaintiffs.

10 MR. BENNETT: Right. And we are not going to present
11 evidence that we did tell other clinics as well. They have a
12 motion *in limine* on that related to DaVita witnesses that we
13 have agreed can be granted as well.

14 THE COURT: I'm sorry. I want to keep track and to
15 have a discussion with Mr. Hohler afterwards to be sure we've
16 got it. So, we have got No. 3, I will get to No. 4, which is
17 defendant's No. 3, which is allowed with the agreement of the
18 parties --

19 MR. BENNETT: Yes, your Honor.

20 THE COURT: -- agreement of the plaintiff?

21 MR. KETTERER: Yes, your Honor.

22 THE COURT: So, if we can just talk in terms of
23 specific numbers.

24 MR. BENNETT: Yes, your Honor. And the plaintiffs
25 didn't number theirs, so it's a little bit harder. They have

1 one that has "DaVita" in the title that was one of the last
2 three --

3 THE COURT: No more than Exhibit No. 3 having been
4 resolved? The rest of them are still out there?

5 MR. BENNETT: No. Fresenius Motion *in Limine* No. 7
6 regarding discovery disputes has been resolved.

7 THE COURT: And that resolved -- how do I refer to it?

8 MR. BENNETT: Neither party is going to introduce
9 evidence of discovery disputes.

10 THE COURT: So, allowed by agreement of the defendant,
11 with the agreement of defendant.

12 MR. BENNETT: Yes. Of the plaintiff.

13 THE COURT: Plaintiff, excuse me.

14 MR. BENNETT: Fresenius Motion *in Limine* No. 8
15 regarding manufacturing defects in the NaturaLyte or GranuFlo
16 product that was used on the patient has been granted by
17 agreement. Plaintiffs had a question that whether that
18 extended to the design of a dialysis screen, machine screen,
19 and our motion did not contemplate that, and so we have agreed
20 that their agreement doesn't extend to that issue.

21 THE COURT: So, as framed, anyway, No. 8 is allowed
22 with the agreement of the plaintiffs.

23 MR. KETTERER: True.

24 MR. BENNETT: Yes, your Honor. Fresenius's Motion *in*
25 *Limine* No. 14 to exclude testimony and argument about the

1 numbers of cases and other litigation or testimony in the
2 Ogburn case has been agreed to be granted, and neither party
3 will bring that up.

4 THE COURT: That is allowed with agreement of the
5 plaintiffs.

6 Let me just say something about that, not to spoil the
7 agreement, but if there is reference, for instance, if someone
8 is cross-examined from the Ogburn, simply, "Didn't you in
9 another proceeding say this," rather than identifying the
10 particular proceeding.

11 MR. KETTERER: The other context, and I'm just
12 reminded of it, your Honor, is that we did have a challenge in
13 the Ogburn trial about there was something -- I don't
14 anticipate actually it's an issue -- actually that's not true,
15 because they are calling one of the same experts again, where
16 the expert had opined and had an inconsistency about another
17 case. There was some challenge about how to resolve the fact
18 that he had, in fact, opined in other cases. Just something
19 for the Court to consider as an issue potentially.

20 THE COURT: My default on this, subject to
21 modification, if the parties have some better way of dealing
22 with it, or one party wants to push one as opposed to another,
23 is to simply say, "Didn't you on another occasion say under
24 oath that," without getting into what the other occasion is.

25 MR. KETTERER: I don't know that this will even come

1 out in this particular context, but in the report that had been
2 generated he had misnamed the plaintiff. It looked like it was
3 a cut-and-paste job, and he had forgotten to do that. I was
4 making a certain point. My point isn't to get into a specific
5 example, but that may have to be something that would be raised
6 on that kind of issue.

7 THE COURT: What I want is, or what I will be looking
8 for, is something that permits the impeachment but without
9 bringing in the attendant baggage of the other case.

10 MR. KETTERER: Fair enough. If that becomes a case,
11 we will let you know in advance.

12 MR. BENNETT: Fresenius's Motion *in Limine* No. 15 to
13 exclude reference to an *International Journal of Nephrology*
14 being an Egyptian journal has been agreed.

15 THE COURT: I am just using the format allowed with
16 the agreement of the plaintiff.

17 MR. BENNETT: Fresenius Motion *in Limine* No. 17
18 regarding undisclosed exhibits or witnesses has been agreed,
19 and the plaintiffs listed three people who we didn't know on
20 their witness list from the Pembroke area, North Carolina, and
21 Mr. Gotz confirmed that they weren't calling them.

22 THE COURT: So, that has been allowed with the
23 agreement.

24 MR. BENNETT: Yes.

25 MR. KETTERER: Yes, your Honor.

1 MR. BENNETT: Plaintiff's Motion to Exclude the Death
2 Certificate, we have agreed that we are not going to offer the
3 death certificate.

4 THE COURT: Which one is this, the number?

5 MR. BENNETT: Plaintiff didn't number theirs.

6 THE COURT: Oh, these are plaintiffs.

7 MR. BENNETT: Yes.

8 THE COURT: Go ahead.

9 MR. BENNETT: Plaintiff's Motion *in Limine* to Exclude
10 the Death Certificate has been agreed in the sense that we will
11 not offer that document as proof of cause of death reflected on
12 the document. Dr. Buchanan is the person who assessed the
13 cause of death as myocardial infarction, and it would be a
14 prior consistent statement by him if the claim is made on his
15 cross-examination that he is fabricating his view that it
16 wasn't caused by the dialysate, which would be a different
17 purpose than cause of death. So, I have described the
18 agreement of the parties on that death certificate issue.

19 THE COURT: Let me understand your view with respect
20 to that, because I have given some thought to it.

21 MR. KETTERER: Yeah. I don't know that there's a
22 difference of an opinion with what Mr. Bennett stated. This is
23 a hypothetical. If we were to cross using the basis being,
24 "Well, this is the first time you have ever offered this
25 opinion," I am sure, then, that they would, and I believe the

1 agreement would be that, then, that would reopen the door to
2 them bringing in the death certificate.

3 THE COURT: No, but if the cross were you set up a
4 story here about what this was, "And you never examined the
5 decedent, did you?", that would be a different use of it, that
6 it is a consistent story that you say is false.

7 MR. KETTERER: Yeah, and I think, you know, I'm sort
8 of just mentally turning in my head about those
9 cross-examination questions, your Honor. I think it would
10 depend on the phrasing. The direct line that you're alluding
11 to philosophically of if you challenge that this is the first
12 time that they have come up with this cause of death, that
13 opens the door, we agree.

14 THE COURT: Well, I will wait and see on that.

15 MR. BENNETT: Okay.

16 THE COURT: My own view is probably, not that you need
17 to know, since you have already agreed to it, is more or less
18 the same as yours. Getting this thing in directly seems to me
19 to be wrong, but it may come in in some fashion having to do
20 with impeachment of Dr. Buchanan.

21 MR. KETTERER: Fair enough.

22 THE COURT: I treat that as allowed by agreement.

23 MR. KETTERER: Fair enough.

24 MR. BENNETT: Yes, your Honor, and we did say that, of
25 course, before we thought the door had been opened to it we

1 would approach.

2 Then, the plaintiffs did have the motion *in limine* to
3 preclude us from playing depositions of DaVita personnel, and
4 we have agreed we are not going to do that.

5 THE COURT: Okay.

6 MR. BENNETT: We filed a Motion to Quash Mr. Powell's
7 deposition, and we previewed that issue earlier in the week.
8 We have agreed to make other witnesses available in the
9 plaintiff's case in chief, namely, Dr. Pulliam (ph) and Ben
10 Lipps available to the plaintiffs during the second week of
11 trial at a mutually convenient time. They have, in exchange,
12 withdrawn the subpoena.

13 MR. KETTERER: Agreed.

14 THE COURT: I am not sure it even was filed -- I was
15 alerted there was an issue, but I am not sure it was filed.

16 MR. KETTERER: We have resolved it, your Honor.

17 THE COURT: All right.

18 MR. BENNETT: It should appear on the individual Dial
19 docket, so there is a motion to be resolved filed on Monday
20 night.

21 MR. KETTERER: Oh, that's right, a Motion to Quash.

22 THE COURT: Ms. Gioia is not here, but Mr. Hohler will
23 check to be sure. If it appears on there we will treat it as
24 withdrawn by agreement of the defendant -- not withdrawn but
25 treated as moot, I guess.

1 MR. KETTERER: That will be fine, your Honor.

2 MR. BENNETT: Your Honor, I believe the rest of the
3 motions are -- we have been talking and we have narrowed them
4 down to where the areas of dispute have gotten narrower, but
5 there is no agreement on the remainder.

6 THE COURT: So, we have Tuesday, in any event, to take
7 this up further, and I intend to do that, take advantage of
8 that time.

9 We have this discussion about length of openings. Not
10 too long. What are you talking about?

11 Let me go through the process. The Jury Clerk will be
12 here, as I said, on Tuesday. The way we probably will do it is
13 like this: that there will be about 120 jurors who will be
14 dedicated to this case for purposes of the venire. They will
15 fill out the questionnaire, which will be shorter than the
16 questionnaire that you have tendered, but we will talk about
17 that on Tuesday. I will probably give them a little
18 introductory talk about what the case is about in a general
19 sort of way. I think I would like to have trial counsel
20 present there. I do not think that Mrs. Dial needs to be
21 present -- although she is a party, she could, I suppose --
22 that we will probably do it in the jury room itself, that is,
23 the Jury Assembly Room, which is on the second floor, but this
24 is all to be discussed with the Jury Clerk, because he has got
25 other cases and that sort of thing.

1 Then they will fill it out. It will not take them
2 that long to fill it out, and we would likely send it out for
3 replication on discs. The discs will be provided to you. You
4 can go through the discs, and I would hope to be able to at
5 least get rid of some people, some people who say, "I am a
6 believer in total buffer," that someone like that might be
7 excludable. You will look through it, and my hope is that you
8 are not going to be having different views about who gets
9 excluded at this level, and I will be very indulgent. I will
10 view as cause anything that you both agree to, I think, unless
11 there is something funny going on, which I can't imagine.

12 So, then we get ourselves down to, let's say, 50
13 jurors, something like that. Then I will do an individual voir
14 dire, depending. I may do voir dire with everybody present, do
15 it at the sidebar, that kind of thing, but we will do that on
16 Wednesday morning. And we should be able to get enough jurors
17 there so that we have a 12-person jury. That is what I look to
18 have on that. And I will give you the customary strikes, but
19 at that point you pretty much have had strikes. It is just
20 kind of last-minute you do not like the cut of his hair or
21 something like that as being a grounds for excluding a juror,
22 which I do not, of course, inquire about.

23 And then I think we would do the closings Wednesday
24 afternoon. That is my more realistic view of what we are doing
25 Wednesday afternoon.

1 depends on the timing. If we get it like that (indicating), we
2 will start the opening statements then. But if you want an
3 hour, your call. The alternative to saving souls is
4 lobotomizing the mind, and that sometimes happens with an hour.

5 MR. BENNETT: 45 might be better, because that would
6 allow for sure it all be done without a break.

7 THE COURT: Well, we are going to have to take a break
8 probably between them, anyway.

9 MR. BENNETT: Okay.

10 MR. KETTERER: Yes your Honor, we will be prepared
11 with our first witness, should jury selection be -- we are
12 prepared to go right on through opening, and we hope to use the
13 entire day, given the timed nature of the trial.

14 As you were going through the jury selection,
15 something just occurred to me, and it was just a question.
16 Let's say whenever it is the panel is brought up after whatever
17 challenges we have agreed on, will you seat them all in the
18 audience or will some be in the jury box?

19 THE COURT: The way I generally do it, I refer to it
20 as a "modified struck system" but it works something like that.
21 I fill the jury box, and I think by filling the jury box, I
22 always have to look, but I think you get three challenges
23 apiece. Am I correct on that?

24 MR. KETTERER: I believe that's right.

25 THE COURT: So, I fill the jury box. The jury box, as

1 you can see, has 18 seats in it, or can have 18 seats, we have
2 got some seats that we move around, and I would let you
3 challenge against that box.

4 MR. KETTERER: I see.

5 THE COURT: Now, if we get under -- if you say, oh,
6 please, please, let me have four challenges and I have people
7 in the courtroom, I might do that, in which case if you
8 challenge somebody who is in the box I have to put somebody
9 else in there, we will do it that way. And I am going to do it
10 back and forth. Sometimes I just make you do simultaneous
11 challenges. I do not think I will do it this time.

12 MR. KETTERER: So, pass.

13 THE COURT: So, we will go back and forth, plaintiffs
14 first, defendants, plaintiffs, defendants and you may say,
15 "Jeez, there's one person there who is squirrely, and I do not
16 want them on the jury. You may not say that, but you would
17 say, "I would like to have another challenge, please," and if I
18 have got people in the courtroom I will let you have them.

19 MR. KETTERER: Okay.

20 THE COURT: But when you go back and forth, let's say
21 you knock off Number 1. I will not fill that seat, and then
22 the order in which they will sit continues to change. Now,
23 because we are talking about 18 people in the box and three
24 challenges, that works out, assuming that you use your
25 challenges there.

1 MR. KETTERER: Peremptories, right.

2 THE COURT: I probably will have a few more here, just
3 in case there is some problem.

4 MR. KETTERER: Okay. And you mentioned 12. Are you
5 12 plus 2 alternates or 12?

6 THE COURT: 12. As I read the rule, it is a 12-person
7 jury. Now, maybe I have reached that point where I should read
8 all the stuff again each time, but I think I have got that
9 right, don't I? I have had confirmation. But, in any event,
10 you will get all you are entitled to, which I think is three
11 apiece.

12 MR. KETTERER: Fair enough. I meant alternates, is
13 what I was asking about.

14 THE COURT: There are no alternates in civil cases --

15 MR. KETTERER: No alternates, okay.

16 THE COURT: -- in the Federal Court.

17 MR. KETTERER: Right. So, if it just drops, you just
18 drop the number.

19 THE COURT: Right, and we can drop it down to, I can't
20 remember, five, something like that.

21 MR. KETTERER: Yeah, yeah.

22 MR. BENNETT: On the subject of opening, your Honor,
23 and factoring in your statements about surprises, what is the
24 Court's preference regarding use of exhibits in openings?

25 THE COURT: Anything that you have a good-faith basis

1 for believing will be introduced you may use. You have got to
2 share it with opposing counsel. I will permit chalks, again,
3 on a good-faith basis. The chalk should not, from the
4 plaintiff's perspective, say, "They did it," at the top and
5 then something else. It is a straightforward kind of, "I just
6 want to show you a timeline," or whatever it is.

7 MR. KETTERER: Sure.

8 THE COURT: But anything that you realistically think
9 is going to be introduced I will probably let in, but the first
10 order of business is to make sure you have shared it with
11 opposing counsel and any objections have been addressed, or you
12 bring them to me.

13 MR. BENNETT: Tuesday after court would be, because we
14 won't open on Tuesday, if we have any disagreements would that
15 be an appropriate time to raise them?

16 THE COURT: I am multitasking, so I have a few other
17 things on then, or I have got defendants and stuff coming in.
18 But, yeah, we can deal with it then. I will find the time.

19 MR. BENNETT: Hopefully we will agree.

20 THE COURT: Yes. It is going to be very brief in the
21 morning, kind of my Boy Scout lecture to the jury about the
22 importance of what they are doing and generally what the case
23 is about and who the people are, the lawyers that they will
24 see, according to you, but you will not have a speaking role at
25 that time, and then they will be left to do their

1 questionnaires, and they will go home. And so, the rest of the
2 day, except as the schedule, we can take up various matters.

3 MR. BENNETT: You mentioned Mrs. Dial perhaps
4 appearing up there. Would it be expected that we would have a
5 representative?

6 THE COURT: Here is my preference. But a party is
7 entitled to be present. My preference would be simply to say,
8 "These are the lawyers," and then when we are doing the
9 openings, before the openings, just kind of point out people
10 who are going to be in the courtroom on a regular basis.

11 MR. KETTERER: Okay.

12 THE COURT: I also, in connection with the
13 questionnaire, I think I would like to have identified counsel
14 who are going to be there on a regular basis so that the jury
15 can check off as to them and the witnesses, likely witnesses,
16 just to avoid the unhappy experience of having the juror look
17 across at the witness box and see their brother-in-law. We can
18 foreclose that by asking the question. I realize you are still
19 tightening this up, but if you can provide me with a list
20 sufficiently in advance so I can get it into the questionnaire
21 it will be helpful.

22 MR. BENNETT: We had actually reached an agreement
23 that we would disclose retained experts Monday and then final
24 witnesses on the 12th. If it is just a checklist, is that a
25 sufficient time to give you the list of witnesses?

1 THE COURT: I don't know about the 12th. We can talk
2 to Mr. McAlear, but he has got to make the copies and that kind
3 of stuff.

4 MR. BENNETT: We are happy to do it whenever he says
5 any time after Tuesday.

6 THE COURT: And especially since we have got a holiday
7 on Monday, they send it out to get the discs and that kind of
8 stuff. So, maybe if you can be thinking in terms of the 11th.

9 MR. BENNETT: We agree to the 11th, your Honor.

10 THE COURT: I don't want a lengthy list. I want a
11 list that is realistic. On the other hand, if there are people
12 that you are not quite sure of, we'll include them on the list.

13 MR. KETTERER: Your Honor, one of the logistical
14 questions with respect to the jurors. How long will we have
15 with those discs to look at them?

16 THE COURT: I am not sure. We have to ask
17 Mr. McAlear. But my hope is you get them in the early
18 afternoon, and you could run through them and at least identify
19 some people that do not have to be invited back again.

20 MR. KETTERER: Very good.

21 THE COURT: The reason for me is, if there is no
22 chance that they are going to be sitting in this case let's get
23 them out of here --

24 MR. KETTERER: Fair enough.

25 THE COURT: -- and if we can do that logistically, I

1 would like to do it, but we are at the mercy of both the
2 Xeroxing and the disc-making aspect of it. I assume that the
3 first thing you will do when you get the disc is make copies of
4 everything. But I would like to think that we could get back
5 here and go through the list, at least as to agreed ones, by
6 3:30 or 4:00 that day, and that will give me a chance --

7 MR. KETTERER: Okay.

8 THE COURT: But Mr. McAlear is, A, very accommodating,
9 and, B, he can do magic, and so if we tell people that they do
10 not have to call in until 8:00 to see, then we can probably
11 take that time to do it, too.

12 MR. BENNETT: And on trial exhibits -- and I was
13 trying to do this last time I was before you -- but what we
14 suggested and talked about agreeing to is starting with 1
15 before we show up, the plaintiffs would have all the medical
16 record compilations, that there's no dispute as to
17 admissibility up to a certain number, and then we would mark
18 ours consecutive to that.

19 THE COURT: Yes.

20 MR. BENNETT: And I think the parties have agreed that
21 those could be just received in evidence, if that's okay.

22 THE COURT: That is, except the only thing that I
23 would like you to do is identify that you are tendering, to
24 which there is no objection, "I offer Exhibit No. 2, to which
25 there is no objection," because it is helpful for the Clerks to

1 keep track of it, it is helpful for the Court of Appeals to
2 keep track of it, for the record to reflect it. So, you would
3 make a formal tender, but I would simply say, "Admitted," or
4 something like that.

5 MR. BENNETT: And then on that, I know that we talked
6 about making sure the documents were received in sequential
7 order. As to the premarked and pre-agreed, I guess, in
8 essence, joint exhibits, even though they are selected by both
9 parties, would the expectation be that those could start at 1
10 and then end up wherever they are on the list?

11 THE COURT: Yes. I will tell the jury, and they will
12 know that there may be numbers that were not used or that they
13 are skipped around or something happened like that. I will
14 want at the end, and of course you know that we now have a JERS
15 system, that is to say one in which the jurors will not only
16 get the hard copy, but they will have discs of their own that
17 will be in there that will have a list that they can follow, a
18 menu that they can follow, again, not something that says,
19 "Critical document that shows that Fresenius had nothing do
20 with this," or something like that.

21 MR. BENNETT: That was my Exhibit 1.

22 THE COURT: Right, I understood that. Just generic
23 explanations so that that would prompt their recollection.

24 MR. BENNETT: And then after the agreed-upon medical
25 records we were thinking then the Court would want us to go

1 sequentially, but in the last case I know the plaintiffs took
2 one group, and then we took another and numbered them in
3 advance. Is that acceptable, or would you rather have us just
4 pick up on sequence?

5 THE COURT: If you know that you are pretty firm on
6 the agreed-upon exhibits, I would like you to just go through
7 the plaintiff's first, defendant's, agreed-upon ones, and then
8 we will go from there on that.

9 MR. BENNETT: Okay.

10 THE COURT: I do not stand on the ceremony that this
11 is a defendant's exhibit or a plaintiff's exhibit. It is an
12 exhibit the Court let get in, so it does not take on some
13 different dimensions simply because one party or the other
14 introduces it. Generally I give an instruction to the jury and
15 say it doesn't make a difference how many exhibits or which
16 party introduced them. It is the quality of the evidence that
17 counts, that sort of thing.

18 MR. BENNETT: Thank you, your Honor. I think that
19 answers the logistical questions that I was trying to work out
20 with the plaintiff yesterday.

21 (The Court conferred with the Clerk off the record)

22 THE COURT: Mr. Hohler was mentioning I guess, because
23 of the conversations he has had about some place to put
24 equipment and that sort of thing, I hope it is not additional
25 cell phones you are planning on. I think there will probably

1 be fewer, one would hope, fewer cell phones that make their way
2 into the courtroom.

3 Generally the way we do it is that the party that is
4 presenting evidence has presumptive rights to the conference
5 room that is just to the right as you go out here, but I would
6 assume that you could share it for various kinds of purposes
7 there. It is just that if you want to keep your witnesses
8 somewhere or have a place to talk and stuff, the party who is
9 putting it on at that time gets to use that space.

10 I don't know what other real estate you might like. I
11 don't think there is much on offer.

12 MR. BENNETT: I think the only thing we were thinking
13 about is just if we needed copies of exhibits, but now that you
14 have gotten our exhibits down to a bread box size, I think we
15 are going to be okay.

16 THE COURT: Right, right. It will just be the number
17 of loaves of bread.

18 MR. KETTERER: Very good, your Honor.

19 THE COURT: So, I will see you, shall we say, 9:30? I
20 don't know. People are out of town.

21 MR. BENNETT: We'll all be in the night before.

22 MR. KETTERER: 9:30 is fine with us.

23 THE COURT: So, 9:00?

24 MR. KETTERER: 9:00's fine.

25 THE COURT: I don't want to wake somebody up or

1 anything.

2 MR. KETTERER: 9:00.

3 THE COURT: 9:00 is okay? All right.

4 Oh, let me pass back the Hakim memo that was passed up
5 to me and also the April 8, 2010 Acid/Base Concerns memo.

6 MR. BENNETT: Thank you, your Honor.

7 MR. KETTERER: Thank you, your Honor.

8 MS. BROOKS: Thank you, your Honor.

9 THE CLERK: All rise.

10 (The Honorable Court exited the courtroom at 3:47 p.m.)

11 (WHEREUPON, the proceedings adjourned at 3:47 p.m.)

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C E R T I F I C A T E

I, Brenda K. Hancock, RMR, CRR and Official Reporter of the United States District Court, do hereby certify that the foregoing transcript constitutes, to the best of my skill and ability, a true and accurate transcription of my stenotype notes taken in the matter of *In Re: Fresenius GranuFlo/ Naturalyte Dialysate products Liability Litigation*, No. 1:13-md-02428-DPW and *Dial v. Fresenius Medical Care Holdings, Inc.*, No. 1:14-cv-11101-DPW.

Date: February 5, 2016

/s/ Brenda K. Hancock
Brenda K. Hancock, RMR, CRR
Official Court Reporter