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1 P R O C E E D I N G S

2 (The following proceedings were held in open court
3 before the Honorable Douglas P. Woodlock, United States
4 District Judge, and the Honorable Maynard M. Kirpalani, Suffolk
5 Superior Court Judge, at the John J. Moakley United States
6 Courthouse, One Courthouse Way, Courtroom 1, Boston,
7 Massachusetts, on Wednesday, October 14, 2015.)

8 THE CLERK: This is Civil Action 132428 In Re:
9 Fresenius GranuFlo Litigation and 13340 In Re: Consolidated
10 Fresenius cases.

11 JUDGE WOODLOCK: Good morning. Let me make a couple
12 of brief introductory remarks in large part because I'm host
13 here in the sense that we're doing it in this courtroom, but it
14 is truly a joint hearing. And in saying that, I'm going to
15 emphasize a couple of things that are probably obvious to you
16 but bear emphasizing.

17 We're doing this on a consolidated basis or a
18 coordinated basis because we recognize the importance of having
19 these cases, both in the State and Federal Court, litigated in
20 more or less the same way. But we also recognize that we have
21 to make our own determinations, and there is somewhat different
22 case law in the First Circuit than there is in the
23 Massachusetts state courts. Fortunately, we've had an
24 opportunity to chat together. We will have further
25 opportunities to chat together. But you should understand that

1 you're speaking to two different courts in making your
2 arguments.

3 I think there's another dimension that I want to
4 emphasize at the outset. There's lots of paper, but we've been
5 trying our best to keep up with it. So while I won't call it a
6 hot bench, I will say that you don't have to do a lot of
7 remedial work here. You can get right down to the meat of the
8 arguments generally. Because chronologically this litigation
9 is going to start first in the state court, I think that Judge
10 Kirpalani will be taking the laboring oar, at least initially,
11 in the way in which we shape these hearings. But anybody who's
12 been in my courtroom knows that I can't keep my mouth shut, so
13 you're likely to hear from me, too, during the course of the
14 arguments.

15 One very practical point. This is technical stuff.
16 The court reporters are terrific, but don't make their life
17 more difficult. Speak slowly. And if you don't speak slowly,
18 then I'll tell you to speak slowly, with increasing decibel
19 levels, so speak slowly here. But having provided that general
20 kind of introduction, I'll turn it over to Judge Kirpalani.

21 JUDGE KIRPALANI: Thank you, Judge Woodlock. And of
22 course at any time during the proceedings feel free to
23 interrupt me or jump in.

24 And so we have a schedule. We're essentially going to
25 follow that schedule to the best of our ability. And on

1 Friday, just a housekeeping item, Friday we're going to be here
2 as the parties requested and Judge Woodlock was gracious enough
3 to offer us the courtroom. It won't be a joint hearing, so I
4 have to find my own court reporter, so I'm working on that. So
5 I should know later today that we have a state court reporter
6 dedicated to the session.

7 Failing that, there's the option of recording here, I
8 think. And failing that, or perhaps in preference to that, the
9 parties can retain a court reporter which I'm authorized to
10 certify as the official record keeper of the proceedings. So
11 I'll keep you posted. Hopefully later today I'll know that one
12 of our court reporters from Boston can cover this on Friday.

13 So with that, I don't know if the parties had any
14 contemplation of proceeding other than just picking up motion
15 by motion. Is there anything anyone -- any party wants to say
16 at the outset? I guess I'll invite that.

17 If not, we're leading off with the motion by Fresenius
18 to exclude portions, I would say, of statements, conclusions,
19 opinions contained in the so-called Hakim memo and the opinions
20 of experts who rely at least in part on those things.

21 So who will be arguing for Fresenius?

22 MS. BROOKS: I will, your Honor. Juanita Brooks.

23 JUDGE KIRPALANI: Thank you. And I will echo what
24 Judge Woodlock said. We've read the papers. I may not be able
25 to conjure up every footnote and every journal article cited,

1 so if there is a detail or scientific point that bears
2 explanation, then feel free to expand. I'll certainly ask you
3 if I have a question about something. Okay. So Ms. Brooks.

4 MS. BROOKS: Thank you very much.

5 JUDGE KIRPALANI: I am going to be taking notes on my
6 computer. I'm not playing solitaire, so I'm not distracted,
7 although I may not be looking at you at all times.

8 MS. BROOKS: Thank you for letting me know that, your
9 Honor. With the Court's permission, may I do the argument
10 predominantly from here rather than the podium?

11 JUDGE KIRPALANI: Absolutely.

12 MS. BROOKS: May I also approach? What I have are
13 copies of the Hakim memo in its entirety so we don't have to
14 keep flipping back and forth. For your Honors, I have one I
15 will share with the clerks, and I do have copies of PowerPoints
16 for both courts and clerks and for opposing counsel. So if I
17 may approach.

18 JUDGE KIRPALANI: Yes.

19 MS. BROOKS: Thank you.

20 Mr. Clerk, if we could put on the PowerPoints, the
21 screen, we can begin. Your Honor has asked us to get right to
22 the meat, and so we will do that, which is, this challenge goes
23 to certain opinions that were stated in what we refer to as the
24 Hakim memo, which was distributed among Fresenius medical
25 directors and physicians on November 4, 2011. From that, this

1 entire litigation began. And from that, plaintiffs' experts
2 base their first line of causation on the Hakim memo. So if I
3 could have just a moment, I have a board that I'm going to be
4 referring to back and forth. So if I could put it up, we can
5 show the Court.

6 Is this a good spot for your Honors?

7 JUDGE WOODLOCK: Yes.

8 JUDGE KIRPALANI: Perfect.

9 MS. BROOKS: So plaintiffs' general causation theory
10 is essentially this. It begins with the accused products,
11 GranuFlo and NaturaLyte. What are GranuFlo and NaturaLyte? As
12 you saw from our briefs, dialysis, nowadays bicarbonate-based
13 dialysis is a three-stream process. There is a stream that is
14 purified water, there is a stream that is bicarbonate itself,
15 and then there is a stream that is an acid concentrate.
16 GranuFlo and NaturaLyte are acid concentrate products of
17 Fresenius. Based on the Hakim memo and opinions in the Hakim
18 memo, there was an allegation that GranuFlo and NaturaLyte
19 cause alkalosis.

20 Now, for a moment I'd like to discuss terminology.
21 Alkalosis, which the plaintiffs use regularly that term, isn't
22 really defined in the Hakim memo, and it's really not defined
23 in the plaintiffs' papers, other than referring to high serum
24 bicarbonate. Technically alkalosis is not really a state or
25 condition. It is a process. The osis meaning like osmosis,

1 for example, it is a process that occurs when the serum
2 bicarbonate is raised. That actually happens in every dialysis
3 session deliberately. Once a patient's kidneys fail, they no
4 longer can excrete bicarbonate, for example, through their
5 urine. I'm sorry. They can no longer excrete the acid through
6 their urine. And yet, they continue to build up acid. We
7 build it up what they call endogenously from our bodies. We
8 build it up from what we eat, especially high protein diets
9 will lead to a lot of the acid.

10 So a dialysis patient whose kidneys don't buffer that
11 tend to run what's called acidotic, meaning on the low end of
12 the pH scale. So the natural pH is 7.4. Hopefully we're all
13 that right now. I could raise my pH right now by simply
14 breathing rapidly. I wouldn't raise it to dangerous levels,
15 but I would raise it perhaps to 7.45 or even as high as 7.5. I
16 could lower it by just not breathing, and down it would go.
17 But essentially our kidneys and our respiratory system keep us
18 around 7.4.

19 What happens in a dialysis patient, however, is
20 because you don't have the kidneys buffering the way they
21 normally do, in between the dialysis periods, in the
22 interdialytic period, the acid is building up and there's no
23 bicarbonate to counteract it. So the whole purpose of dialysis
24 is actually to raise serum bicarbonate so that the patient
25 walks out of there with a much higher serum bicarbonate than

1 they walked in with to tide them over during the 48 hours where
2 they will not be receiving dialysis.

3 Sort of the holy grail of dialysis companies is what's
4 called the wearable kidney where you don't have to go to the
5 dialysis center. 24 hours a day you would have something. Dr.
6 Lipps, the founder of Fresenius, has tried for many, many years
7 to come up with it and has been unsuccessful. So patients now
8 still come to the dialysis center three times a week, Monday,
9 Wednesday, Friday, or Tuesday, Thursday, Saturday. So there is
10 always at least that 48-hour period or some time between the
11 last session of one week and the first session of the other is
12 a 72-hour period. And during that entire period, the patient's
13 serum bicarbonate is dropping. Then they go in and get
14 dialysis. Their serum bicarbonate is raised.

15 So what Dr. Hakim and plaintiffs are really talking
16 about is not really alkalosis. They're talking about a patient
17 being alkalotic. That is the state. Alkalotic, a patient
18 being alkalotic is defined as having a pH of higher than 7.45.
19 So it really isn't even the serum bicarbonate we're talking
20 about when we talk about someone being alkalotic or suffering
21 from alkalemia. However, serum bicarbonate has come to be
22 known as sort of a proxy because taking pH levels, you do a
23 blood gas where you actually kind of have to do it on-site
24 rather than ship it to a laboratory. And most dialysis
25 patients have their blood drawn once a month before the

1 dialysis session, so you're going to hear this term
2 "pre-dialysis" quite a bit, before the dialysis session, to see
3 how well they are doing. And in that lab draw is going to be
4 their magnesium, their potassium, their calcium, their
5 bicarbonate, their hemoglobin, their hematocrit, et cetera.
6 That's all in the lab. So once a month the doctor can look and
7 see how the patient is doing month by month on dialysis.

8 So the allegation in the Hakim memo is that the acid
9 concentrates, GranuFlo and NaturaLyte, which contain acetate --
10 NaturaLyte has 4 milliequivalents of acetate, GranuFlo has 8
11 milliequivalents of acetate because it is a sodium diacetate.
12 The reason it has more than NaturaLyte is that GranuFlo is a
13 dry powder. The reason that the company went to a dry powder
14 from liquid is that NaturaLyte is delivered in 55 gallon drums.
15 They're difficult to transport. They're difficult to store.
16 There are occasionally leaks, so it could be dangerous.
17 GranuFlo is in a bag, and it is mixed fresh every day with a
18 big mixer that's there at the clinic.

19 And the reason there has to be an acid concentrate as
20 one of the streams is that the bicarbonate is at too high of a
21 pH. So the equivalent, if you get up too high, you're up on
22 sort of the lye end of the pH spectrum versus the acid end of
23 the pH spectrum. So what the acid concentrate does is it
24 reacts with the bicarbonate to create a physiologically
25 comfortable pH and to prevent some of the electrolytes that are

1 in the acid concentrate from precipitating out, particularly
2 calcium and magnesium. So that's why we have to have the acid
3 concentrate. And ever since the beginning of bicarbonate-based
4 dialysate there has been an acid concentrate as one of the
5 streams.

6 Now, what's interesting is that even before
7 bicarbonate-based dialysate, dialysis was done using only
8 acetate of levels of anywhere from 35 to 42 milliequivalents of
9 acetate. And the theory was that the acetate would metabolize
10 in the patient's body into bicarbonate and that that process
11 would help raise the serum bicarbonate. So a patient who
12 walked in acidotic would walk out slightly alkalotic.

13 It wasn't the best system, but it was the only system
14 at that point they had because they weren't able to do this
15 bicarbonate-based dialysis because they didn't have these
16 three-stream and proportioning machine. They hadn't yet been
17 developed. So it was acetate only of very, very high amounts.

18 It was somewhat successful. It would raise their
19 serum bicarbonate somewhat, not good enough, and some of the
20 acetate would sort of oversaturate the ability to metabolize
21 it, and patients would have cramping, nausea, sometimes even
22 vomiting as a result of having too much of acetate, but we're
23 talking about levels up there where they were exposed to
24 anywhere from 35 to 42.

25 Now modern day, we've got the three-stream. Everyone

1 has -- and I don't mean just Fresenius. All makers out there
2 have to have an acid concentrate, all makers of dialysate. But
3 the Hakim memo zeroed in on GranuFlo and NaturaLyte and alleged
4 that the use of these two products was causing alkalosis,
5 meaning really alkalemia or patients to become alkalotic.

6 So now let's look at how we got there.

7 So the patients -- excuse me -- the plaintiffs make
8 much of, this memo was supposedly vetted by the top scientists
9 at Fresenius and therefore it gives it some semblance of
10 reliability. The truth is that most of the conclusions that we
11 are challenging were not vetted. Dr. Hakim added them after
12 the final draft of the memo was circulated.

13 And just to be clear, when I say the conclusions we're
14 challenging, we're actually moving to exclude conclusions, but
15 we're moving to exclude them because they were based on
16 unreliable methodology. So it is the methodology we are
17 challenging, not really the conclusions per se. But in a
18 *Daubert*, one moves to preclude certain opinions because they
19 are based on unreliable methodology.

20 So if we look here, this shows us what Dr. Hakim
21 changed right before the memo was circulated and without
22 authorization or even review by anyone else at Fresenius. So
23 the first one is obviously minor. He got rid of the term
24 "revised draft" and turned it into "internal memo." The second
25 again is minor. It's simply changing the date.

1 The third one, though, he adds the term "Conclusion."
2 Now, this terms what originally looked like sort of an opinion
3 piece of Dr. Hakim hypothesizing, "Well, these are my
4 observations. This is what I think may be going on," into
5 something that looked much more like a peer review paper, but
6 it wasn't a peer review paper. And so Dr. Hakim adds the word
7 "conclusion" as if these conclusions have somehow been proven
8 through a reliable methodology.

9 Note the next thing he does is he deletes the
10 definition of alkalosis. So while making the accusation that
11 GranuFlo and NaturaLyte cause alkalosis, he gives the reader no
12 guidance as to what he means by that. Dr. Lazarus had
13 suggested the definition of alkalosis be a pre-dialysis
14 bicarbonate, pre-dialysis of greater than or equal to 28
15 milligrams per liter. That was inserted by Dr. Lacson per Dr.
16 Lazarus's request, and that was deleted by Dr. Hakim before the
17 memo was circulated but without giving anyone a chance to weigh
18 in on that deletion.

19 The next additions are that Dr. Hakim added the terms
20 "cardiopulmonary" or "CP arrest," and then the last, and the
21 one that was essentially the match that lit the firestorm was
22 this next sentence: "The major cause of metabolic alkalosis in
23 dialysis patients is inappropriately high total buffer
24 concentration." That was put in by Dr. Hakim again with no
25 review by anyone else. It was not authored by Dr. Lacson, who

1 authored other portions but not this statement.

2 So we will come back in a moment to why this
3 conclusion -- how this conclusion is based on faulty
4 methodology and why that methodology is faulty.

5 The next addition Dr. Hakim did was take the summary
6 and add the term "of findings," thereby again giving it much
7 more weight and gravitas. Originally these were simply the
8 ipse dixit of Dr. Hakim and some preliminary conclusions of Dr.
9 Lacson as to what his analysis showed, but now they've become
10 officially findings. And then -- and Dr. Hakim also deletes in
11 the second bullet point the word "likely." So it goes from
12 again a hypothesis to a stated absolute fact.

13 And the last thing was that the words -- essentially,
14 it's simply saying let's look at these issues and we ought to
15 address them as soon as possible. The words "as soon as
16 possible" were deleted and Dr. Hakim put in the word
17 "urgently." Now, that would seem not to be a big deal, but
18 that word "urgently" was grabbed by The New York Times when
19 they saw this memo. That word "urgently" was grabbed by a
20 gentleman named Gary Peterson who does a blog called RenalWEB,
21 and that word was grabbed by the FDA. Because apparently, to
22 read this, to a reader who doesn't know how this came to be, it
23 looks as if there's a crisis when in fact there was no crisis
24 at all.

25 So let's take the first challenge. The first

1 challenged finding is the one that Dr. Hakim added with no
2 one's permission or review; that the major cause of metabolic
3 alkalosis in dialysis patients is inappropriately high
4 dialysate total buffer concentration.

5 Now, as your Honors probably saw in looking at all the
6 paper that has been filed with the Court by both the defendants
7 and the plaintiffs, it's very difficult to show in medicine
8 that anything is an actual cause of something else. You may be
9 able to show an association, but to show an actual cause that
10 something actually is causing something, you need not just
11 observational studies but very detailed epidemiological
12 analysis and, if possible, even a clinical trial where you can
13 actually test this hypothesis. None of that took place before
14 Dr. Hakim inserted that conclusion in this memo.

15 There is, in the memo, it is devoid of any methodology
16 describing how he came to this conclusion. It is devoid of any
17 data to support this finding, literally. The data you see in
18 the memo does not talk about inappropriately high total buffer
19 concentration. The data in the memo talks about pre-dialysis
20 serum bicarbonate levels. It shows no data regarding what the
21 physicians' prescriptions were, what the total buffer
22 concentrations were, et cetera.

23 So as a result, since there is no methodology and
24 there is no data in the memo, we can't replicate this finding.
25 We can't even test it because there's no way to go about it.

1 The memo was never peer-reviewed, including this finding. It
2 was never published. It was, as I mentioned already, never
3 even reviewed or approved internally. And I know the term ipse
4 dixit was used repeatedly throughout the pleadings by both
5 sides. But this is essentially the most classic form of ipse
6 dixit from an expert.

7 Why is this true? Because Dr. Hakim believed it and
8 said so with absolutely no analysis or methodology to back it
9 up. One of the problems, it talks about inappropriately high
10 dialysate total buffer concentration. There is no definition
11 of what Dr. Hakim meant by "inappropriately high." One could
12 assume that he meant that the physicians didn't realize they
13 were prescribing as high a total buffer concentration as they
14 meant. But there's nothing in the memo about physicians'
15 bicarbonate prescriptions, not one word.

16 There is nothing in the memo about the total buffer --
17 we'll talk about that term in a bit -- about the total buffer
18 prescriptions, not one word. And there is nothing about
19 whether physicians did or did not change their prescriptions
20 for bicarbonate as a result of knowing that there was 4 acetate
21 in NaturaLyte or 8 acetate in GranuFlo. And in fact, there is
22 no survey data where physicians were surveyed about, "Do you
23 realize that there is acetate in NaturaLyte and GranuFlo that
24 could be metabolized into bicarbonate?" Once it reaches the
25 patient, it is metabolized into bicarbonate by the liver.

1 There's no survey where the physicians were asked, "Do you
2 intend to be delivering X amount of bicarbonate to the
3 patients?" So this statement is devoid of any methodology or
4 data whatsoever to support it.

5 And this is the key statement. I don't mean to be
6 hyperbolic, so I will quote the plaintiffs. Plaintiffs say in
7 their brief that the 2010 study, which is referring to the
8 study that was done in 2010 by Dr. Lacson that became the 2011
9 memo, "play a key role in the events giving rise to the
10 litigation and address key issues in the case, excess
11 bicarbonate, alkalosis, hyperkalemia," which means low
12 potassium, "and CPA, cardiopulmonary arrest. Indeed the FDA
13 recall of GranuFlo and NaturaLyte was precipitated by the
14 November 2011 memo and the defendant's 2010 study."

15 So the plaintiffs agree this memo and particularly
16 this statement is the linchpin to this entire litigation. It
17 is rare where you have a litigation that comes down to one
18 document, but that is what we have here.

19 JUDGE WOODLOCK: Can I just ask --

20 MS. BROOKS: Yes, your Honor.

21 JUDGE WOODLOCK: How does this work on the ground?
22 That is to say, what do you want them to do? Do you want them
23 to say, "We never saw this," pretend that they never saw it?
24 How is it going to play out in examination?

25 MS. BROOKS: The way I would see it playing out, your

1 Honor, is that they are not allowed to base their expert
2 opinion that GranuFlo or NaturaLyte delivers excess bicarbonate
3 and in turn therefore causes alkalosis, they are not allowed to
4 base that opinion on the Hakim memo. They can look for it.

5 JUDGE WOODLOCK: What does that mean, that if someone
6 says, "What are the foundational bases for your opinion," they
7 can't say "Hakim"?

8 MS. BROOKS: Correct.

9 JUDGE WOODLOCK: They can rely on anything else?

10 MS. BROOKS: Correct.

11 JUDGE WOODLOCK: And maybe you, depending on the
12 strategy, you inquire about whether or not they looked at
13 Hakim, but that's up to you. Is that what you want out of it?

14 MS. BROOKS: Correct. Yes, your Honor. Also, to be
15 clear, plaintiffs have argued, "Wait a minute. You can't just
16 make a document that you, Fresenius, authored disappear." And
17 we're not trying to do that.

18 Clearly this memo will come in. I mean, it explains
19 how we got here in the first place, but it won't come in with
20 the imprimatur of an expert blessing it and blessing its
21 conclusions. In fact, it could even come in with a limiting
22 instruction that it is not part of the basis for any expert
23 opinions in the case.

24 And there is case law that specifically says that if
25 something stands alone itself, it would not be admissible as an

1 expert opinion, for example, Dr. Hakim coming in and giving
2 these opinions -- now, he said he's not coming, so we won't be
3 able to have him give these opinions. But if he were to, it
4 would be the subject of a *Daubert*.

5 Now, the fact that he's not coming doesn't mean that
6 the experts of the plaintiffs can act as his mouthpiece and
7 simply regurgitate his opinions in their opinions if his
8 opinions don't pass *Daubert-Lanigan* muster.

9 JUDGE WOODLOCK: Can I ask another practical question?
10 You say he's not coming. Is his deposition available for use
11 by the parties here?

12 MS. BROOKS: Yes, it is, your Honor.

13 JUDGE WOODLOCK: And does his deposition include an
14 opinion?

15 MS. BROOKS: Yes.

16 JUDGE WOODLOCK: Are we being asked to exclude that
17 opinion, that is, the deposition opinion as opposed to this?

18 MS. BROOKS: Your Honor, I guess the answer would be
19 yes. We would be asking to exclude that as an expert opinion.
20 Now, again, as evidence that Fresenius's one-time chief medical
21 officer said it with a limiting instruction that it is not in
22 the form of an expert opinion, that certainly is going to get
23 before the jury.

24 Now, can the jury hopefully then decide in their mind
25 and understand the difference between expert opinion and simply

1 someone saying something -- I mean, to take an extreme example,
2 if Dr. Hakim had opined in a memo that the world was flat and
3 what Fresenius was doing was driving people to the edge, and if
4 we weren't careful, people were going to start falling off and
5 dying, he said it, it would come in that he said it. But
6 certainly no one could rely on it for their expert opinion that
7 Fresenius was liable for killing people because they fell off
8 the edge of the Earth.

9 Because he said it does not make it so. And that is
10 why it's so important not to give this, as I said, the
11 imprimatur of an expert opinion. That's how we all began with
12 *Daubert*. I believe the *Daubert* case ends with a quote from, I
13 think it was Justice Weinstein about how juries are in some
14 ways dazzled by experts. They tend to believe whatever they
15 say despite what the cross-examination is. And that's why the
16 Court must act as the gatekeeper and prevent the jury from
17 hearing expert opinion that does not meet the *Daubert-Lanigan*
18 criteria.

19 JUDGE KIRPALANI: So it's been a few years since I
20 applied the Federal Rules of Evidence, but under Mass. Rules of
21 Evidence, you know, isn't the party admission rule an exception
22 to the opinion rule so that opinions in a party admission come
23 in for their substantive value? So you're talking about a
24 limiting instruction to a jury if this memo is in that I guess
25 they can't rely on it or they can't treat it as scientifically

1 reliable. Is there case law that supports that request to tell
2 the jury that there's a limit to what they can treat this for?

3 MS. BROOKS: Yes, your Honor, there is. And we cite
4 it in our brief, and I'd be happy to cite it. At the break
5 I'll get the specific cases, but they talk about exactly that.

6 Now, experts are allowed to rely on other documents,
7 some that may not even be admissible themselves, but only if
8 those particular documents are the sort that would normally be
9 relied upon by a scientist. And in this case where you have no
10 methodology, no data, nothing but ipse dixit, experts are not
11 allowed to rely and base their opinions on this. And should
12 this come in as a party admission against us, if the jury is
13 then instructed that that's the purpose of it coming in but it
14 is not coming in as an expert opinion on this premise -- and
15 I'll go back to the first one we're talking about -- then the
16 jury can decide, "Well, we actually want to rely on it," and
17 they may. But at least it will not be coming in as expert
18 opinion per se, and they will be told in fact that it is not
19 coming in as expert opinion.

20 And to the extent the Court wishes to elaborate on why
21 it's not coming in as expert opinion, it's been deemed by the
22 Court to be based on unreliable methodology, then the jury can
23 decide the weight they decide to give to the admission by the
24 company.

25 So we're not asking to exclude the memo. I think that

1 would be unrealistic. I wish it had never happened, but we're
2 not allowed to go back in time and get in the time capsule and
3 wish that Dr. Hakim perhaps had been escorted out of the
4 building on October 19 when there was a discussion about he and
5 the company parting ways.

6 JUDGE WOODLOCK: I'm just trying to think through the
7 fact base.

8 MS. BROOKS: Yes, your Honor. So if we go to the
9 next --

10 JUDGE WOODLOCK: I have this question --

11 MS. BROOKS: Sorry, your Honor. Yes.

12 JUDGE WOODLOCK: -- which has to do with the limiting
13 instruction. Just thinking strategically -- I know nobody here
14 is thinking strategically, but I am. This is a trap play. Let
15 them come in, introduce the Hakim thing and then get the judge
16 to say, "That's worthless. Doesn't mean anything." That
17 essentially is what you're asking us to do, isn't it? That is,
18 first they make the first move. That's why I call it a trap
19 play. They come through the hole, and then all of a sudden the
20 guard comes across and nails them. And the guard happens to be
21 the Court itself, which is involving the Court in an evaluation
22 of the credibility of a particular witness.

23 MS. BROOKS: Well, interestingly, your Honor, in this
24 case, the plaintiffs would have had a preview. They would have
25 seen films of that exact play and know that they don't have to

1 introduce the Hakim memo or rely on it. They could simply have
2 their experts rely on anything but the Hakim memo. And in
3 fact, I think your Honor at one of our last hearings asked
4 Mr. Rotman if the Hakim memo and its opinions were excluded or
5 their experts were not allowed to rely on it, did they still
6 have a case, and Mr. Rotman said absolutely.

7 So they don't have to go into that play. They can put
8 in the Hakim memo as simply an admission by the company, but
9 they don't have to have their experts rely upon it. They can
10 have their experts rely on anything but it, and then they don't
11 have the issue come up. They proceed at their own peril if
12 they decide they want their experts to rely on it because they
13 believe it's reliable after the Court has found that it's not.

14 So they don't have to rely on it. They have,
15 according to them, a lot of other literature which they could
16 rely on. Does that answer your question, your Honor?

17 JUDGE WOODLOCK: It does. It makes the formulation of
18 a limiting instruction rather challenging, though.

19 MS. BROOKS: I concede that. And again, this is a
20 rather unique case where you have an ipse dixit of an expert
21 starting or -- well, we'll say Dr. Hakim is an expert. But
22 it's his opinions and his methodology and his data that we're
23 questioning but where you have it start an entire case and then
24 it turn out not to be reliable. And we know that it wasn't
25 reliable, and I'll jump ahead for a moment.

1 So as a result of the Hakim memo, as plaintiffs said,
2 FDA gets involved and says, "Boy, it looks like, according to
3 this memo, doctors don't realize that the acetate is
4 metabolizing into bicarbonate, and therefore they are
5 prescribing inappropriately high total buffer concentration,
6 which is the bicarbonate in the dialysate but plus the acetate
7 in the dialysate, and they don't realize it, so you need to
8 change your warning label, Fresenius. You need to change your
9 warning label to say that doctors need to be aware and
10 prescribe based on total buffer."

11 And so over the course of the year, Fresenius changed
12 all their labels on GranuFlo and NaturaLyte, all their user
13 manuals for their machine to reflect this total buffer concept.

14 Now what happens? What happens is litigation begins,
15 experts are hired, Dr. Lipps -- and we'll get to that later
16 this afternoon -- who has a Ph.D. in chemical engineering from
17 MIT and actually helped invent the hollow fiber dialyzer where
18 all this diffusion goes on looks at the issue and says, "Wait a
19 minute. We've missed something key here. We've missed the
20 concentration gradient and dynamic equilibrium" -- and again,
21 I'll get to that in a moment. But if physicians start dialing
22 their bicarbonate prescriptions back to take account of the
23 GranuFlo and NaturaLyte acetate, you're going to end up with
24 patients severely acidotic, and that is dangerous.

25 Fresenius over the several months had correspondence

1 with the FDA about this. There was a meeting in May of last
2 year. And FDA in almost an unprecedented move recalled the
3 recall. And what took Fresenius a year to put in about the
4 total buffer language on the warning labels and user manuals is
5 now all gone, pursuant to FDA agreeing that to leave that total
6 buffer language on there was indeed dangerous. So we've got
7 even FDA agreeing that Dr. Hakim's conclusions were not based
8 on science, were not based on reliable methodology, were not
9 even based on data.

10 JUDGE WOODLOCK: The FDA didn't actually say that.
11 We're supposed to infer that from their back and fill?

12 MS. BROOKS: Absolutely, your Honor. I mean, they
13 didn't condemn the Hakim memo. But since the original
14 recall -- and just to be clear, nothing was ever recalled as in
15 off the shelves. GranuFlo and NaturaLyte are being used today
16 as we speak, and over 100,000 people are getting dialysis
17 treatments in Fresenius clinics today as we sit in the
18 courtroom.

19 So the recall was simply changing the label to reflect
20 this total buffer language that Dr. Hakim has in this first
21 sentence that you see -- yes, "inappropriately high dialysate
22 total buffer concentration." That was the label change. And
23 now that language is off the labels.

24 And so one can certainly infer that FDA believed that
25 this is wrong or it would have had this remain on the label,

1 especially after having Fresenius put it on the label in the
2 first place. It now has been taken off.

3 JUDGE WOODLOCK: Do you intend to introduce that
4 affirmatively?

5 MS. BROOKS: Yes, we do, your Honor. We have the
6 minutes of the FDA meeting reflecting the discussions that were
7 had that resulted in FDA giving Fresenius permission -- let me
8 back up. If the plaintiffs don't introduce the recall, we of
9 course won't introduce the recall of the recall. But if the
10 plaintiffs do introduce the recall, then of course we need to
11 bring the jury up to speed on what's happened since then.

12 Going to Finding 2 that we challenge, "The bicarbonate
13 prescription entered into the dialysis machine underestimates"
14 -- and here the total buffer language again -- "the total
15 buffer that the patient receives from the dialysate by 8
16 milliequivalents in the case of dialysate from GranuFlo
17 (powder) or by 4 milliequivalents in the case of dialysate
18 prepared from NaturaLyte liquid since acetate is rapidly
19 converted into bicarbonate by the liver."

20 Now, we agree there's 8 milliequivalents in GranuFlo
21 of acetate, 4 milliequivalents of acetate in NaturaLyte. We
22 agree that acetate is rapidly metabolized into bicarbonate by
23 the liver, but there is no data or methodology disclosed in the
24 memo as to, again, how Dr. Hakim came to the conclusion that
25 the bicarbonate prescription entered into the machine

1 underestimates the total buffer.

2 First of all, again, as with the previous statement,
3 the memo is devoid of any description of methodology. The memo
4 is devoid of any data supporting this statement. Neither the
5 memo or this particular finding was ever peer-reviewed. And so
6 once again, we cannot test it. We cannot replicate it. It is
7 nothing more than the ipse dixit of Dr. Hakim.

8 Now, what is so wrong with this? First of all, the
9 term underestimates the total buffer that the patient receives.
10 So Dr. Hakim's use of "total buffer" in this context ignores
11 the fundamentals of dialysis, which is why that is unreliable
12 methodology. To ignore the law of gravity, to ignore the laws
13 of physics, to ignore the fundamentals in dialysis results in
14 an unreliable finding based on unreliable methodology.

15 So with the Court's permission, I would like to give
16 the Court a dialyzer since we're going to be talking about what
17 goes on inside this dialyzer, if that's all right with the
18 Court. Thank you.

19 JUDGE WOODLOCK: Sure.

20 MS. BROOKS: So your Honors, these dialyzers are
21 prescription items. They are prescribed by the doctor for a
22 patient, and they are used -- they are used once by the patient
23 and then thrown away. It used to be in the United States and
24 it still is in some countries where these are reused. For all
25 sorts of reasons you can imagine why that's not a good idea.

1 But what happens when a patient receives dialysis --
2 and you can take these little caps off if you'd like. The
3 tubing that comes from the patient into the dialyzer here and
4 here, that's where the blood goes. And all the patient -- over
5 the course of three and a half to four hours, all of their
6 blood is removed from their body and put through the dialyzer,
7 returned to their body. And this is done several times during
8 the course of the dialysis treatment.

9 And patients, once they have to go on dialysis, they
10 have what we call an access port, either in the form of a
11 fistula or a catheter that's always with them, always on them,
12 and it's capped and very important to keep it sterile and not
13 have it clot up, so that when they go they can just get hooked
14 up to the machine. So the blood comes in this way. Inside, if
15 your Honors look very carefully, you can see there are
16 thousands and thousands of fibers that are really no bigger
17 than a human hair, and these fibers are actually hollow.

18 JUDGE WOODLOCK: I'm sorry, they're --

19 MS. BROOKS: They're hollow. You wouldn't think they
20 could take a fiber that is this small, but they're actually
21 like microscopic straws, so they're hollow inside. And Dr.
22 Lipps, again who founded Fresenius USA, his Ph.D. thesis from
23 MIT was on hollow fiber membranes.

24 Before that advance, a dialyzer was a giant tub. And
25 through this advance, it was able to be made this small and

1 this sterile and single use. So the blood goes inside the
2 fibers, and then we see these two ports. And I think your
3 Honors may have caps on them. You can pull those off. The
4 tubing comes with the dialysate into this port and then runs
5 up. So the blood is coming down inside the fibers, and the
6 dialysate is running on the outside of the fibers in the
7 opposite direction and then will come out.

8 Now, the blood obviously is a closed system because
9 the patient only has so much blood. So it will come from the
10 patient into the dialyzer and back into the patient. The
11 dialysate is an open system, so it will come in through the
12 dialyzer up through the dialyzer, and this process of diffusion
13 will occur, which I will explain in a moment, and then the what
14 we'll call dirty dialysate goes out and is thrown away. So the
15 dialysate or dialysis solution, or sometimes you'll hear the
16 term "bath," is always being refreshed, and it will carry with
17 it various electrolytes.

18 So how does this work then? It works on something
19 called concentration gradient. And no one disputes this.
20 Unfortunately, Dr. Hakim seemed to forget it when he did his
21 total buffer let's add these two things together.

22 But this is how the concentration gradient works. In
23 the dialysate, let's take bicarbonate, for example, common
24 prescription is 35 milliequivalents per liter of bicarbonate in
25 the dialysate.

1 So here is the membrane separating the dialysate from
2 the blood, which is going up through the center of the hollow
3 fiber. And this is a semipermeable membrane, and it's really
4 very brilliant. This took over the work of the kidney. Now,
5 it's not perfect. Our kidneys are perfect. This does as good
6 a job as one can do considering it's not a kidney.

7 And what happens is if there is more bicarbonate in
8 the dialysate than there is in the patient's blood, then the
9 bicarbonate will diffuse through the semipermeable membrane
10 into the patient's blood, thereby raising their serum
11 bicarbonate level during the course of dialysis. This works on
12 every single thing that is in the dialysate. It works the same
13 way with the acetate. If you have 8 acetate in the dialysate,
14 and most of us have a trace of acetate in our blood, then
15 again, the acetate will diffuse through the semipermeable
16 membrane, down the concentration gradient into the blood.

17 But you know the bigger the difference between what's
18 in the dialysate, for example, and what's in the blood, the
19 steeper the gradient. This is important because it controls
20 the speed of diffusion. The more shallow the gradient -- let's
21 look over here at potassium. Most patients come to a dialysis
22 session with too high of a potassium, again because they're out
23 of equilibrium because their kidney is not functioning well.
24 So they come in with what's called hyperkalemia, too much
25 potassium, which can be very dangerous. So the average

1 dialysate potassium level is a 2 or a 3, sometimes a 1. It
2 used to be they did zero, but that had its own danger, so now
3 the most common one is a 2.

4 So if you have a patient comes in with a potassium
5 level of 5, now their blood has more potassium than the
6 dialysate does. So what happens is the potassium goes from the
7 blood and diffuses through the semipermeable membrane into the
8 dialysate and is then carried away, and since it's an open
9 system, is flushed away as the dialysis process continues. So
10 that hopefully when the patient leaves, they will have a lower
11 amount of potassium, and then it will slowly rise during the
12 interdialytic period of the 48 to 72 hours.

13 So let's look at what happens in animation that we
14 have of the concentration gradient. This is bicarbonate. A
15 patient walks in with a 22 pre-dialysis serum of bicarbonate,
16 and they are dialyzing against a 35 bicarbonate bath or
17 dialysate. As the serum rises during the course of the
18 treatment, you can see that the concentration gradient gets
19 more and more shallow.

20 Now, let me stop right there and go back for a moment.
21 This is done very rapidly in my animation. This is actually
22 done -- during dialysis, it happens much slower. The diffusion
23 process is over the course of three and a half to four hours.
24 And this animation shows the patient's serum bicarbonate
25 reaching the same level as that in the dialysate. Most

1 patients rarely reach the level that's in the dialysate because
2 the dialysis is just not long enough. To actually reach
3 equilibrium, experience is you need a minimum of eight hours,
4 12 hours more likely, but you just don't have patients willing
5 to do that. Some do nocturnal where they do come to the
6 hospital and spend the night. Usually it's a three-and-a-half
7 to four-hour session, so they don't actually reach equilibrium,
8 but they do get extra bicarbonate during the dialysis to pull
9 them up. So we have them here showing a 24, a 26, a 28, a 30
10 and keep going up just for the purpose of demonstrating to the
11 Court that once the amount should -- the amount of bicarbonate
12 in the blood equals the bicarbonate in the dialysate, the
13 diffusion stops because there is no concentration gradient.

14 Now, let's say the patient eats Tums in the middle of
15 their dialysis session, or let's accept the plaintiffs' theory
16 that somehow the acetate after it's metabolized into
17 bicarbonate in the patient will somehow bring the patient,
18 their serum bicarbonate higher than that in the dialysate.
19 What happens? What happens, as you can see on the screen, is
20 then diffusion will reverse itself just like it's happening
21 over here with potassium. If the patient's serum bicarbonate
22 ever gets higher than the bicarbonate in the dialysate, the
23 laws of diffusion, the physics, the fundamentals of dialysis is
24 that then the bicarbonate in the serum will begin diffusing
25 back into the dialysate.

1 And that is why Dr. Hakim's total buffer theory is
2 wrong. Because his total buffer theory is that because acetate
3 is metabolized in the patient into bicarbonate, what he was
4 saying in this memo to everybody is, "You physicians need to
5 add this 35 to this 8 and understand that this patient will be
6 dialyzing against a 43 total buffer." And sometimes he would
7 even change the word "buffer" to "bicarbonate" and say they're
8 going to be dialyzing against a 43 bicarbonate.

9 And we cite in our moving papers e-mails where Dr.
10 Hakim says, "This patient will come off the machine at a 43.
11 That is very dangerous," is what he was saying. But it's
12 physically impossible. If the patient's serum bicarbonate ever
13 got higher than the amount of bicarbonate in the dialysate for
14 whatever reason, be it the acetate, be it oral ingestion of
15 oral bicarbonate, for whatever reason, as soon as it goes over,
16 it will begin -- then diffusion will then reverse itself.

17 So his total buffer theory is not reliable because it
18 defies the laws of diffusion and concentration gradient and
19 equilibrium, which is why plaintiffs' experts who start their
20 entire analysis in this case with the presumption that GranuFlo
21 and NaturaLyte result in excess buffer, or as Dr. Hakim put it,
22 underestimates -- that there is an underestimation of the total
23 buffer that the patient receives or in his point or Finding 1,
24 that the major cause of metabolic alkalosis is inappropriately
25 high, dialysate total buffer concentration is simply not so.

1 It is not based on any scientific principle but again on the
2 ipse dixit of Dr. Hakim.

3 And it was that mistake and that failure to recognize
4 this that resulted in this entire litigation and the FDA recall
5 requiring the language, the total buffer language to be put on
6 the label which, thankfully, as I mentioned, is now off the
7 label. Secondly, that Dr. Hakim failed to recognize that the
8 machine in fact does not underestimate, if you want to call
9 total buffer the amount of the bicarbonate plus the amount of
10 acetate, this is a screen shot of what a Fresenius machine
11 looks like. And as you can see, the red box we have around
12 where the number 33 is, that is the bicarbonate, and that's how
13 you actually set your bicarbonate prescription. So if a
14 physician wants the patient to receive a bicarbonate dialysate
15 of 33, that field right there, you will enter a 33 into it.

16 Above it is a field for sodium, which can also be
17 altered by the physician. And on the left you see smaller
18 fields, and those are the electrolytes that are in the acid
19 concentrate. The first one, the K, you see potassium, then you
20 see calcium, then you see magnesium, and then you see acetate.
21 So a physician, if they want to know how much acetate is in the
22 acid concentrate, they need only look to the machine to see.
23 They don't even need to go back in the back and look on the
24 label where it also is displayed. They can see right here
25 there is 8 acetate in this particular acid concentrate. And

1 then the last field is dextrose.

2 So again, Dr. Hakim's finding that somehow the machine
3 is underestimating total buffer -- first of all, the total
4 buffer concept is simply wrong. But secondly, the machine
5 shows exactly how much bicarbonate is in the dialysate and
6 exactly how much acetate is in the dialysate.

7 Findings 3 and 4 -- do your Honors have any questions
8 about Finding 2 before I move on?

9 JUDGE KIRPALANI: Yes. How fast do the kidneys
10 metabolize acetate into bicarbonate?

11 MS. BROOKS: Actually, it's the liver, your Honor,
12 that does that.

13 JUDGE KIRPALANI: The liver. I'm sorry.

14 MS. BROOKS: The term -- there's a lot of organs that
15 we talk about during this process, including the lungs and
16 respiration. Everyone agrees "very rapidly" is the term they
17 use. They can't tell you to the second because frankly it
18 appears to happen almost instantaneously that as the acetate is
19 passed through the liver, it will then turn into bicarbonate.
20 But one of the things that we have seen repeatedly in various
21 studies is that -- and this is another issue -- so just to be
22 clear, the acetate stays acetate in the dialysate. It never
23 becomes bicarbonate. It has to go into the patient in order to
24 become bicarbonate.

25 So this total buffer idea of adding these two together

1 is just fundamentally wrong because this number right here is
2 what will control the amount of bicarbonate in the blood.

3 JUDGE WOODLOCK: Is there no association between the
4 two? That is to say, let's assume that in reaching equilibrium
5 for purposes of the acetate, you get to 8, and now it's 8 in
6 the blood as well, the kind of simple arithmetic that Dr. Hakim
7 did assumes an association with that bicarbonate as a result of
8 that. Are you saying there's no association?

9 MS. BROOKS: I'm saying there is no association in
10 terms of how he was using total buffer. He was using total
11 buffer as far as the dialysate was concerned. He was saying
12 you need to add 35 to 8 and understand your patient is
13 dialyzing against a 43. They're not. They're dialyzing
14 against a 35.

15 JUDGE WOODLOCK: But if their blood goes to 8 for
16 purposes of acetate, that is, equilibrium is reached for
17 purposes of the acetate, you say that doesn't add -- it's
18 simple addition -- doesn't add to bicarbonate?

19 MS. BROOKS: That's correct, your Honor. What it will
20 do -- and first of all, there's another premise. There is a
21 difference between infusion and diffusion. And what we've seen
22 over and over in looking at actual patient data is there is not
23 complete diffusion of the acetate. There's maybe half. So if
24 you've got 8 acetate over here, maybe 4 will diffuse into the
25 patient. And if all 4 of that acetate metabolizes into

1 bicarbonate, yes, you will have an additional 4 bicarbonate in
2 your serum as a result of the acetate diffusing and
3 metabolizing.

4 But then let's say that results in a patient reaching
5 equilibrium. Let's say a patient who didn't get the additional
6 acetate didn't reach equilibrium, okay? So they're wherever
7 they are. And let's say a patient who did as a result of that
8 extra acetate metabolizing into bicarbonate, that causes the
9 patient to reach equilibrium. Then the same fundamental
10 principle still applies, though. If their serum bicarbonate
11 goes higher, whether it's because of the acetate metabolizing
12 into bicarbonate or them eating a package of Tums, whatever the
13 reason, if it goes higher than 35, diffusion reverses itself
14 and the bicarbonate goes then from the serum back into the
15 dialysate.

16 And that's why in terms of concentration gradients
17 there is no association. Each of these electrolytes have their
18 own gradient. That's why I put potassium over there, because
19 it has its own gradient. And it makes no more sense to add
20 potassium to the bicarbonate than it does to add the acetate to
21 the bicarbonate. Because Dr. Hakim was saying this patient
22 could go as high as 43, but the patient couldn't because this
23 is the -- the term delimiter has been used. It doesn't mean
24 they can never go higher, but if they go higher, then diffusion
25 reverses itself.

1 JUDGE WOODLOCK: It's a dynamic process. And at some
2 point --

3 MS. BROOKS: Exactly.

4 JUDGE WOODLOCK: We'll play with the numbers. But at
5 some point it's going to go more than 35 and less than 43 I
6 guess is what you're saying. And I want to get some idea of
7 what the real or what is the perceived association for those
8 purposes.

9 MS. BROOKS: And so your Honor, the answer is actually
10 almost no patient has ever -- whether it's GranuFlo or
11 NaturaLyte, almost no patient has ever reached equilibrium at
12 all for the bicarbonate because they're just not on dialysis
13 long enough. So that's the first issue. They just don't.

14 When a patient who is receiving more acetate from
15 GranuFlo -- GranuFlo has 8, NaturaLyte has 4 -- could that
16 patient's serum bicarbonate go a little bit higher a little bit
17 quicker than a NaturaLyte patient because of the extra 4
18 acetate that's in GranuFlo over NaturaLyte? The answer is
19 sure, it could. But then what happens? What would happen is
20 then that patient's concentration gradient would become more
21 shallow more rapidly than the NaturaLyte patient. And so as
22 dialysis continues, the bicarbonate going from dialysate into
23 the serum, that diffusion would slow down. Because the more
24 shallow the concentration gradient, the slower the diffusion.

25 So at the end of the day, the GranuFlo patient and the

1 NaturaLyte patient will end up with virtually the same, all
2 other things being equal, will end up with the virtually the
3 same serum bicarbonate at the end of the dialysis because the
4 NaturaLyte patient, their serum bicarbonate may not rise as
5 quickly, and so their concentration gradient may stay more
6 extreme, so they will get more bicarbonate from the dialysate
7 for a longer period of time than the GranuFlo patient will.
8 And so they end up with, as I say, all things being equal,
9 virtually the same post-dialysis serum bicarbonate.

10 Does that make sense? I know I'm throwing out a lot
11 of concepts here.

12 JUDGE WOODLOCK: Yeah. I suppose the question is how
13 much and when, and that has to be the result of some careful
14 analysis of this.

15 MS. BROOKS: That's where we get back to, your Honor.
16 If Dr. Hakim is going to render these kind of opinions, you
17 need to do a very careful analysis. There was no analysis
18 whatsoever for these. And that's exactly right. We could
19 answer all of those questions and in this memo should have
20 answered all those questions before opining in the fashion that
21 it did.

22 So if we look at Findings 3 and 4, these are a little
23 bit different than Findings 1 and 2. Findings 1 and 2 are
24 simply Dr. Hakim threw it out there with no data, no
25 methodology, no nothing.

1 Now, Findings 3 and 4 are a little bit different. In
2 Finding 3, Dr. Hakim talks about how over time there's been a
3 progressive shift toward higher pre-dialysis serum bicarbonate
4 levels, which implies that more patients have alkalosis and
5 that an even higher percentage of patients have alkalosis
6 post-dialysis. And then the second one is, he talks about the
7 KDOQI guidelines, also talked about the correction of acidosis.

8 Your Honors may remember I talked about that's the
9 biggest problem from patients. So KDOQI stands for Kidney
10 Dialysis Outcomes Quality Initiative. They want to try to give
11 guidance as to how to treat dialysis patients to set them up
12 for the best outcomes possible.

13 These people are very sick. Your kidneys don't fail
14 all by themselves. They always fail secondary to something
15 else, either through trauma where you're actually hit in the
16 kidneys or through some other disease process that you have
17 that harms your kidneys. For example, diabetes is one of the
18 leading causes of kidney failure. Another one is uncontrolled
19 hypertension. Another one are inflammatory diseases that
20 attack your lungs, your sinuses and your kidneys, and that
21 causes kidney failure. So these are very sick people to start
22 with.

23 So KDOQI tries to set guidelines to give physicians
24 guidance on how to provide the best outcomes for people that
25 frankly would be dead but for being on dialysis. If you have

1 end stage renal disease and you don't go on dialysis, you will
2 die within days or weeks at the most, and it's an ugly death.

3 So patients go on dialysis. So KDOQI recommended
4 that -- in 2000, KDOQI recommended a target for physicians.
5 It's not perfect. Patients are going to kind of be all over
6 the place, but they recommend a pre-dialysis serum bicarbonate
7 of greater than or equal to 22. So higher, 22 or higher is
8 what you were shooting for because they were concerned about
9 acidosis.

10 Well, Dr. Hakim decided that that overcorrected and
11 they should be more concerned about what's happening on the
12 higher end now on alkalosis. So Dr. Hakim picks out two data
13 points and says that -- he's talking about Fresenius. He says
14 that Fresenius's pre-dialysis serum bicarbonate mean went from
15 22.9 in 2004 to 24.1 in September of 2011. So that looks like
16 it's steadily rising, right?

17 So what's the problem with these findings? First of
18 all, again, they're based on unreliable methodology because his
19 comment about pre-dialysis bicarbonate levels ignores six years
20 of data, which I'm about to show your Honors. His finding
21 regarding pre-dialysis serum bicarbonate levels is based on
22 cherry-picked data. The memo contains no data about
23 post-dialysis bicarbonate levels even though Dr. Hakim opines
24 on them. And again, it is simply the ipse dixit of Dr. Hakim
25 about the post-dialysis, and the post-dialysis finding ignores

1 seven years' worth of data.

2 So let's walk through those. The first is, those two
3 data points that he does cite, 22.9 in 2004 and 24.1 in
4 September of 2011, the case law is very clear that an expert is
5 not allowed to cherry-pick the data upon which he relies, or he
6 will render his opinion unreliable.

7 JUDGE WOODLOCK: Apart from use of the tag word
8 "cherry-pick," why isn't that simply appropriate editorial
9 selection and that's a question for experts, not for us?

10 MS. BROOKS: The answer, your Honor, is because the
11 case law specifically says if an expert did cherry-pick, their
12 opinion is precluded under *Daubert*.

13 JUDGE WOODLOCK: That just begs the question of what
14 cherry-picking is.

15 MS. BROOKS: We see it right here, your Honor. Here
16 is what Dr. Hakim did. He looked at the year, the whole year
17 of 2004, and he picked that data point for the year 2004, 22.9,
18 and then he looked at the month of September of 2011 and he
19 picked out that data point of 24.1. So there's the
20 cherry-picking. He clearly did that. He clearly only took --
21 he took a one-year data point in 2004 and compared it to a
22 one-month data point in 2011.

23 And what were the results of that? The results were
24 this, on the next slide. The results were that by
25 cherry-picking the year 2004 and comparing it to the month of

1 September of 2011, he ignored six years of year-over-year data.
2 This is directly from the expert report of Dr. Norma Ofsthan,
3 and Dr. Ofsthan's expert opinion has not been challenged by the
4 plaintiffs. And what Dr. Ofsthan did was get hard data points
5 for every year of Fresenius from 2000 -- Fresenius clinics from
6 2000 through 2014. And what you can see here is that the
7 pre-dialysis serum bicarbonate levels peaked in 2005 and then
8 remained steady or even slightly declined through 2011 when Dr.
9 Hakim claimed they were going up.

10 JUDGE WOODLOCK: Could I just ask a question about the
11 comparison between the two data points? If I read the Figure 1
12 on slide 16 --

13 MS. BROOKS: Yes, your Honor.

14 JUDGE WOODLOCK: -- it seems to say that 2004 is
15 23.68, and you have Dr. Hakim saying 22.1 in 2004. What's the
16 cause of that disparity?

17 MS. BROOKS: My recollection, your Honor, is he looked
18 at an incomplete data set. So actually, I hadn't even picked
19 up on that, your Honor, but you're right. He actually looked
20 at an incomplete data set.

21 Just to give the Court some background, dialysis
22 patients have their blood drawn once a month, pre-dialysis, all
23 these labs are done. And the data, if they're at a Fresenius
24 clinic, are all entered into Fresenius's database. So this is
25 a very robust database. And in order to determine what the

1 mean is, so that would be the entire patient population, then
2 all one needs to do is extract the pre-dialysis data for every
3 single patient and then establish the mean.

4 So Dr. Ofsthan did that for the purpose of this graph.
5 But Fresenius always did it because they were very concerned.
6 So for example, when we talk about it in our papers, in 2000
7 when KDOQI came out with the recommendation that patients'
8 pre-dialysis serum bicarbonate levels, the target should be
9 greater than or equal to 22, our then chief medical officer Dr.
10 Lazarus looked at our patient population and saw that 58
11 percent were below that.

12 And that's when Dr. Lazarus began this memo campaign
13 of encouraging physicians to dial up the bicarb prescription
14 because this is what controls what your bicarbonate and your
15 serum is going to be. So he was recommending to physicians,
16 "Dial it up. If you've got it at 32, dial it up at 35. If
17 you've got it at 35, you might want to dial it up to 40,
18 assuming your patient is having problems with acidosis. If
19 they're not, if they're not acidotic, then leave where it is,
20 obviously. But if they're coming up acidotic, dial up your
21 bicarbonate."

22 And as a result of that educational campaign -- I will
23 say this, he also said, "And by the way, GranuFlo is going to
24 give you an extra boost because it has four additional acetate
25 which will metabolize into bicarbonate, so you're going to get

1 in a little extra boost from GranuFlo. So keep that in mind
2 that GranuFlo is an extra four," he said, "and dial up your
3 bicarbonate prescriptions." And as a result, you can see that
4 the mean pre-dialysis serum bicarbonate levels went from the
5 20s in 2000 to 24.61 in 2005.

6 Then Dr. Lazarus issued another memo, and he said,
7 "Okay. We got there. Let's not go any higher because, you
8 move the bell curve over, then you're going to be pushing
9 patients into the alkalotic range, so everybody, let's put the
10 brakes on. We're good." And it's indicated right here, as you
11 see, it never went up after that. The mean pre-dialysis, if
12 anything, went down. Yet Dr. Hakim ignored that, completely
13 ignored that data.

14 And what's interesting is that as the use of GranuFlo
15 went up, the pre-dialysis bicarbonate levels did not. So Dr.
16 Hakim's total buffer theory is again disproven by this very
17 data. But that would be a topic for cross. What is not a
18 topic for cross, what is a topic for *Daubert* is an expert is
19 not allowed to cherry-pick two data points to prove his point
20 and ignore six years' worth of data. And that's what I meant
21 by cherry-picking, your Honor. I try to stay away from that
22 type of terminology, but it is in the *Daubert* cases. They do
23 say an expert is prohibited from doing that.

24 JUDGE WOODLOCK: What would be -- let's assume that
25 somebody wants to not do a graph that's year by year but says,

1 "I'll take three points. I'll take 2000; I'll take 2005; I'll
2 take 2011." Why isn't that, you know, defensible? Someone can
3 say, "Well, you missed the points in between," but they tell a
4 story. There's a narrative that can be derived from that that
5 is fairly unclear, but something was happening between 2000 and
6 2005, and then it plateaued, I guess.

7 MS. BROOKS: Correct. If Dr. Hakim had said that --
8 if he picked 2000, 2005 and 2011, then he would not have been
9 able to say what he says there, that there has been a
10 progressive shift toward higher pre-dialysis serum bicarbonate
11 levels. There hadn't been since 2005. He's saying this in
12 2011. So if he had done the three data points your Honor
13 talked about, that would have been perfect because he would
14 have said from 2000 to --

15 JUDGE WOODLOCK: That's three cherries. He's got two.
16 Why is my hypothesis more defensible for purposes of
17 determining whether or not someone can express an opinion?
18 That's what I guess I'm getting at.

19 MS. BROOKS: Your two cherries --

20 JUDGE WOODLOCK: Three.

21 MS. BROOKS: -- three, show the actual picture. They
22 show that there was indeed a progressive shift toward higher
23 pre-dialysis bicarbonate levels from 2000 to 2005. And then
24 from 2005 to 2011, when the memo was written, there was not.

25 And so what Dr. Hakim did by taking out cherry number

1 one and only looking at two and three, he created a false
2 picture. He created a picture of supposedly a constant
3 progressive shift from 2004 to 2011 when the real data shows
4 that was not the case. So that's what happens when you do
5 cherry-picking if you only pick two cherries. Your Honor
6 happened to pick the right three to give the full picture. You
7 don't have to do year over year. You could do two or three
8 data points, provided that those data points give a true
9 picture and not a picture that is not accurate.

10 JUDGE WOODLOCK: So the problem is with the word
11 "progressive" as opposed to, they plateau between 2004 and
12 2011?

13 MS. BROOKS: Absolutely. We have to read this in
14 context. He was making the point that there was a problem,
15 Fresenius, of these rising serum bicarbonate levels that needed
16 to be addressed urgently. That was the point he was making,
17 when in fact there wasn't a problem of rising serum bicarbonate
18 levels. There hadn't been since 2005. There hadn't been for
19 six years when he put the word "urgently" into his memo.

20 So we have to read in context what argument he was
21 trying to make here, what message he was trying to send. And
22 in fact, what happened? People believed this, but it turned
23 out not to be true, none of it.

24 JUDGE WOODLOCK: Can I just ask kind of a procedural
25 question? Because the parties wanted equal time. Are we still

1 on track for equal time for this? Because I think we're going
2 to be spending the morning really on Hakim.

3 MS. BROOKS: I think so, too, your Honor. It's 10:30
4 now. I probably have maybe 20 more minutes, depending on what
5 the Courts' questions are. So these are easier to go through
6 because there is actual data we can look at.

7 We contest his hypothesis and say, "Okay. Can we
8 replicate it?" "No." It turns out when you look at all the
9 data, it's not true. Next he talks not just about the
10 progressive shift toward higher pre-dialysis serum bicarbonate
11 levels, but he says that it implies an even higher percentage
12 of patients that have alkalosis post-dialysis. There is no,
13 not one -- not even cherry-picked data -- no data regarding
14 post-dialysis serum bicarbonate levels in the memo.

15 So let's look at what the real data would show if Dr.
16 Hakim had put it in the memo. Here is why he didn't. So not
17 very often are post-dialysis serum bicarbonate levels done.
18 Only if a doctor is very concerned about a patient's specific
19 issue will they order one. But what Fresenius does to make
20 sure that they're doing right by their patients is they will
21 order special post-dialysis testing. And they did that in
22 2004, 2007 and 2010.

23 In 2004, Dr. Lazarus was chief medical officer. Dr.
24 Hakim was at a competing -- he was chief medical officer of
25 Renal Care Group, a competing set of clinics. And Dr. Lazarus

1 ordered a full data set of over 2,000 patients post-dialysis
2 tests to be run and saw that the mean post-dialysis level in
3 2004 was 28.75. And remember, you want the patient to be
4 slightly alkalotic when they walk out because it's going to
5 drop over the course of the next 48 hours. So Dr. Lazarus was
6 very happy with this number. This is a great, almost a perfect
7 post-dialysis number. And he shared it with his colleague over
8 at Renal Care Group. Dr. Hakim knew that in 2004 the mean
9 pre-dialysis serum bicarbonate levels of Fresenius patients
10 were 28.75, and his own group had very similar pre-dialysis
11 serum bicarbonate levels.

12 Now, after that, the use of GranuFlo continued to go
13 up, the use of NaturaLyte down. In 2007, Dr. Lazarus is still
14 chief medical officer at Fresenius, and Dr. Hakim is now at
15 Fresenius because Fresenius has acquired Renal Care Group, and
16 he is working in the medical office with Dr. Lazarus. Dr.
17 Lazarus decides to do an even more robust post-dialysis study
18 to see how the levels in 2007 compare to the levels in 2004.
19 And he has -- the study subset was over 16,000 patients.

20 Dr. Hakim was in on this study. Dr. Lazarus in fact
21 asked him, "Is there anything else you'd like us to look at,
22 Ray?" And radio silence from Dr. Hakim. The results came
23 back, and the mean post-dialysis serum bicarbonate level was
24 28.61, actually lower than it was in 2004, even though the use
25 of GranuFlo had gone up and up. Dr. Hakim's response to this

1 was to send to Dr. Ofsthan, who did the analysis, "I question
2 the 'scientific'" -- he put scientific in quotes, "analysis
3 that you did." And that's all he said. Basically, he didn't
4 like this data.

5 JUDGE WOODLOCK: Because there was what I'll call
6 non-verbal expression of views with respect to Dr. Hakim, maybe
7 this is the point to raise it. This is friendly fire, right,
8 for you? And so what's your theme of Dr. Hakim? Sloppy, or
9 was there something else going on? How is it that you found in
10 your camp someone shooting him?

11 MS. BROOKS: I can't get inside Dr. Hakim's head, but
12 if you look at sort of the history between he and Dr. Lazarus,
13 Dr. Lazarus was kind of deemed to be a giant in the field of
14 dialysis, and he and Dr. Hakim at one point were peers; one at
15 Renal Care, one at Fresenius. And Dr. Lazarus was all about
16 correcting acidosis. And Dr. Hakim in 2004 -- in October of
17 2004, a study came out called DOPPS. Dialysis -- I always
18 forget what it is. Mr. Denning knows -- outcomes, practice,
19 something. It's call D-O-P-P-S, DOPPS, and the lead author was
20 a gentleman by the name of Bommer. This is October of 2004.

21 It came out. And if you looked at the unadjusted
22 data, it looked as if there was indeed an association between
23 higher pre-dialysis serum bicarbonate levels of greater than or
24 equal to 28 pre-dialysis, not post, and an increased risk of
25 mortality. So Dr. Hakim picked that up and said, "You know,

1 you people are paying way too much attention to acidosis and
2 you're overcorrecting for it, and you're creating alkalosis,
3 which DOPPS, the unadjusted data in DOPPS shows has an
4 association with an increased risk of mortality." And so that
5 became his rallying cry. And it's a legitimate scientific
6 debate.

7 Last year at the American Society of Nephrology
8 meeting where thousands of nephrologists come, they actually
9 had literally a debate called, "Is it better to be acidotic or
10 alkalotic." In 2014, that was still being debated. So it was
11 an honest intellectual difference in views that were honestly
12 debated between Dr. Lazarus and Dr. Hakim.

13 Now, Dr. Hakim in 2007 is working under Dr. Lazarus.
14 Dr. Lazarus still has his, "It's bad to be acidotic" view, and
15 Dr. Hakim has his, "It's bad to be alkalotic" view. And
16 frankly, whether Dr. Hakim, if the data didn't fit his view
17 would either ignore the data or just assume in good faith that
18 it was wrong, I don't know. What I do know is that his
19 statement that there had been an increase in post-dialysis
20 serum bicarbonate levels he knew was not accurate because it
21 shows here it not only had not increased, it had actually gone
22 down slightly.

23 JUDGE WOODLOCK: You're saying he knew it.

24 MS. BROOKS: He absolutely knew it. It's in black and
25 white. He got the results.

1 More importantly, in 2010, when he began working on
2 what would eventually become his memo, he ordered -- now Dr.
3 Hakim is now chief medical officer. So let's fast-forward to
4 2010. Dr. Lazarus is retired. He still is on as a consultant,
5 but Dr. Hakim now is at the helm. He is chief medical officer.
6 And he orders a special post-dialysis serum bicarbonate test to
7 be done, this is the 2010 one, of over 6,000 patients. The
8 results come back, 28.83. Just like it was in 2004, just like
9 it was in 2007, it is now in 2010 on a test that he, Dr. Hakim,
10 commissioned. You don't see this data in his memo.

11 What you see in his memo is the hypothesis that an
12 even higher percent of patients have alkalosis post-dialysis,
13 when he knew there was data that would either agree or not
14 agree with this. And I can't -- again, I can't get in his head
15 to tell you why he didn't put it in the memo, but he didn't.
16 But there it is in black and white, the summaries from 2004,
17 2007 and 2010. So why it's left out, one could ask Dr. Hakim
18 if he would come to court. But what we do know is this: he
19 knew it.

20 JUDGE WOODLOCK: Did you ask him at his deposition?

21 MS. BROOKS: Yes. And his explanation was, "Well, it
22 must have been artificially low," the readings, with no backup
23 for that. He didn't recall why it didn't go into the memo, but
24 when shown the data itself, he said, "Well, you know, that
25 seems too low to me."

1 So that's Findings 3 and 4. Are there any more
2 questions on those specifically? I will go quickly through
3 these next ones.

4 This is again simply him talking about over time
5 there's been a shift.

6 JUDGE KIRPALANI: I did have a question. You said the
7 unadjusted data in the DOPPS study suggested a problem. When
8 was the data adjusted?

9 MS. BROOKS: Thank you, your Honor. I missed that
10 point. In the study.

11 So they actually did four. They had unadjusted, and
12 then they did I believe a case matching. And they had four
13 models, they called them Models 1, 2, 3 and 4. Model 3 they
14 adjusted for malnutrition and inflammation.

15 So let me digress for a moment. There is a school of
16 thought in the nephrology community that the reason one sees an
17 association between higher serum bicarbonate and increased
18 mortality isn't because the higher serum bicarbonate is killing
19 you. It's because the higher serum bicarbonate is a marker for
20 a more seriously ill patient.

21 As patients get older, as patients get sicker, they
22 eat less, particularly less protein. And so they don't
23 generate as much acid as -- this is going to sound like an
24 oxymoron -- a healthy hemodialysis patient. So a healthy
25 hemodialysis patient will tend to run acidotic. If you're

1 running alkalotic on a regular basis, it's probably because you
2 either have an inflammatory disease, which also tends to
3 generate more bicarbonate, or you're not eating right, or
4 you're just basically sicker and kind of on your last leg. So
5 it is a marker. And it's called -- it's a confounder is what
6 it's called.

7 An example I think we put in our brief is you can see
8 an association, there is an association between consumption of
9 ice cream and crime rate. The more ice cream that's consumed,
10 the higher the crime rate. Now, it turns out that more ice
11 cream is consumed when it's hotter, and it turns out there is
12 more crime that is committed when it's hotter. Why? Because
13 people tend to leave their doors open, their windows open, they
14 go walking in the street, there's more opportunities to commit
15 crime. But temperature doesn't make you commit a crime, and
16 eating ice cream certainly doesn't make you commit a crime. So
17 the high serum bicarbonate doesn't kill you. It's a marker of
18 you being on your last legs, unfortunately, and being much more
19 ill.

20 So thank you, your Honor. Because what happened in
21 Model 3 is they took malnutrition and inflammation into account
22 by looking at certain markers, like creatinine, albumin,
23 something called PCR, and adjusted for those. And when they
24 adjusted for those, the association between high serum
25 bicarbonate and increased mortality became, in their words,

1 non-significant. So it essentially went away.

2 So did that answer your question?

3 JUDGE KIRPALANI: Yes. Thanks.

4 MS. BROOKS: When we come to Finding 5, it's basically
5 repetition. He talks again about -- I'm sorry, it's not, not
6 quite. This one he says, "Over time there's been a shift
7 toward higher dialysate bicarbonate prescriptions, and as a
8 result of that you've got increased pre-dialysis serum bicarb
9 and even higher post-dialysis serum bicarb, and it needs to be
10 addressed urgently." This is how he ended the memo.

11 Well, there is no data about bicarbonate prescriptions
12 in the memo. There is no survey. There is nothing.

13 JUDGE WOODLOCK: You say, emphasize, "in the memo."
14 Was there available this such information as there was, you
15 say, with the post-dialysis bicarbonate?

16 MS. BROOKS: I would assume Dr. Hakim could have gone
17 into the knowledge center or had Dr. Lacson go into the
18 knowledge center and pull up, for example, what was the average
19 or the mean.

20 JUDGE WOODLOCK: But are there any documents that
21 indicate that that was done and it was looked at and ignored?

22 MS. BROOKS: No, no, not that it was done or looked at
23 or ignored. And we would submit the fact that it wasn't done
24 means that you can't make this statement, that there's higher
25 dialysate bicarbonate prescriptions, when you have no data to

1 support that opinion.

2 So it contains no data. It is again the ipse dixit of
3 Dr. Hakim. He just believes it to be true. And again, I don't
4 want to repeat myself on the post-dialysis and pre-dialysis
5 levels. We've already talked about that. He repeats them
6 here. And the same problem with the methodology and lack of
7 underlying data or deliberate ignoring of contradictory data
8 applies to Finding 5.

9 Lastly, Finding 6, what Dr. Hakim says is -- it's
10 interesting. If you look in the memo, he makes it look like
11 he's quoting something where it says, quote -- and this is in
12 the memo. It says, quote, "Borderline elevated pre-dialysis
13 bicarbonate levels and overt alkalosis are significantly
14 associated with a six- to eight-fold greater risk of CP arrest
15 and sudden cardiac death in the dialysis facility," unquote.

16 Now, what's interesting is you don't know where that
17 comes from. There's no citation to where is this quote coming
18 from.

19 What's also interesting is that he equates
20 cardiopulmonary arrest with sudden cardiac death, and it turns
21 out that is absolutely not true, and plaintiffs agree. So this
22 is from plaintiffs' brief. They talk about how we do sleight
23 of hand because death risk is not the same as risk of sudden
24 cardiac arrest in the unit. They are different outcomes. And
25 we actually agree. There is a big difference between having a

1 patient logged in as experiencing a cardiopulmonary arrest and
2 having a patient suffer sudden cardiac death in the clinic.

3 Now, what is that difference? Well, the experts,
4 plaintiffs' experts believe there is no difference. They
5 conflate the two. They say cardiopulmonary arrest is the same
6 as sudden cardiac arrest or sudden cardiac death. And your
7 Honors can do this at a later time. I'm going through quickly,
8 but these are snippets from each of the plaintiffs' expert
9 reports where they conflate cardiopulmonary arrest with sudden
10 cardiac death, and they do it because Dr. Hakim conflated it.
11 So it's not their fault. I mean, he did it, and they just
12 followed suit. So Dr. Goldfarb did it, Dr. Borkan did it, Dr.
13 Waikar, Dr. Eldata, Dr. Schwartzbard, Dr. Zipes.

14 This is what really happened. Of the 941 patients in
15 the Hakim study that were identified as having experienced a
16 cardiopulmonary arrest in the clinic, if you look at the
17 underlying data, 763 of them were entered by a clinician as
18 having survived an in-clinic cardiopulmonary arrest. So there
19 is a huge difference between an identification of having
20 experienced a CPA and having actually died in the clinic. To
21 look at the memo, you would think 941 people died while
22 undergoing hemodialysis in the year 2010 when it turned out 178
23 of them did and 763 of them did not.

24 Why is this so significant? Well, despite Fresenius
25 and every other dialysis providers' best efforts, about 20

1 percent of dialysis patients die every year. As we explained,
2 they start out very sick, and a large majority of them die of
3 cardiopulmonary arrest.

4 Now, what's interesting is cardiopulmonary arrest
5 simply means that your heart has stopped beating and your lungs
6 have stopped breathing. It doesn't mean that you had an
7 arrhythmia and experienced sudden cardiac death, which is
8 defined as, A, sudden, meaning unexpected, and B, that you die
9 there. You are not able to be revived. This tells -- the
10 underlying data tells a very different story, which again shows
11 the unreliability of the methodology that Dr. Hakim and Dr.
12 Lazarus used in coming to the conclusions -- Dr. Lazarus used.

13 So let's look at it, speaking of Dr. Lacson, how he
14 described his own methodology. It's described at length in our
15 papers. Dr. Lacson said at the time, not now, at the time he
16 described his analysis as rough, rushed, quick and dirty and
17 requiring more rigorous protocol for publication. It was as if
18 Dr. Lacson had -- and again, at the time, in 2011, it was as if
19 he had the *Daubert* checklist. So was this a rigorous protocol?
20 No. Did you take your time? Was this thorough? No. Was this
21 clean? No. Was it polished? No. Was it unhurried? No. It
22 was rough, rushed, quick, dirty and requires a way more
23 rigorous protocol before being ready for peer review
24 publication.

25 At his deposition -- now, plaintiffs argue that

1 somehow we've turned Dr. Lacson and now he's trashing his own
2 work. Those statements, the first group, he said at the time
3 in 2011. His testimony at his deposition was when plaintiffs
4 asked him, "What did you mean by that?" And he then
5 elaborated, "I meant that it was premature. I meant that our
6 work was still ongoing. I meant that it was in process. I
7 meant that it was not final. I meant that it was incomplete."

8 And what's interesting is that the day after the memo
9 was circulated, Dr. Hakim e-mailed Dr. Lacson and said, "I'm
10 getting a lot of positive feedback. Maybe we should publish
11 it." And Dr. Lacson said the day after, "It would require much
12 more rigorous work before we could submit this to a peer review
13 publication." And the day after he circulated the memo, he
14 said, "I've contacted Dr. Jennifer Flythe at Brigham and
15 Women's about doing a follow-on analysis, a more rigorous
16 analysis." And Dr. Hakim wrote back and said, "Is she still
17 just a fellow doing her fellowship?" And Dr. Lacson wrote back
18 and said, "Yes, she is, but has expressed an interest in doing
19 a follow-on analysis." And Dr. Hakim said, "Well, I think you
20 should then also bring in Steve Brunelli," who was her
21 supervisor who had been at Brigham and Women's for a long time,
22 so Dr. Brunelli was brought in.

23 Now, mind you, this is all happening on November 5,
24 and Dr. Hakim knows he's going to be leaving after ASN, which
25 is November 8 through 11 of that year. But he doesn't tell Dr.

1 Lacson that. Dr. Lacson did not know that Dr. Hakim was on his
2 way out. So Dr. Lacson thinks that he and Dr. Hakim are
3 discussing the follow-on study, the more rigorous study that's
4 going to be done on the Hakim memo. Dr. Hakim leaves. Dr.
5 Lacson continues with the study, along with Dr. Flythe and Dr.
6 Brunelli at Brigham and Women's. And that becomes what's
7 called the Flythe paper. That was peer-reviewed. Plaintiffs
8 make fun of it because it's an open access journal where the
9 publisher is in Egypt. But it is rated now 20 out of 50, I
10 believe, in nephrology journals. It is peer-reviewed. It is
11 published.

12 And the more rigorous analysis when malnutrition and
13 inflammation -- no surprise here -- is accounted for, the
14 association, the six to eight-fold association, gone. Just
15 like it happened in the DOPPS paper and just like the DOPPS 2,
16 where Dr. Tentori was the lead author, they had the exact same
17 results.

18 Lastly -- and this just shows even the six to
19 eight-fold isn't even supported by the data that is actually in
20 the memo. The most we have here is unadjusted was six and
21 adjusted just for case mix lab vascular access was four.

22 Figures 2 and 3 -- and then I am finished, your
23 Honors -- these purport to show the relative risk of
24 cardiopulmonary arrest as it relates to serum bicarbonate,
25 that's Figure 2, and the relative risk of CPA as it relates to

1 your serum bicarbonate levels and your potassium levels.

2 Now, these are supposedly not rough. According to
3 plaintiffs, they're not rough. They're not quick. They're not
4 dirty. These are a legitimate look at these tables. So what
5 we did was we showed these tables to each one of plaintiffs'
6 experts at their depositions and asked them to interpret this
7 data for us. And here were their comments.

8 Dr. Akar: "Well, you know, I can't tell what this
9 percentage of patients refers to." Dr. Borkan: "I don't know
10 how to interpret that information because it doesn't seem to
11 make common sense that 90 percent of patients would be in that
12 category. But well, that's how the data is portrayed." Dr.
13 Eldata: "I don't know if that's 4 percent of the 941 or of the
14 global total exactly. It's unclear to me." Dr. Waikar: "You
15 know, I don't think from this graph, we don't know the answer
16 to that. I can't tell from this graph whether it includes all
17 the patients or just the cases or just the controls."

18 And Dr. Zipes, who is one of the leading
19 electrophysiologists in the country that plaintiffs' expert --
20 we'll give them that -- he is one of the leading
21 electrophysiologists in the country. We showed him the Hakim
22 Figures 2 and 3. And this is what he said -- we asked him to
23 interpret it. He goes, "You know, I don't know the answer to
24 that," and that may reflect what Dr. Hakim was saying about
25 quick and dirty, that these things, if this went to

1 publication, would obviously have to be added.

2 JUDGE WOODLOCK: Just a point of clarification. It
3 wasn't Dr. Hakim who said "quick and dirty." It was Dr.
4 Lacson?

5 MS. BROOKS: He didn't, no. Correct. Dr. Lacson
6 described his own analysis as quick and dirty, but Dr. Zipes --

7 JUDGE WOODLOCK: Conflated it.

8 MS. BROOKS: He conflated it, just as CP and sudden
9 cardiac death was conflated.

10 So Dr. Zipes says it all. Dr. Zipes says before this
11 thing could get published, before it could be submitted to peer
12 review, it would need to be cleaned up. And that's the -- we
13 have everything that *Daubert* says. If this is missing and it
14 hasn't been peer-reviewed, hasn't been accepted in the
15 scientific community, doesn't have a reliable underlying
16 methodology, doesn't have supporting data or is based on
17 cherry-picked data and ignores contradictory data, it does not
18 pass *Daubert-Lanigan* muster. And the Hakim memo and the seven
19 findings that we are challenging clearly does not meet that
20 criteria.

21 Thank you, your Honors.

22 JUDGE WOODLOCK: Want to take a break?

23 JUDGE KIRPALANI: Why don't we take about a ten-minute
24 break then.

25 (Recess taken 10:59 a.m. to 11:18 a.m.)

1 JUDGE KIRPALANI: Okay. For the plaintiffs.

2 MR. KETTERER: Your Honors, good morning. My name is
3 Brian Ketterer. I'll be arguing in part on behalf of the
4 plaintiffs and Mr. Rotman in part behalf of the plaintiffs
5 depending on where the direction of this response goes.

6 One housekeeping matter, could we switch over so that
7 I have the access to the PowerPoint? And Ms. Brooks, if we
8 could take that board down with respect to your presentation.

9 JUDGE KIRPALANI: It wasn't influencing us.

10 MR. KETTERER: I wasn't sure.

11 JUDGE WOODLOCK: It wasn't influencing Judge
12 Kirpalani. I was just thunderstruck with it.

13 MR. KETTERER: Very good, your Honor.

14 Your Honors, one thing I want to do is zoom out a
15 little bit. And the reason being is because the fundamental
16 nature of what we're here to discuss is in fact a *Daubert*
17 motion. And the motion that's been proffered by the defendants
18 is not a *Daubert* motion.

19 JUDGE WOODLOCK: Let me -- so that you know part of
20 the target you're shooting at. As I reflect on this a bit,
21 let's assume that I think that the Hakim -- just assume. I
22 haven't made that determination. But assume that I think the
23 Hakim memo is provocative, interesting speculation that
24 prompted a lot of activity but itself is not sufficiently
25 reliable as a scientific document that it would be admissible

1 as expertise. And assume also that I'm concerned about
2 confusing the jury. For very strategic reasons both sides
3 would like to put parts of Hakim in front of the jury or maybe
4 set a trap play or not.

5 The question I guess for me, and it's a larger
6 question of what *Daubert* is all about, is exercising some
7 control over what is admitted in court so that the jury is not
8 confused, is not speculating, as I speculated, about why was it
9 that Dr. Hakim took this position. For example, you might say
10 that it was a ritual killing of elders that led him to that
11 approach. All of that is really interesting to me, but it
12 better not go before a jury, at least I had that view.

13 And so maybe the view is to say a plague on both of
14 your houses, none of this Hakim stuff comes in because it's
15 just too preliminary. And now you're going to have to deal
16 with the issue of going beyond the speculative stage or the
17 provocative stage. That's why it's a *Daubert* -- from my
18 perspective a *Daubert* hearing. So maybe you can respond.

19 MR. KETTERER: Let me respond to that sort of
20 philosophical underpinning about the way we which we look at
21 *Daubert* and the way this specific piece of evidence would fit
22 under that analysis.

23 And I think that when we look at that from a
24 philosophical standpoint, we're looking at a couple of things,
25 some building blocks to build up to that question. The first

1 thing that you have to do under either Massachusetts law or
2 under federal law is you're looking at Rule 702 or 703, right?
3 So we're looking at what is the expert considering, and then
4 we're looking at what is the admissibility of the evidence that
5 the expert is allowed to consider. *Daubert* clarifies some of
6 that rule. And in essence, as your Honor just restated
7 completely accurately, the function of the Court is to act as a
8 gatekeeper to make sure that we don't have pieces of evidence
9 that are unreliable or an expert testifying on something that's
10 completely or wholly unreliable.

11 The trap in this particular motion, though, is what
12 *Milward* talks about, and also what you, Judge Woodlock,
13 referenced in *Dyer*. That is that we get into a fact-by-fact
14 analysis of what it is and a judgment about the evidence. And
15 it would be true under *Lanigan* as well. Under *Lanigan*, Lanigan
16 is adopting a *Daubert*-type analysis, and what we're doing for
17 *Milward* is looking at the totality of the evidence.

18 If you make a judgment factually about that analysis,
19 right, you say, "Listen, was the memorandum" -- and by the way,
20 I want to get away from this language about a Hakim memo
21 because Dr. Hakim's name does not appear anywhere on the
22 November 4, 2011 memo. It is a memorandum that is issued by
23 the Fresenius Medical Services Department.

24 And as Mr. Rotman will go through in detail, the
25 Fresenius medical department all signed off on at least one

1 iteration of the memo with only a minor adjustment afterwards
2 by Dr. Hakim. So let's get away from calling it that because
3 what essentially that becomes is an ad hominem attack.

4 JUDGE WOODLOCK: Well, put that to one side. I think
5 I'm not above ad hominem attacks, but assume that I'm sensitive
6 to that. The real issue is for me is whether or not this
7 document, words from this document, reference to this document
8 is necessary for purposes of expert opinions. And it seems to
9 me that all of your experts can take views with respect to the
10 several elements of what I would call -- should I call it the
11 defendant's medical memorandum? But they can take their
12 positions about it, but an argument is you just don't refer to
13 that memorandum. You refer to the concepts.

14 So that's not a kind of picking and choosing among the
15 facts. Maybe it is. Maybe I have to look at each one, we have
16 to look at each one of these elements and say, "Does that stand
17 alone even though Dr. Hakim is not going to be testifying?"

18 MR. KETTERER: Well, first of all, Dr. Hakim is not
19 being offered as an expert witness. That's number one. Number
20 two, it's a factual piece of information and an admissible
21 piece of evidence. As Judge Kirpalani alluded to earlier, it
22 would come in as an admissible piece of evidence.

23 JUDGE WOODLOCK: Not necessarily --

24 MR. KETTERER: It could.

25 JUDGE WOODLOCK: -- admissible on those grounds. I'm

1 talking about 403 purposes. Is this going to be confusing to
2 the jury to have this dragged around in the courtroom, or do we
3 kind of make it more rigorous by saying, "You've got your
4 experts. Let them testify with respect to their expertise
5 without reference to what was said in the defendant's medical
6 memorandum"?

7 MR. KETTERER: And not at all, it's not going to make
8 it more confusing. And I'll tell you why, your Honor. What
9 the experts are supposed to do, their purpose -- and this is
10 what *Milward* talks about, is to take the evidence and assist
11 the jury in understanding it. So what Rule 703 and what
12 *Daubert* and in essence what *Milward* says is, "Look. You have
13 to look at the total amount of evidence and look at the weight
14 of the evidence that each expert looks at in their analysis."
15 This is a piece of evidence which they are allowed to look at.

16 Now, the criticisms that are being offered by the
17 defendant in terms of leveling as to whether or not were the
18 proper adjustments being made, were the proper pieces or
19 elements of evidence also considered, did Dr. Hakim or really
20 Dr. Lacson -- and that's another point I want to make is if
21 you're going to make a methodological attack on the actual
22 memorandum -- and I want to answer your question so I don't
23 want to get off on the wrong track here -- but really, you had
24 to file the motion against Dr. Lacson, the chief epidemiologist
25 who actually gathered all the data.

1 JUDGE WOODLOCK: That would be ad hominem, and we
2 don't want to do that.

3 MR. KETTERER: Well, no, it wouldn't be ad hominem,
4 your Honor, because that would be at the actual individual,
5 right, who is saying things on a personal level. Their
6 intimation about Dr. Hakim is there's a motive or bias about
7 the reason for the memo, right? But with Dr. Lacson, it's
8 strictly methodological, the attack. The attack would be on
9 how the data was collected. The attack would be on how the
10 data was analyzed. The attack would be on how the data was
11 presented, all choices that Dr. Lacson made, not Dr. Hakim.

12 JUDGE WOODLOCK: Let's assume -- this is at a high
13 level of generality and I realize you're going to go into the
14 specifics of it. But let's just assume for present purposes
15 that all six of the findings that are attacked are
16 unsupportable if they were presented directly by whoever
17 presents it, Lacson or Hakim. What value do they have, if any,
18 to your other experts who have made their own determinations --
19 they've made reference to Hakim or the medical memorandum, but
20 what value do they have if that memorandum itself has no value?
21 That's the assumption. I'm not taking that position yet.

22 MR. KETTERER: Okay. If you were to make that factual
23 assumption, your Honor, then the expert has to take it and look
24 at it and integrate it in the context of all the other evidence
25 that they have that they're weighing, right? That is in

1 essence what *Milward* is saying.

2 JUDGE WOODLOCK: *Milward* said a lot of things, but one
3 of the things it said is we have to look with some sort of
4 methodological rigor at what's going on and the Courts should
5 be deferential. I'm assuming for these present purposes so I
6 can understand the perspective you bring that it lacks
7 methodological rigor sufficient for itself to get in. So if
8 someone, a passerby, a chemistry student in his sophomore year
9 has some observations to make about diffusion and dialysis, do
10 we have to let that come in?

11 MR. KETTERER: I think you have to look at it -- this
12 is the issue. The issue is are you looking at it in the
13 context of how the expert is taking it and looking at it, or
14 are we looking at it in a singular vacuum? And there's a
15 difference between those two things.

16 What *Daubert* and *Milward* and its progeny and all the
17 cases talk about is, they talk about the lens of how the expert
18 looks at the evidence, right? That we're not taking it and
19 separating this one piece of data off and we're going to make a
20 judgment call about this one piece of data, right? What we're
21 doing is the --

22 JUDGE WOODLOCK: If the assumption is that this is
23 junk science or at least not adequately developed science, I
24 understand your argument to be that it can come in if it's part
25 of a crowd, if there are lots of other things, the weight of

1 the evidence, all of that, we can bring it all in together, and
2 then we say, "Mr. Expert, what do you think about all of these
3 things," and it's up for cross-examination. That I understand
4 at least to be the thrust of what you're saying.

5 MR. KETTERER: In essence I think that's true, your
6 Honor. Let me explain why, though. The reason why is because
7 it's not that we just allow something that's so blatantly wrong
8 and that I'm suggesting, your Honor, look, a chemistry student
9 off the street, we just take that and he can consider it and he
10 can say whatever he wants about it.

11 But this isn't exactly that. Even if we make the
12 assumption that you think it's junk science -- let's make that
13 assumption right now that your determination is going to be, "I
14 think that Fresenius is right. It's not really properly
15 methodologically constructed." Now, you, expert, what the job
16 is and what the rule is on *Daubert* is how is the expert's
17 opinions impacted by that junk science, okay?

18 So if you say, "Well, Dr. Waikar," or any of the other
19 plaintiff experts, "when you looked at that junk science, tell
20 me how you analyzed that and how that impacted your opinions?"
21 "Oh, well, then I'm going to strike you from being able to talk
22 about general causation because it is predicated too greatly on
23 this piece of evidence which I say ought to go out, which I'm
24 saying shouldn't be true."

25 JUDGE WOODLOCK: No. It would seem to me that a way

1 of thinking about this -- I don't want to dominate too much,
2 but I do want to be sure I understand the perspective.

3 A way of thinking about it is to say your experts can
4 have whatever positions they want to take that are supported.
5 They simply won't be able to use this as a grounds, unless
6 somebody improvidently permits it to come in by opening the
7 door. This is why I asked that question way back when kind of
8 off the cuff. Assuming Hakim is out -- I'll use the shorthand
9 for present purposes.

10 MR. KETTERER: Sure.

11 JUDGE WOODLOCK: Assume Hakim is out. I'm told you're
12 going to be able to present your case without it. You would
13 like to have Hakim in there, but you can present your case
14 without it. And my question is why not then do that?

15 MR. KETTERER: Well, number one --

16 JUDGE WOODLOCK: Because it seems to me that Hakim can
17 become quite confusing. That is to say, "See, one of their
18 people actually said this. Didn't know what he was talking
19 about, but he said this."

20 MR. KETTERER: I think that's making a fundamental
21 assumption which Mr. Rotman is going to address about the
22 reliability. I think that's important to do, your Honor. I'm
23 not suggesting to you that they should arrive at that
24 conclusion. What I'm saying is taking your conclusion on its
25 face, though -- let's make that assumption. The problem with

1 doing that is -- one of the things you alluded to is jury
2 instruction. I think it's even a more difficult thing because
3 the experts themselves, they have already integrated it as part
4 of their opinions. It's already been seen. It's already part
5 of the general causation theme. How do you separate out the
6 opinions that have already been offered, right? And by the
7 way, the last slide they presented, you can see that they're
8 not a mouthpiece for Hakim. What they did is they did their
9 own independent analysis of the totality of the information,
10 right?

11 JUDGE WOODLOCK: If they did, that's fine, and that
12 gets to the jury. I guess that's my point.

13 MR. KETTERER: But how do you separate those things,
14 your Honor? How do you say, "This was Dr. Waikar's opinion"?
15 He didn't offer an opinion on the November 4, 2011 data or the
16 Hakim memo. He didn't offer an opinion on that. He offers
17 opinions on general causation.

18 JUDGE WOODLOCK: Okay. Let me see if I can focus this
19 more specifically to get to this philosophical question. Let's
20 assume that we say -- I say, we say -- that there will be no
21 reference to Hakim.

22 MR. KETTERER: At all?

23 JUDGE WOODLOCK: By anybody on this, because it's just
24 inherently confusing no matter what strategic value people
25 might think, okay? Is the case then subject to summary

1 judgment at that point?

2 MR. KETTERER: No.

3 JUDGE WOODLOCK: You don't think so. Do you?

4 MS. BROOKS: Yes, I do, your Honor.

5 JUDGE WOODLOCK: So by doing this, we throw everything
6 out of the schedule on the trial. That is, we'd have a round
7 of summary judgment based on the dismissal or our saying that
8 we're not going to consider Hakim.

9 MS. BROOKS: Well, I think I'm a bit of still in
10 Charybdis if I say, "Well, yes," then the Court may be less
11 inclined to exclude the Hakim memo, but I have to be candid
12 with the Court. My chart was up there for a reason. The first
13 premise, which is that GranuFlo and NaturaLyte cause excess
14 serum bicarbonate, is based solely and exclusively on the Hakim
15 memo.

16 So if that is out, the plaintiffs can't get over that
17 first hurdle. Whether alkalosis leads to low potassium and
18 that in turn leads to arrhythmia, that's all subject to
19 scientific debate. There's been papers going either way. But
20 the accused product, the only linking GranuFlo and NaturaLyte
21 to anything bad is from the Hakim memo. If I'm wrong,
22 Mr. Ketterer I'm sure will correct me.

23 JUDGE WOODLOCK: I have every reason to believe he
24 will try. The question I guess is really kind of scheduling
25 and procedure. The suggestion is that this could be knocked

1 out on the basis of, if Hakim goes, then you've lost a basic
2 building block. I don't think either of us is that interested
3 in changing the schedule. So the question is can it be tested
4 in some other fashion than by inviting a summary judgment
5 round. And I'm not sure I know the answer to that.

6 MR. KETTERER: Let me see -- let me make sure I
7 understand your question. When you say, "It can be tested in
8 some other way," tell me -- I don't know if I understand that.

9 JUDGE WOODLOCK: Okay. One way I think about it
10 generally is I give everybody their best shot at their case,
11 and then we hear what the jury has to say after they've both
12 had a best shot at their case. Sometimes those are mutually
13 exclusive, but you do your best to try to permit everybody to
14 develop their case. And then you deal with it as a post-trial
15 matter and say, "Based on the evidence that's been presented,
16 Hakim should never have been in there." If I take Hakim out of
17 it, then that reverses the decision, let's say, for the
18 plaintiff. That's the way of dealing with it. I'm not sure
19 that can be done here when it is that your experts' opinions
20 are marbled with it, but it's not all the meat of their
21 testimony.

22 MR. KETTERER: Not only is it not all the meat, your
23 Honor. I'd argue that it is -- it is a piece of data, it's an
24 important piece of data, but it's certainly not the whole
25 schtick, so to speak. It's not the whole thing. I think that

1 comes through in our briefing, that there's a litany of
2 evidence that's been considered. And in fact, that's one of
3 our later motions against the defendants, that they have not
4 considered that same evidence, which is one of the reasons they
5 take this position of, "Well, it's only all about this November
6 4, 2011 memo."

7 Let me just bring up something, when we're referencing
8 this whole notion of, "This is our only piece of evidence, and
9 FDA has recalled the recall," let's look at what the FDA says.
10 Can we bring up slide 12?

11 JUDGE WOODLOCK: I hope in this you tell me why I
12 should permit another agency that doesn't do adjudication, is
13 not binding in any way, to constitute something that the jury
14 should hear, rather than simply say it's up to the jury to make
15 the determination without reference to the FDA at all.

16 MR. KETTERER: I understand that is a larger
17 philosophical question that the Courts may have with respect to
18 what is FDA's role or not. What I'm going to use this to
19 illustrate, your Honor, is simply, look, when we start going
20 fact by fact or when you make a representation that the FDA has
21 recalled the recall or there's some statement out there, this
22 is the kind of factual analysis to say, to somehow say, "Well,
23 Hakim is wrong. This is how it was used. Hakim was wrong, and
24 one of the things that you ought to consider and why Hakim was
25 wrong is because when FDA considered the evidence, they undid

1 their action," right? That was one of the arguments that was
2 made.

3 And the problem with going down this road of fact by
4 fact -- which we're happy to do and we're in fact going to do
5 because I understand some of your concerns. But the problem
6 with going down this road is here is the other fact. It's
7 going to require the Courts to make this sort of judgment from
8 a factual standpoint, and I think that's the role of the trier
9 of fact.

10 If you look at this slide, here is what FDA says today
11 about these two products specifically.

12 JUDGE WOODLOCK: I don't know if it's been transferred
13 yet. Jarrett, do you have it?

14 MR. KETTERER: We have it down here, your Honor.

15 JUDGE WOODLOCK: We're the last to know.

16 MR. KETTERER: I don't want to hold things up too
17 much, your Honor.

18 JUDGE WOODLOCK: We're just not seeing it on our
19 screen.

20 MR. KETTERER: For this, may I hand this up to you?

21 JUDGE WOODLOCK: Do you have a collection of slides or
22 not?

23 MR. KETTERER: I do. I can give you this copy, and I
24 can read myself off the screen. I have another copy myself
25 here. So may I approach?

1 JUDGE WOODLOCK: Yes.

2 MR. KETTERER: Not necessarily going in order here.

3 JUDGE WOODLOCK: Right.

4 MS. BROOKS: Your Honor, might we inquire if there's
5 an extra set of PowerPoints for us?

6 MR. KETTERER: Do we have one extra? I don't believe
7 so.

8 JUDGE WOODLOCK: This is like the Gutenberg Bible. I
9 would have thought that you and in the future I hope that
10 people bring enough for everyone who wants to look at.

11 MR. KETTERER: I will hand over this copy, your Honor.

12 MS. BROOKS: We'll read off the screen. I don't want
13 to take Mr. Ketterer's.

14 JUDGE WOODLOCK: You have the screen. We're the ones
15 in the dark. Perhaps that says something, too.

16 MR. KETTERER: The portion I want to read is just the
17 top portion. It say, "Dialysate Concentrate Used in
18 Hemodialysis Safety Communication Alkali Dosing Errors." It
19 says, "FDA issued a class one recall notice for Fresenius
20 Medical Care North America, NaturaLyte Liquid Acid Concentrate
21 and NaturaLyte GranuFlo (powder) Acid Concentrate."
22 "Inappropriate prescription of these products can lead to a
23 high serum bicarbonate level in patients undergoing
24 hemodialysis. This may contribute to metabolic alkalosis which
25 is a significant risk factor associated with low blood

1 pressure, hypokalemia, hypoxemia, hypercapnia and cardiac
2 arrhythmia, which, if not appropriately treated, may culminate
3 in cardiopulmonary arrest. This product may cause serious
4 adverse health consequences, including death."

5 The point of that, your Honor, is simply to say, look,
6 when we're engaging in the analysis as we're going to go
7 through of the reliability of Dr. Hakim's memo or the question
8 of whether or not this is reliable information or not reliable
9 information, what it requires is factual gathering, right? Did
10 the FDA agree or not agree? Is that going to be allowed?

11 JUDGE WOODLOCK: It's one way to look at it. Another
12 way to look at it is we're letting the FDA vouch. And the
13 vouching is somewhat ambiguous in this setting. So a way of --
14 another way of looking at it is to say keep out the ambiguities
15 and go right down to the guts of it. The guts of it are,
16 you've got experts. Those experts take a particular position.
17 In order to take that particular position, they can't make
18 reference to X and Y. The defendant can't say, "By the way,
19 the recall was recalled." All of that is taken off the table,
20 and now we focus on the science by scientists.

21 MR. KETTERER: So my suggestion would be, if that were
22 your ruling, would be to say the data is the data and that the
23 data from the November 4, 2011 memo would certainly be
24 something that would be subject to analysis by any of the
25 experts. And the experts could say, "We've reviewed internal

1 Fresenius data. That's where it's from." In fact, there's a
2 litany of internal Fresenius data and that they would be able
3 to consider it.

4 The memorandum, you would make a separate ruling as to
5 how that would come in. Would it -- it obviously is an
6 admission and a statement of a party opponent and all these
7 other things we could argue about, but that the data is the
8 data and the consideration of how an expert would look at it
9 would be simply, "I've reviewed all of the internal Fresenius
10 data," or, "I've reviewed these pieces of Fresenius data and
11 this is what I believe that it says."

12 And then however it comes in separately, "These are
13 memoranda that were set up by the company, and these were the
14 things that were sent out." It would also avoid, by the way, I
15 would argue, that should your Honor make that ruling, either of
16 you or both of you were to make that ruling, then the
17 concomitant part of the ruling would be there can be no
18 suggestion that this was all done by some individual employee
19 at the company. So for instance, the very fact that you and I
20 are talking about it in the context of it being the Hakim memo,
21 the logical outcome then is if we are going to remove that and
22 we're only going to talk about the data, there is no more story
23 about the development per se of, "This is the problem with the
24 information that's contained therein."

25 JUDGE WOODLOCK: Right. I think that's a fair way of

1 saying it.

2 MR. KETTERER: Okay.

3 JUDGE WOODLOCK: But what it does say is data as data,
4 except that it comes from materials developed -- data-gathering
5 by the company but not the characterizations that occur in the
6 memorandum and not the time spent talking about recall and
7 sur-recall. It's focused on the data itself, and then they can
8 ask about, you know, "Do you think that, dot to dot, between
9 2004 and 2011 is fair or not? We'll show you this."

10 The point I guess I'm getting at is talking about it
11 as the Hakim memo or even talking about it as the defendant's
12 memo is potentially misleading and confusing to the jury. And
13 we want the jury to be making the determination on the basis of
14 real experts who testify here and are subject to
15 cross-examination, not shadow experts.

16 MR. KETTERER: Well, the one thing I would just ask,
17 though, your Honors, is I'm particularly a little confused
18 since we're having the discussion about is the memo is a
19 separate freestanding document that they sent out to thousands
20 of physicians. So the memo itself --

21 JUDGE WOODLOCK: If it were material or relevant for
22 the notice to physicians, that would be another matter. But
23 that's not what we're talking about here. What we're talking
24 about here is you got experts. They look at all kinds of
25 things. They look at their college textbook, their chemistry

1 textbook when they were sophomores in college. That doesn't
2 mean that gets in. What does get in is what they actually
3 relied on in terms of the data that support the ultimate
4 conclusions they make.

5 MR. KETTERER: Let me see if I can clarify. Let me
6 make sure I can clarify what it is you're saying so I can
7 respond accordingly, which is, I take it what you're saying is
8 you don't want or your suggestion is if we are to find that it
9 is somehow unreliable, the underlying information, then what we
10 would allow is the expert can consider any of the data that
11 comes from there without an attribution as to where they got
12 that data from, other than this is Fresenius internal data.
13 Thereby, the cross-examination can certainly be on the actual
14 data, and if the memo were to come into evidence -- and I would
15 argue it certainly would for a variety of other reasons, and
16 that would have to be a determination made by the Court -- that
17 because it's gone out to physicians and is notice and it's been
18 publicized and it's a public record it comes in for those
19 purposes but not being asked of the expert to say, "You
20 considered the November 4, 2011 memo as a scientific document
21 per se." Is that correct?

22 JUDGE WOODLOCK: I think that's fairly stated, except
23 I'm not sure I accept the premise that that memo is going to
24 get in anyway.

25 MR. KETTERER: I'm not accepting the premise either

1 way, your Honor. What I'm suggesting is that's a separate
2 argument, right?

3 JUDGE WOODLOCK: Yes.

4 MR. KETTERER: It's a separate argument based on what
5 is it that was done with the particular document? What did
6 they do with it? Did they send it out? Did they do whatever?
7 If you were to accept that argument or Judge Kirpalani were to
8 accept that argument, then that piece of evidence would come
9 through these other independent bases, potentially.

10 JUDGE WOODLOCK: Yes, I think that that's right. If
11 it's got some other basis, then it comes in. But what we're
12 talking about here is not that. We're talking about whether or
13 not that memo, qua memo, is something that can be relied upon.
14 I'm suggesting that it's only the data that can be relied upon
15 there. And so your experts are just going to have to say, for
16 example, "Was there ever any evidence about X?" "Yes, there's
17 data that shows that," and then they can cross-examine.

18 MR. KETTERER: Well, I think the other thing, though,
19 that has to be clarified is where they got the data from when
20 they received the data. And what I mean by that is they have
21 to say, "Look, we looked at internal Fresenius data. We looked
22 at the data that was collected, which reflected this, the data
23 in our opinion reflects this based on that data."

24 JUDGE WOODLOCK: That may be fine-tuning. That's a
25 motion in limine. But I guess what I'm really talking about is

1 how, if at all, the materials referred to in the memorandum are
2 brought to the attention of the jury. That's really the
3 concern I have.

4 MR. KETTERER: So the one thing -- what I want to turn
5 to, your Honor, is the entire dialogue that you and I have just
6 spent 25 minutes on is really predicated on an assumption,
7 which is that you don't believe that it's reliable. And I
8 think what I want to do is, I want to come back at the end and
9 talk about how this kind of fits into the entire context, but I
10 want to give Mr. Rotman a chance to sort of talk about all the
11 evidence that we have to suggest certainly that this is a
12 reliable memo.

13 JUDGE WOODLOCK: Okay. And I think I've been speaking
14 too much, but this is on my mind, so I want you to be able to
15 address it. And that is why the reliability or lack of
16 reliability of the memorandum, the outcomes of the memorandum
17 can't be dealt with by simply talking about it in terms of
18 data, why this document has to be waved in front of the jury,
19 because it just takes on a different aspect when it's referred
20 to as Hakim, Lacson, and the defendants.

21 And so referring to this, if there's a conclusion that
22 somebody is reaching and they've used the data, then that's
23 fine. But if it's going to be a backdoor effort to get before
24 the jury this document, which is delicious but not necessarily
25 nutritious, is something that we have to be concerned about.

1 MR. KETTERER: And I think that's sort of the
2 underlying point, which is you also do have to be concerned or
3 you should look at the evidence that we have to suggest that it
4 certainly is nutritious before you decide that it's not
5 nutritious. But even assuming that, your Honor, what we're
6 saying is that if you look at the piece of evidence you are to
7 say, just look at the data, I understand that. But that's
8 predicated on this underlying notion that you don't think that
9 there's reliability.

10 And I think that before we jump ahead then, I think
11 there is a way to deal with the fact that, if it wasn't
12 reliable, can we just use the data. And I do think that's a
13 fundamental error in calling it the Hakim memo, because it's a
14 company document. It isn't a memo sent out by one individual.

15 JUDGE WOODLOCK: It doesn't become an expert's report
16 and reliable expert's report simply because it's a company
17 document. So what I guess I'm getting at is to perhaps address
18 the question of whether or not, standing alone, if this were
19 the only piece of evidence in the case and Hakim was going to
20 be here, that we would say that's sufficient for *Daubert*
21 purposes. Let's assume that's the only piece of evidence in
22 the case. That's a way of I think surgically approaching this
23 issue.

24 MR. KETTERER: If you do that, then I'm going to let
25 Mr. Rotman deal with all the different pieces of evidence. And

1 if there's time, I will come back and address other questions
2 on this front.

3 And can we have five minutes? Because now we have a
4 series of PowerPoints, and we need to make sure they're on your
5 screen.

6 JUDGE WOODLOCK: Right. And I just emphasize again,
7 it is very helpful to have -- because we absorb our information
8 different ways, but it's very helpful if you're going to use
9 PowerPoints to give us the PowerPoints, tell us what slides
10 you're using if you're kind of mixing and matching or jumbling
11 them up. But the xerox machine is pretty well established as
12 technology, and I think you can probably make copies for
13 everybody around. Okay?

14 MR. KETTERER: Understood, your Honor.

15 JUDGE WOODLOCK: We'll take a five-minute break.

16 (Recess taken 11:50 a.m. to 12:02 p.m.)

17 MR. ROTMAN: Thank you, your Honor. I understand that
18 the technology has been repaired.

19 JUDGE WOODLOCK: Steps have been taken, and we have it
20 on the screen, but I emphasize again, if you're going to be --
21 anybody's going to be using PowerPoint for any of this, then
22 there should be adequate numbers of PowerPoint slides in hard
23 copy that can be handed up to us and to others who are in the
24 courtroom and to the degree you have to refer to it, you can
25 refer to particular pages, that sort of thing.

1 MR. ROTMAN: Your Honors, the November 11 memo
2 addresses the results of an internal epidemiological study. It
3 also provides advice and safety information regarding the use
4 of the dialysis products GranuFlo and NaturaLyte and safety
5 information, patient safety information.

6 So there are two separate issues here. One is the
7 study, and the other is information in the memo about use of
8 the product and safe use of the product. And we've got to keep
9 the two separate.

10 Defendant challenges the 2010 study itself and they
11 challenge the memo, so they're challenging both. The 2010
12 study they're claiming is unreliable because it was preliminary
13 and quick and dirty, and they've got some other specific
14 arguments about adjustments and confidence intervals and
15 matching. And then the product advice part of the memo, which
16 has nothing to do with the study itself or is separate from the
17 study itself, they're claiming is unreliable because they say
18 it's based on the subjective and speculative opinions of one
19 man who was their chief medical officer who became rogue.

20 The facts, though, are different. And the document
21 trail is clear. And we can show the Court and we can show the
22 jury that the facts really tell a very different story, both
23 about the memo and its genesis, the information in the memo
24 about product use and safety and about the study itself. The
25 conclusion that one will draw from the consideration of the

1 facts is that the memo itself is a company document, that it
2 was indeed peer-reviewed by people at the highest levels within
3 the company and in the medical department and epidemiology
4 department, and that they approved a draft that was virtually
5 identical to the one that went out on November 4.

6 And Ms. Brooks showed side-by-side the October 25
7 draft to the November 4 memo, but that presentation was perhaps
8 creating an impression that I think is not accurate. If your
9 Honors were to look yourselves at the two memos side by side,
10 October 25 and November 4, or with the assistance of your law
11 clerks, and I will show -- I would like to show in this
12 courtroom, in this hearing, that we are talking about two
13 documents that are almost, almost identical and that six out of
14 the seven conclusions in the memo that the defendants are
15 challenging, six of them out of the seven appear in the
16 November 4 memo and in the October 25 memo. What's significant
17 about that --

18 JUDGE WOODLOCK: What will be helpful to me is not an
19 argument about this being the defendant's memo or having been
20 done within the defendant's organization but whether or not --
21 and maybe the organization argument is around the findings that
22 are challenged here and how good the data is that supports that
23 and the methodology that supports that data.

24 This argument has given me and the previous argument
25 has given me pause about what is going to be argued to the jury

1 that seems to me to be potentially confusing and irrelevant.
2 So I really want to get to the science of this and whether or
3 not this memo discloses science that is sufficiently reliable
4 to be presented to the jury as science, not as statement of
5 someone from Fresenius.

6 MR. ROTMAN: Right. And your Honor, I will get to
7 that, if I could just complete the thought that I was trying to
8 make. The November -- sorry -- the October 25 memo was
9 reviewed and approved specifically we know because of a
10 specific document in litigation, which is GFPL2196. It was
11 specifically approved by Frank and Mike. And Frank and Mike
12 are the current chief medical officer and a defense expert and
13 the former chief medical officer, and so we have the memo
14 approved by Dr. Hakim and its former chief medical officer and
15 its subsequent chief medical officer, three chief medical
16 officers of the company approving six out of the seven
17 conclusions that the defendants are claiming is unreliable.

18 JUDGE WOODLOCK: That's peer review? That's peer
19 review for purposes of *Daubert*?

20 MR. ROTMAN: Yes.

21 JUDGE WOODLOCK: That people within a company reach a
22 conclusion and they express it? Let's assume the conclusion is
23 not in your favor. It's in their favor. It's wholly
24 self-serving. That's going to be peer review? For purposes of
25 *Daubert*, that's going to be peer review? Why is that any

1 better than, say, publishing in Cairo?

2 MR. ROTMAN: I believe this is better than peer review
3 and the plaintiffs believe it's better than peer review because
4 we have a memorandum that is disclosing information about
5 patient safety that is against the company's interest.

6 JUDGE WOODLOCK: Okay. That's all kind of admission
7 stuff. We're talking about the science here. So I really --
8 you know, I'm not a jury. I'm somebody who is supposed to
9 exercise gatekeeping responsibilities, and I'm looking at this
10 and asking questions about the science.

11 MR. ROTMAN: I'm going to answer the questions about
12 the science, but you asked me a question about the peer review.

13 JUDGE WOODLOCK: This really, this is not *Daubert*
14 light. This is an odd situation in which the defendant has
15 shot itself in its feet by its internal people. That makes it
16 kind of fun, delicious, as they say.

17 But in terms of our exercise of our responsibilities,
18 I think we have to ask is this science and is it reliable
19 science. And one thing that you say about reliable science is
20 peer review, and peer review is not Mike and Frank writing to
21 Jay. It involves something broader in terms of the scientific
22 community, I think. But maybe I don't have peer review
23 understood.

24 You know, I had a defendant once in a case who was pro
25 se. It was a criminal case, and it was a bank robbery case.

1 And we learned that some of the jurors had felonies. They
2 hadn't told us that. And I moved to take the people off the
3 jury, and the defendant objected. Why did he object? I asked
4 him. He said, "You're depriving me of a jury of my peers,"
5 that is, fellow felons. That's not peer review. That's not
6 what "jury of your peers" means.

7 So using the word "peer" really doesn't help things at
8 all. I've taken your time, I know, and I apologize for that,
9 but I think you better direct yourself to the things that are
10 particularly meaningful, and that's the science.

11 MR. ROTMAN: Okay. So we can look at the science for
12 the seven challenged statements, and we can look at the science
13 for the results of the study. And if we look at it -- and we
14 can go through each one of those things.

15 Just going back to the point about peer review, what
16 happens in the publication process is somebody submits an
17 article and the editors send it out to somebody that's
18 independent, or two or three, and they review it and they give
19 comments. Here, the company had its own top medical officers
20 review this and give comments. And we know from the paper
21 trail that six out of the seven conclusions appeared almost --
22 are literally verbatim. You can go from the defendant's brief
23 of what they're challenging, find it on the October 25 memo and
24 then find it in the November 4 memo.

25 So there's certainly a relationship to peer review

1 there. However -- whether you want to call it something
2 different, it was reviewed by people who clearly had an
3 interest in finding problems with it because it was against the
4 interest of the company.

5 And the other thing about it is, okay, going back to
6 the study, the study started a year and a half earlier. It was
7 done first as a pilot study. It arose out of concerns that
8 patients were having cardiopulmonary arrest in the unit, and
9 they were seeing those patients with high bicarbonate in their
10 blood and exposed to high bicarbonate total buffer. And Dr.
11 Lazarus testified that it was his idea to do a study. This is
12 Lazarus's idea, not Dr. Hakim. And the study was then
13 conducted first as a pilot study for a reporter, for three
14 months, based on the company's own data for 2010, for three
15 months conducted by the chief epidemiologist, assisted by a
16 biostatistician and a data analyst and by Dr. Hakim.

17 They came up with a result. They then vetted that to
18 a number of people within the company, to the patient safety
19 organization, to people that saw the results, the data, the
20 adjustments, the statistical significance, the correlations,
21 the bicarbonate distribution, all in a series of presentation
22 slides. And so we know that this occurred a year and a half
23 before the November memo comes out. And then they prepare a
24 memo like the November 4 memo a year earlier than November 4,
25 it was October 27, 2010, and it described the results of this

1 pilot study, again, a study that had been fully vetted
2 internally where other people besides Dr. Lacson and Dr. Hakim
3 reviewed the methodology.

4 They didn't send that memo out. Instead, they decided
5 to look at the full year data. They looked at the full year of
6 2010 in their own patient data. And there's value, reliability
7 value in having this database of their own patient data. And
8 the company documents are quite proud of this database. Even
9 in published literature, they talk about the quality of the
10 data.

11 So they then in March of 2011, eight months before the
12 study, before the November memo, they have replicated the
13 results with a full year study. And there's another
14 presentation, and that's showing the results for the full year.
15 And Dr. Lacson writes an e-mail saying, "I've replicated the
16 results from the first quarter to the full year."

17 So now we have replication and using the same
18 methodology, which, if the analysis was preliminary, there were
19 months to make it different. If they wanted to do a different
20 analysis, there were months to do so. So the characterization
21 that it has only come after the litigation began, that it was
22 preliminary and they wanted to do more, is not borne out by the
23 fact that there was a year and a half to make whatever changes
24 to the analysis that they wanted.

25 That result in March 2011 of the full year was then

1 vetted as well. And it was reviewed by the patient safety
2 organization, and it was showing what the adjustments were, the
3 P value, without confidence intervals, how they adjusted for
4 confounders, what the results were, the number of patients, the
5 number of controls, the distribution of bicarbonate, the bar
6 chart that you see in the November memo with all of the
7 different results appeared in this presentation eight months
8 earlier. These are all exhibits that are part of the record
9 here. And what we see is that they then waited eight months
10 before the memo.

11 So again, if it's preliminary, there's plenty of time
12 on the calendar to do whatever they wanted to do. They
13 didn't -- the plaintiffs' position is there's no indication
14 before the litigation that there ever was a plan to do anything
15 different than what they did, and they then relied on that
16 result in a memo that was approved by top level officers within
17 the company, including three chief medical officers and the
18 chief epidemiologist. And they distributed it to 2,000 medical
19 directors of 2,000 clinics, which means they relied on it
20 themselves.

21 If reliability is an issue under *Daubert*, then relying
22 on it themselves is relevant, and then it was relied on again
23 by the Food and Drug Administration, and it was relied on again
24 three months later when Dr. Diaz-Buxo, after Dr. Hakim had left
25 the company, who was senior vice president of medical and

1 regulatory affairs, sent a memo out to not only all medical
2 directors but all nursing home facilities and all
3 administrators and all customers of Fresenius products outside
4 of their own clinics, saying that -- giving a reference to the
5 findings of that study. Relied on again.

6 And then it was relied on also when experts in the
7 field published in a peer review journal the existence of the
8 memo and the findings of the study. So we have it relied on by
9 the company multiple times. We also had it relied on again
10 when another medical director memo went out. It's undated, but
11 we believe it's 2012. And it was issued by Dr. Maddux, who
12 took Dr. Hakim's place as chief medical officer, where he's
13 also making reference to the same memo and the same study.

14 So we have reliance on the study. We have a study
15 that was vetted. And we have the chief epidemiologist who has
16 great credentials testify in his deposition that the study used
17 a standard methodology and followed good science. This is
18 their epidemiologist, not Dr. Hakim, that it utilized a case
19 control study design, which is one of the standard types of
20 study designs used in epidemiology; that it used the logistic
21 regression model for adjusting for confounders, which is a
22 standard tool used in case control studies; that it evaluated
23 the data both in an adjusted and unadjusted form and reported
24 the results both ways; that it analyzed the data controlling
25 for a set of confounders, which your Honor will find in our

1 brief, they used a similar methodology in other studies, other
2 companies' studies that were published in the medical
3 literature in the peer review literature, other studies that
4 also use the same types of adjustments, same type of
5 methodology, that also did not match cases to controls but
6 instead used cases compared to the entire patient cohort. And
7 we cited those in our brief.

8 So we have a methodology in this study which was
9 following a methodology that the company had used multiple
10 times, including in published studies. They also used the same
11 methodology in their own internal studies going back to 2003,
12 2004, 2008, 2009, where they looked at bicarbonate and
13 mortality. And when they did those studies, they did the same
14 methodology. They used the same adjustments. They reported
15 the results without confidence intervals but just with P
16 values.

17 So over and over again they used methodologies which,
18 if it was preliminary and quick and dirty, it just doesn't make
19 any sense to us. You know, what did Dr. Lacson mean when he
20 wrote the e-mail "quick and dirty"? Well, that's a jury
21 factfinder question. He then says what he says in his --

22 JUDGE WOODLOCK: Can I just say -- I've said it
23 before. I'll say it again. What's of interest to me is the
24 science. You've taken a great deal of time to deal with an
25 issue that I think we've fully ventilated.

1 Now we want to talk about the science. And I raised
2 with your brother the idea that what appears to be going on
3 here is the ability to label as an admission some form of
4 document, and that takes on some special credibility because of
5 that. And I want to think about it differently. I want to
6 think about it in terms of whether or not the studies
7 themselves are things that people can rely on without referring
8 to, "and they said it," as you have repeatedly said.

9 MR. ROTMAN: All right.

10 JUDGE WOODLOCK: So will you go to the science or not?
11 If not, I guess I can understand that. I don't think it's
12 effective advocacy, but you can do whatever you want.

13 MR. ROTMAN: What I was trying to convey is the way
14 you evaluate the science if you're challenging the reliability
15 of the study -- of the study -- is whether the methodology of
16 the study was reliable.

17 So what are the questions? Is the case control study
18 an appropriate method? Are the adjustments appropriate
19 adjustments? Is there something wrong with reporting just a P
20 value instead of confidence intervals? These are -- this is
21 how they've attacked the reliability of the study.

22 And what I was explaining is that the methodology that
23 they use is their standard methodology, which they've viewed as
24 good science and which is good science. And there's no claim
25 that a case control methodology is an inappropriate

1 methodology. The claim that they didn't make an adjustment for
2 nutrition or malnutrition is disputed, because they make an
3 adjustment for albumin, and there are documents showing that
4 the company understood and used albumin as a proxy for
5 nutrition.

6 The claim that having P values without confidence
7 intervals makes the study unreliable is unfounded because,
8 first of all, they talked even today about the DOPPS study.
9 That DOPPS study was published in one of the leading journals
10 on nephrology and kidney disease in the country, and it did not
11 report confidence intervals. It only reported P values. It
12 used the same way of presenting the results with the bar charts
13 and the P values as was used in reporting the results of the
14 internal study.

15 So we have a methodology that stands up to scrutiny.
16 It was vetted. It was standard methodology. And there is
17 nothing about the study itself that withstands the challenge.
18 The claim that it was preliminary is undermined by the fact
19 that it was a one-and-a-half-year study that went through
20 iterations from a pilot study to a full-year study and then was
21 replicated a third -- again based on the 2011 patient
22 population. And Dr. Lacson testified that he then replicated
23 it again.

24 So now we have, again, using the same analysis that
25 they want to characterize as preliminary. Now, if the jury

1 wants to think that this is a valid challenge -- this is a
2 factfinder issue: Is it preliminary or not. But the evidence
3 that it's not preliminary is that it took a year and a half and
4 they replicated it twice using the same methodology, that it
5 was vetted, and nobody suggested, there's not one shred of
6 documentary evidence that anybody said, "This analysis should
7 use different adjustments." In fact, Dr. Lazarus, who was the
8 former chief medical officer, testified that he thought the
9 adjustments were fine; he just thought that there was a
10 calculation error.

11 Now, if there's a calculation error, their experts can
12 come in and show the calculation correction, which they have
13 not done. And their claim that they went ahead and then did
14 another study that actually did the full analysis that they
15 were always planning to do, this Flythe study that got
16 published in Egypt and which found no association, there's more
17 to that story, your Honor -- your Honors.

18 First, the data never left Fresenius. The data
19 analysis never left Fresenius. Even bringing in these outside
20 co-authors, they never saw the data or did the analysis
21 themselves. And it was a different number of cases, a
22 different number of controls, and there was different
23 bicarbonate data. So then there was a different methodology
24 using a linear instead of a non-linear analysis for
25 bicarbonate. And nevertheless, they did find an association in

1 the unadjusted model. And the only reason they didn't find an
2 association in the adjusted model was because they did an
3 analysis based on linear, and there's going to be expert
4 testimony that that was inappropriate and that that was also
5 not dictated by the data. So the study itself is reliable and
6 it was relied on, and it was based on a reliable database, and
7 it used an established methodology.

8 Now, the experts in this case can look at the memo and
9 see what they see there, but they can see information about
10 this study based on the three-month data and the presentations
11 that were provided about the results as well as the full-year
12 data because both -- as I said, one came out in 2010, the other
13 came out in the spring of 2011. And there is data showing the
14 results of this study in much more detail than is provided in
15 the November memo.

16 So if we could put up 2408A. 2408A is -- if you could
17 just go through. That first slide, this is one of the exhibits
18 in the case, your Honor, that's cited in our brief. This is
19 the full-year study result that accompanied the memo from Dr.
20 Lacson when he said he replicated the first quarter. And it's
21 showing the number of cases and the number of controls that are
22 ultimately reported eight months later in the November memo.

23 Next slide -- I mean next page -- is an overview based
24 on demographics. Next page is lab result summaries. And the
25 next page is the dialysate prescription, the bicarbonate

1 prescription and the potassium prescription and the calcium
2 prescription.

3 Next page. Here we see a bicarbonate distribution,
4 and you can see on the right-hand side how it's higher in the
5 boxed area than in the triangle area. That's saying that the
6 cases had higher bicarbonate than the controls. Well, the
7 cases are the patients that had CP arrest. The controls are
8 the patients from the same clinics who did not have CP arrest
9 in the dialysis unit. So that's what's driving the reported
10 odds ratios, relative risks that are reported in the November
11 memo.

12 Next page. This is showing the distribution for
13 potassium, which is relevant because there's a direct
14 correlation between bicarbonate and potassium. It's almost
15 like a seesaw. As bicarbonate goes up, potassium goes down.
16 And potassium going down is dangerous for the heart. It's what
17 causes heart rhythm disturbances, as their own experts have
18 admitted, as Dr. Lazarus has acknowledged in the testimony.

19 So as bicarb is going up, it's predictable that
20 potassium is going down. And so we see that reported here,
21 too. Next page. Now, here we see something that looks very
22 similar to what appears in the November memo. The November
23 memo reports the results of the study. And as you can see,
24 there's these bar charts with asterisks for the statistical
25 significance with a legend on the left showing the adjustments

1 for confounders, case mix, lab adjustments, lab plus vascular
2 access plus case mix. These are exactly what they did in
3 published studies: The same methodology, the same approach in
4 studies that Fresenius did that they then had submitted to peer
5 review journals and had published showing the results the same
6 way. And what's interesting about this also is you can see
7 that on the far right the relative risk is over 6 in the
8 unadjusted and is over 4 in all models. On the far left, it's
9 over 2.

10 JUDGE WOODLOCK: This is Figure 2 from the
11 presentation that the defendant made here?

12 MR. ROTMAN: I'd have to check.

13 JUDGE WOODLOCK: I think it is.

14 MS. BROOKS: It is, your Honor.

15 JUDGE WOODLOCK: So I look at the Akar deposition, I
16 can't tell what percentage of patients this refers to. I look
17 at Borkan. I look at all of these. So the whole point, I
18 guess, is to look beneath the surface of these summary
19 conclusions to see what experts can do with the data that's
20 presented. That's what I was trying to do.

21 MR. ROTMAN: That's the point I'm making.

22 JUDGE WOODLOCK: But you're doing something else. And
23 the something else is you want to drag in this memorandum as a
24 memorandum. And that's not what we're talking about.

25 MR. ROTMAN: I'll stop talking about the memorandum.

1 I'm talking about the study, and I'm showing how this study had
2 a genesis that preceded this memo and where it came from. And
3 it came from first this pilot study, then a full-year study
4 that produced the kinds of results and analyses that are shown
5 in this exhibit, 2408A.

6 JUDGE WOODLOCK: But your experts can't interpret it.

7 MR. ROTMAN: Did you say --

8 JUDGE WOODLOCK: They can't interpret it. They say
9 they can't interpret it.

10 MR. ROTMAN: They say they can or cannot?

11 JUDGE WOODLOCK: Cannot.

12 MR. ROTMAN: Our experts didn't -- I don't believe --

13 JUDGE WOODLOCK: Okay. So I'm looking at it. I can't
14 interpret it. But I look at the Akar deposition, and he's
15 asked, "What do these percentages mean?" He says, "I can't
16 tell what this percentage of patients refers to."

17 MR. ROTMAN: What is he being asked about? Is he
18 being asked about this page?

19 JUDGE WOODLOCK: I guess.

20 MR. ROTMAN: Why do you say that? I don't guess that.
21 I don't know if that's true.

22 MS. BROOKS: Your Honor, Mr. Denning and I took all
23 the depositions of their experts, and we would show them
24 Figures 2 and 3 and ask the same question. "Could you please
25 interpret the data for us." And these were their responses

1 verbatim from their deposition.

2 JUDGE WOODLOCK: It just isn't -- I'll go back --
3 trust me, I'm going back and look at this stuff. But it's not
4 credible to say it was lumped together in something that took
5 18 months that consequently was the subject of an iterative
6 process. That's not enough. You have to show some way that
7 some expert can look at this and say, "I can tell you what the
8 percentage of patients is, what that refers to."

9 MR. ROTMAN: The percentage of patients isn't even
10 something that I'm seeing on this page. There's nothing here
11 about percentage of patients.

12 JUDGE WOODLOCK: I look at the bottom there,
13 "Percentage of Patients." I don't know which one of those --
14 that's the fifth of those, "Percentage of Patients." You don't
15 see "Percentage of Patients" on this?

16 MR. ROTMAN: On page 7?

17 JUDGE WOODLOCK: What's up in front of me. Look at
18 the left-hand side. It says "Percentage of Patients." You
19 don't see it there?

20 MR. ROTMAN: Yes, I do see it.

21 JUDGE WOODLOCK: Okay. They saw it there, too, and
22 they didn't know what it was referring to. Now, I want
23 everybody to get their best shot, but I have to tell you that
24 jury argument about, "See, they said this," I've made it clear
25 is not so persuasive.

1 So we're back to what do we have with data and what
2 can an expert do with that data. Not, "We heard that Hakim or
3 Lacson took a particular position." What does this data show?
4 So we ask or someone asks Akar or Borkan or Eldata, "What does
5 this mean? What does the percentage of 941 patients mean?"
6 And they say, "It's unclear," or, "I don't know."

7 MR. ROTMAN: Your Honor, these bar charts are
8 representing odds ratios, which is the relative risk. So the
9 black one on the far right is showing a relative risk of over
10 6. It's not showing the percentage of patients over 6, and
11 it's showing that it's statistically significant. And that's
12 based on that earlier distribution of bicarb comparing the
13 bicarb levels in the cases who had CP arrests to the controls
14 that didn't. And all I can suggest is this. At a trial, if an
15 expert is shown this document and can't explain it, then he
16 can't explain it.

17 JUDGE WOODLOCK: No. The whole purpose of *Daubert* is
18 to make sure that that kind of stuff doesn't go before the
19 jury; that the judges exercise some gatekeeping responsibility
20 for it. We're past the time before *Daubert* in which everybody
21 said, "That's what cross-examination is for." No. There has
22 to be some minimum level of admissibility by virtue of the
23 science.

24 And what you've just told me is this chart or the axis
25 on the right-hand side, "Percentage of Patients," which by the

1 way you didn't see, is meaningless, right?

2 MR. ROTMAN: I never paid attention to that, your
3 Honor. I paid attention to the odds ratio, which is the
4 essential conclusion.

5 JUDGE WOODLOCK: So what we're asking, what I'm asking
6 anyway, is I want to know the science and what they're going to
7 be doing to rely on it. And what I know now is we can't use
8 this one for percentage of patients. That much I know at this
9 point.

10 MR. ROTMAN: Right. You wouldn't use it for
11 percentage of patients.

12 JUDGE WOODLOCK: Even though it has it on there.

13 MR. ROTMAN: You would use it for the odds ratio.

14 JUDGE WOODLOCK: One would pick and choose, I guess.
15 So the point I guess I'm trying to get at, and it's a point I
16 made with your brother, is you've got data there, and they want
17 to use that data. They can use that data, and it can be the
18 source of examination, cross-examination, but it's not going to
19 be inflected by this, "By the way, this is their own data," or,
20 "This is what a memorandum that was the subject of iterative
21 process leads to." That's what I'm getting at.

22 MR. ROTMAN: So what we have is independent of the
23 November memo. We have information about the study which
24 individual experts can look at and interpret as best each one
25 of them can. There are a number of different experts with

1 different areas of expertise who can be asked questions about
2 what their interpretation is of the company's internal study.

3 JUDGE WOODLOCK: Can I test this a little bit by
4 virtue of the finding that the progressive shift toward
5 pre-dialysis serum bicarbonate levels is that more patients
6 have alkalosis prior to the dialysis but that an even higher
7 percentage of patients have alkalosis post-dialysis?

8 MR. ROTMAN: Yes, your Honor. Let me address that.

9 JUDGE WOODLOCK: Right, okay.

10 MR. ROTMAN: So that progressive shift was observed as
11 the company was going through a period of two things. Between
12 2000 and 2005 they were under the leadership of Dr. Lazarus as
13 chief medical officer. They were paying attention to treating
14 acidosis. And B, they were introducing to their clinics
15 GranuFlo. And what they observed over time -- and there's data
16 to support it referenced in documents that would be evidence at
17 trial where they're reporting that they are looking at
18 patients' blood levels before and after, comparing NaturaLyte
19 and GranuFlo, and seeing that GranuFlo -- patients whose
20 dialysis exposed them to GranuFlo had a larger increase. So
21 there's multiple sources to support --

22 JUDGE WOODLOCK: Multiple sources are the 2004 and the
23 2011 studies, right?

24 MR. ROTMAN: No.

25 JUDGE WOODLOCK: What are the sources?

1 MR. ROTMAN: Okay. If you want to look at that, we
2 start with, in 2012 -- I'm sorry. In 1993, we have the --
3 let's put up 0067. 0067, right.

4 Now, this was a study by Marcia Keane, the company's
5 internal study. The company says that the study is now lost.
6 However we do have this reported result which appeared in
7 marketing material. And what it shows is if you look at the
8 chart on the top, that's months prior to GranuFlo, and at the
9 bottom, months after GranuFlo. And you can see that on
10 GranuFlo, the numbers went up, and that's what we're talking
11 about is an increase --

12 JUDGE WOODLOCK: Let me just pause for a moment to
13 illustrate the problems I think with the Hakim memo. He didn't
14 rely on this, did he?

15 MR. ROTMAN: Okay. Dr. Hakim presumably relied on --

16 JUDGE WOODLOCK: Presumably? Did he rely on it?

17 MR. ROTMAN: So --

18 JUDGE WOODLOCK: Did he rely on it?

19 MR. ROTMAN: Dr. Hakim -- the memo --

20 JUDGE WOODLOCK: This document that you've just shown,
21 did he rely upon it in making his determinations?

22 MR. ROTMAN: I don't know.

23 JUDGE WOODLOCK: Well, "I don't know" means that the
24 party that bears the burden hasn't proven it.

25 Now, this is what I'm trying to get at here. That is

1 to say, you may have experts who have made reference to this,
2 they may make reference to what Hakim said he relied on, which
3 is 2004, 2011, and they may be able to stitch together a
4 determination that there was a shift.

5 But you don't get in the Hakim memo or that portion of
6 study qua portion of study in that fashion. That's what I'm
7 getting at. That's what I was trying to get at with your
8 brother. That's what I'm trying to get at with you. It is
9 seemingly unhelpful to say, "I don't know whether he relied on
10 it or not."

11 MR. ROTMAN: So at trial, your Honor, the plaintiffs
12 will present this study as well as other documents and other
13 data that show the effect of the GranuFlo on the patient
14 population blood levels, totally independent of this memo. But
15 in light of all of that, let's call it a decade's worth of
16 internal experience and internal data that one can assume that
17 the chief medical officer was aware of what --

18 JUDGE WOODLOCK: One can assume no such thing. The
19 point, I guess --

20 MR. ROTMAN: From --

21 JUDGE WOODLOCK: -- for *Daubert* purposes is you really
22 have to look at the science of people who are actually
23 presenting it. So if someone gets up and says, "I relied on
24 the Hakim memo," you know, as you say, you don't even know what
25 he relied on.

1 MR. ROTMAN: Let me put it this way. Let me put it
2 this way. So we have this cumulative data over a period of a
3 decade, and then the question is, "Is this statement in this
4 memo scientifically reliable?"

5 JUDGE WOODLOCK: No. The statement is, "Does this
6 witness have a proper scientific foundation for his view?"
7 Not, "Does this witness vouch for a statement made by someone
8 else?" That's the issue.

9 And all of this -- now let's just talk in a practical
10 way. All of this is an effort to tie in an admission, what's
11 perceived as an admission, and transform it into an expert
12 opinion. It doesn't work that way. It has to be made on the
13 basis of whether the science is solid enough for the underlying
14 document's admission or not. And so I'm saying to you, use it.
15 If your guys are going to use this data, they can use the data.

16 MR. ROTMAN: So I would imagine that the plaintiffs'
17 experts can form their own opinions about each of these
18 challenged seven points based on not looking at the November
19 memo and because there's this ten years' worth of data. And
20 then the question could be asked, "Do you agree with what the
21 company sent out to its clinics" --

22 JUDGE WOODLOCK: No, no.

23 MR. ROTMAN: -- on that point.

24 JUDGE WOODLOCK: I say no. I'll look at it carefully,
25 but I don't think so. I don't think so.

1 MR. ROTMAN: Okay.

2 JUDGE WOODLOCK: "Do you have an opinion?" "Yes, I
3 do." "Your opinion is based on what data?" "It's this data."
4 Not, "Do you then support the opinion that's set forth in this
5 document?" No. It's going to be the opinion of the expert
6 himself.

7 MR. ROTMAN: So what I guess I'm getting at is if the
8 opinion is -- if the opinion reached by an expert is
9 independently arrived at and itself matches what the company
10 admitted, the jury is not supposed to know about that?

11 JUDGE WOODLOCK: You mean the company said something,
12 in this format?

13 MR. ROTMAN: The company said in --

14 JUDGE WOODLOCK: I have some considerable difficulty
15 with that and its 403 analysis.

16 MR. ROTMAN: So separate from the issue of reliability
17 or only because of the issue of reliability?

18 JUDGE WOODLOCK: The larger issue of reliability. If
19 we just dealt with -- and it's the question I kept asking
20 earlier on. If we just got Hakim up on the stand and it was
21 only what he relied upon here and what's evident from what he
22 relied upon here and he was asked about that, I'm not sure that
23 this would be satisfactory. I'm pretty sure it wouldn't.

24 MR. ROTMAN: Shouldn't the question, though, be
25 whether the statement itself is a -- they've claimed that it's

1 subjective opinion and speculative. And if the statements that
2 they're challenging are supportable, independent of just the
3 fact that they appear in the memo and there's no -- and they're
4 not unreliable, if they are reliable statements, each one of
5 them can be looked at, for example, the one about
6 underestimating the --

7 JUDGE WOODLOCK: Then you do it with your own experts.
8 What you're trying to do is piggy-back in someone who is not
9 going to appear as an expert, not going to be subject to
10 cross-examination as an expert and say, "Him, too." You've got
11 to rely on your own experts in this case, not Hakim. If you
12 can rely on them, that's fine. If you can't, that's a
13 different question.

14 MR. ROTMAN: Your Honor, you say "Hakim," but I think
15 you were not interested to know that it wasn't Hakim.

16 JUDGE WOODLOCK: I'm interested in this. I'm looking
17 for a shorthand way of referring to this document. Hakim,
18 Lacson or even Mike and Frank really doesn't make very much
19 difference to me unless I know they've gone through the
20 necessary science to do that. And what is problematic is it
21 doesn't seem that they have here, that it has been done here.

22 MR. ROTMAN: Your Honor, what the memo does is it
23 doesn't -- it's not a textbook. It's a memo that says, "We,
24 the experts within this company, the experts on our product,
25 based on knowing what we know because we've done an analysis,

1 because we've been monitoring our patients, because we know
2 something about bicarbonate and alkalosis and all of that,
3 we've concluded A, B and C"; number one.

4 Number two, the "we" is not just Hakim. It's top
5 people within this organization, including, as I said before,
6 their current chief medical officer and their former chief
7 medical officer as well as Hakim and Lacson and others. So now
8 the question is not what did they consider, but is it right,
9 and is it reliable science.

10 And each one of these statements, each one of them,
11 you can go through and say, "Yes, this is reliable," and you
12 can show where it's reliable, but the memo itself doesn't go
13 into an, "Okay. Now we're going to explain all the reasons we
14 say this statement." You know, when people write memos, they
15 write a memo, and they don't now explain every sentence with a
16 chapter.

17 But it seems like that you're saying the memo itself
18 has to be self-containing of all of the underlying data that
19 led to every statement. That's not the reality of what you'll
20 see in any memo that this company has ever sent out. They say
21 things all the time, and you could look at any sentence and
22 say, "Where did that come from?" Well, it may be reliable and
23 it may not be reliable, but the point is, they make statements
24 all the time.

25 JUDGE WOODLOCK: We're talking about expertise. We're

1 not talking about other forms of evidentiary admission.
2 Admission upper case and admission lower case. We're talking
3 about expertise and how experts are going to present themselves
4 here. That's what we're talking about for these purposes.

5 MR. ROTMAN: Correct.

6 JUDGE WOODLOCK: So I'm just flagging an issue for you
7 that you better be prepared to deal with, and you haven't yet.

8 MR. ROTMAN: One of the things that the -- one of the
9 things that the plaintiffs' experts rely on because it's
10 important to the case, even though it's just one piece of
11 evidence, it's an important piece of evidence, is the study and
12 the study results. And they don't need the November memo to
13 testify about it.

14 JUDGE WOODLOCK: Then this won't be much of a problem
15 for you.

16 MR. ROTMAN: Okay.

17 JUDGE WOODLOCK: If that's the case. But I'm just
18 telling you that from my perspective anyway, I'm looking at the
19 underlying science and not who said what at what time, except
20 for the person who actually gets on the stand and says, "I
21 looked at reports of this data and this data and this data and
22 I drew this conclusion."

23 MR. ROTMAN: Your Honor, Mr. Ketterer wanted me to
24 reserve some time for him to come back and make some points,
25 and I think that based on the amount of time that he'd like,

1 I'm going to hand it over to him.

2 JUDGE WOODLOCK: Okay.

3 MR. KETTERER: Your Honor, I'm going to try to be
4 brief because I've been listening to the dialogue, and based on
5 previous dialogue, I want to make sure that we are coming right
6 at what you want to talk about, which is, as I've heard you
7 begin the discussion with Mr. Rotman, it was, "Tell me the
8 science and the reliability of the science behind the
9 conclusions that Dr. Hakim drew."

10 And one of the issues or one of the problems I think
11 in getting to that is you also would have to know the
12 foundation of information that Dr. Hakim has in his whole broad
13 spectrum of knowledge as a physician, right, as a practicing
14 nephrologist, somebody who is running a huge amount of clinics.

15 So the idea of let's say dialysate bicarbonate is what
16 escalates the serum bicarbonate in a patient, right, or
17 acetate's effect on it, it isn't looking just at the memo and
18 saying, "Well, did he include that in his information?" Part
19 of it is -- and we do have these documents cited in the brief.
20 I'm not just out there throwing stuff out there for you to look
21 at. What I'm saying to you is that if you look back at the
22 historical development --

23 JUDGE WOODLOCK: This is like prosecution history of a
24 patent. And that's not something that is sufficiently helpful
25 to the jury in making its determination.

1 MR. KETTERER: Let me refine what I'm saying, what I'm
2 pointing to exactly, your Honor. If he's looking at a certain
3 data point -- let's say he's looking at this patient population
4 to see how serum bicarbonate is affected in his patients, that
5 affects his conclusions -- and he cited, by the way, 11 sources
6 of information at the back of his data, so it's not like he
7 didn't have any citation or any foundation to the conclusions
8 that he drew, right? The association between cardiopulmonary
9 arrest and the elevated bicarbonate, it's cited literature that
10 he has in the back of the memorandum. If you look at the
11 memorandum, the last page is his 11 cited sources.

12 JUDGE WOODLOCK: See, I really feel I've been speaking
13 too much, and Judge Kirpalani, characteristically, is much more
14 restrained than me. But what you're trying to do is say,
15 "We've got an expert who is going to testify by virtue of this
16 document. We're going to put this document up on the stand,
17 and we're going to say, 'See, here is the expert's testimony.'"
18 And that's not enough.

19 MR. KETTERER: I don't think that's a fair --

20 JUDGE WOODLOCK: Just a moment. So if your experts
21 are relying on the reference list back there, terrific. All
22 11, plus the data, terrific. But the idea of putting someone
23 on the stand, and that's really what it is, whoever the
24 draftsman is, putting someone on the stand and making them
25 an expert when there are underlying problems with materials at

1 least on its face is something that I would be very concerned
2 about permitting a jury to hear.

3 So that's why I'm saying maybe you want to suggest a
4 scalpel use or maybe you want to leave it to a meat axe --
5 that's me -- to try to make these kind of determinations about
6 how this evidence gets in.

7 MR. KETTERER: I think then we're having a
8 misunderstanding of what the characterization is of how we
9 would have our experts testify, your Honor. So let me be clear
10 about that, because if the table has been set with this premise
11 of, "Well, your expert is going to come in," or the idea is
12 that the expert comes in and says, "Let me review this memo.
13 I've reviewed this memo, and therefore because the memo said
14 it, that's the reason why I have" --

15 JUDGE WOODLOCK: Or he's going to say, "I've reviewed
16 this memo. I agree with the memo." And that is I think very
17 close to what your brother was talking about here. No. That's
18 the problem.

19 MR. KETTERER: I get that point, your Honor, that what
20 you don't want is you don't want an expert to come in and
21 say -- to essentially validate for the sake of validation,
22 "Here is this memo. I agree with this memo. Ergo the memo is
23 automatically correct." I mean, that's what I understand you
24 to be saying. Because, because, the reason is if this memo is
25 not scientifically accurate, the Courts as the gatekeeper need

1 to act in restricting that as validated information and not
2 snuck in through an expert to self-validate the information.
3 Is that -- I mean, I think I understand that being some of the
4 philosophy behind the rationale, right?

5 JUDGE WOODLOCK: Yes.

6 MR. KETTERER: I think the way we're intending to have
7 this play out, especially, given the dialogue we're having, is,
8 look, we have to be able to say where the data is, where it
9 comes from because a lot -- a large amount of the data that's
10 being reviewed is internal Fresenius data. So I think that's
11 one of the premises.

12 So look, "Has part of the analysis been yearly data
13 analyses?" "Yes." "Have you looked at that particular
14 data" -- I mean, this is a very informal way of doing it. I
15 don't want to be held to this. "Have you looked at the
16 different data from different years that Fresenius has
17 collected?" "Sure." "And what is it in your opinion that you
18 believe that that particular data set reflects?" "It reflects,
19 and here is my opinion." Then in addition to that, "Are there
20 other things you've considered?" Let's say they started the
21 other way and they've talked about this other data and this is
22 how it's been considered.

23 And what I think that you want to avoid or what I
24 intend to avoid -- and I don't know from Judge Kirpalani what
25 he would like to avoid or not avoid -- is saying that the memo

1 is in and of itself evidence of causation that I agree with,
2 and you should accept it as causation evidence standing alone.
3 There's a separate question out there as to how this memo may
4 or may not come in and for what purposes it may be offered, but
5 you're suggesting that the expert look at the data points, draw
6 their own conclusion of their data points in the totality of
7 all of the evidence that they weigh and make their opinions and
8 offer their opinions based on that construct. Am I to
9 understand that to be basic --

10 JUDGE WOODLOCK: I think that basically says it from
11 my perspective.

12 MR. KETTERER: And I don't think that there's a
13 fundamental disagreement when you're presenting the issue of, I
14 don't want the memo paraded out there as conclusory evidence
15 that the jury might misinterpret, saying this is an internal
16 memorandum. And I don't think it's a correct suggestion
17 either, by the way, because I can hear what's going to happen.
18 The defendant will pop up and say, "This is the only evidence
19 they have. This is the major evidence." I think that's an
20 entirely separate question because we don't have that motion
21 before us.

22 The motion -- and we'll get to it on the
23 case-specific, but the only evidence is not -- and this is the
24 impression I want to make sure the Court understands because I
25 think it's very important in the context of this dialogue,

1 which is that it would be a complete falsity to say that any of
2 the experts are only relying on the Hakim data or the Hakim
3 memo in the formation of their general causation opinions, or,
4 once we get there, the case-specific opinions.

5 It is not evenly the major necessarily piece of
6 evidence in how they arrive at looking at an individual patient
7 certainly and the overall theory of how the product works on
8 affecting bicarbonate, which is ultimately what we say is what
9 leads to the outcome of the condition.

10 And if we're going to get away from all of this, well,
11 how did we get there and the vagaries behind the memo as well,
12 then I certainly can appreciate where the Court is coming from,
13 and I understand that. And I want to make sure that we're
14 addressing head-on -- and I understand that Judge Kirpalani
15 hasn't said anything. But I want to address head-on what
16 you're addressing, Judge Woodlock, and I want to make sure
17 we're very clear on that.

18 JUDGE WOODLOCK: I think you are. I think this
19 response kind of frames the issue. There is the procedural
20 issue that I raised with Ms. Brooks, which is, do you think you
21 have summary judgment. Well, if she did, she should have filed
22 a motion a lot earlier. And so the answer to that is we go to
23 trial, and we look at it afterwards and say, "Was it
24 improvidently introduced?" And if it was improvidently
25 introduced and in its absence the evidence would be

1 insufficient, then that's the procedural way of dealing with it
2 in light of the chronology that we have right now.

3 MR. KETTERER: Sure.

4 JUDGE WOODLOCK: See, I take it that you think you can
5 make your case without the vouching for Hakim.

6 MR. KETTERER: Absolutely, your Honor. I want to make
7 sure because I felt like in the dialogue and in the exchange,
8 especially in the totality of the argument, that there was some
9 semblance of you feeling like, "Look. Maybe this is your
10 centerpiece, and if you couldn't do this, you wouldn't be able
11 to build the case." And I want to make sure that, you know,
12 especially over the course of the next few days, that that's
13 absolutely not the case, that we do have the ability --

14 JUDGE WOODLOCK: No one has made a summary judgment
15 motion. This frequently happens in cases, saying strike this,
16 and once you strike it, there's nothing left. That's where we
17 are.

18 Now, Ms. Brooks has suggested that there will be no
19 there there when this leaves, but the way we're going, at least
20 I think I will test it, and Judge Kirpalani will choose his own
21 methodology, I'm sure, but the way I'll test it is we're going
22 to trial. The trial is going to be shaped in this particular
23 way. And if it turns out that without this information, the
24 data, you don't make it over the bar, that's the problem.

25 MR. KETTERER: Well, I think the data is going to come

1 in, your Honor. It's just that the data won't come in through
2 a methodology which presents it in the form of a memo being
3 scientifically certified, I think is what you're suggesting.

4 In fact, what you're suggesting is the expert should
5 look at the data and draw his or her own conclusions about the
6 data, so it's not that the data will not come in, nor is it
7 that -- the memo is a separate subject, which we'll have our
8 separate argument about. And I believe the memo should come
9 in. There's a variety of reasons. Because this iteration of
10 memo also isn't the only iteration of the memo, so the problem
11 is it's out there in a variety of different fashions and not
12 necessarily presented from Dr. Hakim's lens, who, he didn't
13 touch the memo or the information in it.

14 So in either event, that's an argument for a separate
15 time. But in either event, for an expert to sit up there and
16 certify it, that's what I understand the objection to be. And
17 I'm more than happy to defer to the Courts on this particular
18 issue and to address it appropriately.

19 JUDGE WOODLOCK: Well, I've been fairly upfront about
20 concerns, and I think we -- I won't speak for Judge Kirpalani,
21 but those are concerns that we have to address here, and the
22 response to the motion for preclusion may be shaped by that,
23 the resolution of the motion by us.

24 MR. KETTERER: I'd certainly ask that you consider
25 looking at the foundational process, though, to consider --

1 behind the totality of looking at some of the development of
2 how it came about with Dr. Hakim and Dr. Lacson and some of the
3 other people.

4 You mentioned the peer review process, but peer review
5 is really other physicians and scientists looking at a piece of
6 data. And they are independent, and I understand your
7 question, which is, "Look. If you were on the flip side, you'd
8 be telling me the exact opposite. You'd be telling me how this
9 isn't peer review and how it's not necessarily credible." And
10 I think you have to look at that fact-by-fact situation. I
11 think it's a form of peer review, certainly. You know, whether
12 it satisfies *Daubert*, I think in this instance it probably
13 does. And I think Mr. Rotman's point was accurate.

14 I understand your larger concern and the larger
15 concern behind the presentation. What I did want to do is,
16 Judge Kirpalani, I don't know -- certainly I'm going to be
17 co-counsel on the case so I want to know.

18 JUDGE KIRPALANI: Well, I will say that the way that
19 that the issue has been framed in the last few minutes I think
20 accurately reflects the concerns I have about how experts may
21 use this memo, if at all. And I don't have an issue with the
22 data being relied upon, whatever data the company has, assuming
23 that a sufficient foundation is made for the use of that.

24 MR. KETTERER: And my only response and sort of tail
25 on that is I've certainly heard the Courts' opinion and

1 rationale for it. And we'll certainly understand whatever
2 tailoring or fashioning is done in response.

3 I do want to make the sort of concomitant argument
4 which is that the expert then in terms of any bias that might
5 surround the data, the data is the data. So if we start
6 introducing like, "Hey, do you know where this data came from,"
7 or beyond the company, or you start introducing things about
8 Dr. Hakim specifically or the development of how that memo got
9 issued before the expert, I think that that becomes an unfair
10 ground to get to that.

11 JUDGE WOODLOCK: Right. I can't imagine that the
12 defendants are going to do that. Are you?

13 MS. BROOKS: No, absolutely not, your Honor. We will
14 be relying on Fresenius data as we showed the Court, our year
15 over year data, our mortality data, we will certainly be
16 relying on internal data.

17 JUDGE WOODLOCK: It has to be a live expert that comes
18 in and says, "I looked at this data, and here is the conclusion
19 I drew from that data"?

20 MS. BROOKS: Exactly.

21 MR. KETTERER: And as long as the playing field is
22 level on that sense, then that's appropriate. Now, the other
23 issue of how the document may come in or other documents that
24 are similar, whether there's questioning on those things,
25 that's fine. I will say that the other issue is that Dr.

1 Hakim's deposition will certainly be played, and it wasn't
2 offered as anything more than a fact witness deposition. So
3 the issues concerning this particular memo come out in that
4 deposition as well, but they're not presented from necessarily
5 an expert deposition.

6 JUDGE WOODLOCK: And that, as far as I'm concerned, is
7 motion in limine stuff. This is to deal with what can be used
8 by experts purporting to -- or who will be testifying by either
9 side.

10 MR. KETTERER: I've certainly heard the Courts'
11 concern. I don't want to repeat myself again about what it is
12 that your concern is in terms of I think that we've accurately
13 framed what the understanding is, at least at this point for
14 the Court.

15 The only thing I'd ask certainly is in reviewing or
16 making some sort of final decision, that in looking back at the
17 process of genesis of how some of the information was gathered
18 and put together, I think it is important in looking at this
19 foundational concept of was it reliable or not; was it reliable
20 science. And although I think that you were looking for
21 something a little bit more from Mr. Rotman, I do think the
22 point on the methodology on that was really important that he
23 was making and demonstrating. The methodology is a
24 foundational concept when you challenge the underlying report.

25 JUDGE WOODLOCK: Absolutely, but it's the methodology

1 of the people who are going to be testifying here. I think
2 we're both going back and stating and restating an
3 understanding that we both have at this point.

4 MR. KETTERER: Very good. All right. Thank you, your
5 Honors.

6 JUDGE WOODLOCK: So I guess -- I think both of us view
7 the other two memoranda that popped up in this context is
8 written science day course that we're only dealing with motions
9 to preclude. The only one that was on for this morning is
10 Hakim. And then we'll move on this afternoon to Borkan, Lipps
11 and Colton and Zydney, all right?

12 And one thing I think we were talking about is making
13 sure that we're on schedule for this. It's helpful to all of
14 us I think to shape the rigor with which we approach the
15 issues, so we'll try to keep to the schedule that's reflected
16 here and count on you to make sure that you've had equal time
17 to the degree you think you need equal time.

18 JUDGE KIRPALANI: And maybe you can discuss over
19 lunch, tomorrow we're down to three motions being heard, so
20 it's predictable that maybe we'll shift some of today's
21 scheduled arguments into tomorrow. We do have a whole day set
22 aside tomorrow.

23 JUDGE WOODLOCK: We lost two in the morning. You're
24 prepared to submit on the briefs as to --

25 MS. BROOKS: That's right, your Honor.

1 JUDGE WOODLOCK: So we have some flexibility on it.

2 MR. KETTERER: Also I think on some of the motions, to
3 try to be upfront, I'm going to try to be brief in terms of
4 arguing even those three tomorrow.

5 JUDGE WOODLOCK: I'll try to do the same thing.

6 MR. KETTERER: I don't want to belabor the points that
7 were made in the briefs, but there are some overarching points
8 that I think should be highlighted, and those are things I'd
9 like to discuss tomorrow.

10 JUDGE WOODLOCK: So we're back at 2:00.

11 (Lunch recess taken 1:11 p.m. to 2:00 p.m.)

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

14 MR. ROTMAN: Your Honor, before the break I had made
15 reference to a document that I want to make sure is part of the
16 record, so I have a copy I would like to hand to the Court and
17 to opposing counsel.

18 JUDGE WOODLOCK: Is it part of the record?

19 MR. ROTMAN: Unfortunately, it was inadvertently left
20 off the briefing, but I referred to it and it's a document that
21 we consider to be important. So, a copy for counsel.

22 MS. BROOKS: Thank you.

23 MR. ROTMAN: I have one copy today. Do I need two?

24 JUDGE KIRPALANI: We will manage.

25 JUDGE WOODLOCK: We have a Xerox machine, even if you

1 do not.

2 MR. ROTMAN: This is marked as GFPL2196, and it's the
3 October 27 email that says that --

4 JUDGE WOODLOCK: I'm sorry. "October"?

5 MR. ROTMAN: October 27, 2011 email that indicates
6 that -- I made reference to it as Frank and Mike had approved
7 the --

8 JUDGE WOODLOCK: This is Frank and Mike writing back?

9 MR. ROTMAN: This is the email saying that Frank and
10 Mike approved the draft.

11 JUDGE WOODLOCK: Right. That was the one that was up
12 on the --

13 MR. ROTMAN: Right. I showed it to the Court, but
14 here is the paper copy so that it will be part of the record.

15 JUDGE WOODLOCK: We will make copies of it.

16 There is one other preliminary matter. We had some
17 discussion about further bellwether in the federal cases in the
18 MDL and a request that it be before August 15th, I think, was
19 the time period. I am thinking about June. I talked to
20 Judge Kirpalani, and I think that may crush the schedule there.
21 I just ask you to look and see if the second week in June,
22 starting a trial then would work on it. We can talk about it
23 more. I will try to get greater specificity of my schedule,
24 but that is when it would work now without some extra effort,
25 which I am prepared to make, if it is necessary, but I think I

1 want to have one more bellwether before the summer is over.

2 I do not know enough about how you handle your trial
3 teams and replenish your troops, so you will have some idea
4 about that, and maybe we can talk about it tomorrow.

5 MR. TARRICONE: Your Honor, we will consider that and
6 report tomorrow.

7 JUDGE WOODLOCK: All right.

8 MR. TARRICONE: Beginning the second week in June?

9 JUDGE WOODLOCK: Yes. Let me be sure about it. I
10 should have brought my papers down, actually, on that, and I
11 know there is an overlap or potential overlap with
12 Judge Kirpalani's case, which takes precedence, as far as I am
13 concerned.

14 JUDGE KIRPALANI: And so, I have trials scheduled for
15 April 4th and May 23rd. That probably means that the May 23rd
16 one could be moved up, but I do not remember why we picked that
17 date. I know we adjusted April 11 back to April 4, and it had
18 something to do with another trial; but all I guess I am saying
19 is that if consideration can be given to moving the May 23rd
20 date earlier to facilitate a June trial in the Federal Court, I
21 am amenable to it, unless it is causing a problem that I am not
22 aware of, because I think there are more than three weeks
23 between the end of the April trial and the beginning of the May
24 trial.

25 MS. BROOKS: I think, your Honor, I might have been

1 the problem. I had a trial set for May, early May, and so your
2 Honor put it to later May. But the good news is that just
3 yesterday that trial date was vacated, so if I was the cause of
4 the conflict, my conflict has gone away.

5 JUDGE KIRPALANI: I don't remember, but in your
6 discussions, just keep in mind, if there is an ability to move
7 the May 23rd trial date earlier, that's fine with me.

8 JUDGE WOODLOCK: The ideal date for me would be
9 June 13, but, again, priority goes to Judge Kirpalani's cases
10 and the scheduling of Judge Kirpalani's cases, and if that
11 squeezes people, then tell me, and some other poor devils may
12 find themselves knocked out for July.

13 JUDGE KIRPALANI: So, next on the list, which was
14 actually on the morning list, was plaintiffs' Daubert Motion to
15 Preclude defendants' experts from opining, basically, that
16 there is insufficient evidence for the plaintiffs' general
17 causation experts to rely upon.

18 MR. KETTERER: So, your Honor, I think that this would
19 be better handled when we get to Dr. Chertow and tomorrow's
20 slate, and I think it will give us some -- you actually hadn't
21 raised it when you were leaving the Bench, and I think we can
22 go right to Dr. Borkan's motion so we can stay on schedule.

23 JUDGE WOODLOCK: I think that's helpful, because,
24 honestly, the motion lacks some specificity in terms of what
25 opinions are sought to be included.

1 MR. KETTERER: Right. And I think we can give it
2 context tomorrow.

3 JUDGE WOODLOCK: So, context would be helpful.

4 So, we will move to Fresenius's motion to limit the
5 opinions of Dr. Borkan.

6 MR. MELSHEIMER: May it please the Court, good
7 afternoon, Judge Kirpalani, Judge Woodlock. Tom Melsheimer.

8 Might I approach the Bench with some PowerPoints?

9 JUDGE WOODLOCK: You may.

10 MR. MELSHEIMER: May it please the Court, Dr. Borkan
11 is a nephrologist who has proffered opinions on general
12 causation. We don't question his credentials. What we do
13 question is the content of several of his proffered opinions,
14 which violate, we think, a fundamental premise of the Daubert
15 and Lanigan line of cases, which is simply this: That an
16 expert should not say and act in one way outside the courtroom
17 and then come into court and say something different. That's a
18 fundamental problem that infects several of Dr. Borkan's views
19 which we seek to have these Courts exclude.

20 By way of background -- and we've covered a good bit
21 of this already -- these cases began almost exclusively as a
22 result of what we have talked about as the "Hakim Memo."
23 Thousands of lawsuits quickly followed, and at their inception
24 the focus of these lawsuits was on patients that had high,
25 so-called high predialysis serum bicarb levels, and who had

1 been treated with GranuFlo and who died during dialysis.

2 Specifically, the original Master Complaint in this
3 court and in Massachusetts had language, which we will look at
4 in a moment, which described the offending product as one that
5 had greater than 4 acetate content. Now, as thousands of these
6 cases were filed, it became apparent that many of the
7 plaintiffs did not have high predialysis serum bicarbonate
8 levels, they did not die during dialysis, and they had not been
9 treated with GranuFlo, but, instead, had been treated with
10 another formulation called "NaturaLyte." At 4 acetate
11 NaturaLyte did not fit into the allegation of the Master
12 Complaint, and the plaintiffs sought and were granted leave to
13 add allegations regarding NaturaLyte, and now the offending
14 product is one with either 4 acetate or 8 acetate. So, the
15 plaintiffs needed an expert to opine consistent with their
16 allegation that an acid concentrate of 4 acetate created risk
17 of sudden cardiac arrest or other harms. They also needed an
18 expert to address the thousands of cases where plaintiffs had
19 ideal or model predialysis serum bicarb levels, and finally
20 they needed someone to address the fact that thousands of these
21 plaintiffs had not died during dialysis but had died hours or
22 sometimes days later. So, enter Dr. Borkan.

23 The problem for Dr. Borkan and the plaintiffs with
24 regard to certain of his opinions is that there is not
25 scientific evidence-based foundation for his opinion that an

1 acid concentrate with 4 acetate poses any kind of risk of
2 sudden cardiac arrest, or that plaintiffs who present with
3 normal or model predialysis serum bicarb levels are at any risk
4 of sudden cardiac arrest, or that the effects of serum acetate
5 could only be manifested -- or could be manifested not just
6 during dialysis, but, in one instance, up to 37 hours later.

7 So, that's the context, if you will, your Honors, for
8 the three opinions that we seek to exclude, and they are as
9 follows:

10 Dr. Borkan's opinions -- and these are manifest in his
11 report in different ways. I have cited particular pages, but
12 our briefing also describes other ways that these opinions are
13 manifest. But the first one is that the use of GranuFlo and
14 NaturaLyte or NaturaLyte risks a dangerous bicarbonate spike
15 that can result in cardiopulmonary arrest. So, that's the
16 addition of the NaturaLyte issue.

17 Two, that all dialysis patients, including those with
18 either low predialysis serum bicarb levels or high predialysis
19 serum bicarb levels, are at risk of cardiopulmonary arrest if
20 they are treated with GranuFlo or NaturaLyte.

21 And then the final opinion that we seek to exclude is
22 this notion that blood bicarbonate levels can spike solely as a
23 result of acetate contained in the acid concentrate for some
24 undefined period of time. What we focus on here is that
25 Dr. Borkan does not identify what this undefined period of time

1 is. It apparently simply matches whatever plaintiff he is
2 presented with in terms of timing.

3 So, the first opinion regarding the use of GranuFlo or
4 NaturaLyte causing risks of dangerous bicarbonate spikes
5 resulting in cardiopulmonary arrest, really what this is, is
6 his opinion that even an acid concentrate with 4 acetate is
7 somehow dangerous.

8 Now, as I mentioned earlier, the original Master
9 Complaint, which is here on Slide 4, talks about concentrations
10 of acetate greater than 4. So, that would exclude NaturaLyte,
11 which was 4, and it always has been 4. That was in December of
12 2013. In August of last year the Complaint was amended to
13 include both 4 acetate products and GranuFlo as an 8 acetate
14 product.

15 Dr. Borkan accuses NaturaLyte at 4 milliequivalents of
16 acetate, and he does this -- and I've given specific examples
17 of this. He does this in his report, as we cite on Page 22,
18 but then it manifests itself in specific causation reports that
19 he gives. So, for example, I know we are not here to talk
20 about the Dial case, but this is an example of how he opines
21 that the patient Dial, the plaintiff Dial, who was treated with
22 NaturaLyte, was subjected to excess bicarbonate because of the
23 4 acetate contained in NaturaLyte. He does this also in the
24 Dickson case, where he takes NaturaLyte, focuses on the acetate
25 content there and concludes that that is what caused

1 Mr. Dickson's death.

2 Now, why is this problematic? Why is it problematic
3 or, put another way, why are these opinions an issue for this
4 Court as a threshold matter under the Daubert line of cases?
5 The reason is because an expert cannot live in two different
6 worlds. An expert cannot live in a litigation world where he
7 offers one opinion but in the real world do something else, and
8 we cite here from the Kumho Tire case that experts must apply
9 in the courtroom the same level of intellectual rigor that
10 characterizes the practice of an expert in the field. And I
11 will suggest to you and show to you that that is not what
12 Dr. Borkan has done. He has applied a litigation approach that
13 differs dramatically from his real world approach as a doctor.

14 So, he says here on Page 22 of his report, he explains
15 what the gist of his opinion is, which is, he says, "Given our
16 understanding of the intimate relationship between bicarbonate
17 and other critical electrolytes at the time acetate and
18 diacetate/bicarbonate solutions were introduced, the increase
19 in peri-dialysis deaths due to exposure to excess acetate is
20 both predictable and avoidable."

21 So, "excess" is his term. Now, that's, of course, a
22 term that doesn't really have any fixed meaning. What is
23 "excess"? What is "high"? And what he does is, is he defines
24 "excess" in a particularized way. He says that his
25 understanding is that anything above 2.4 milliequivalents of

1 acetate would enhance bicarbonate delivery but was not
2 necessary to maintain the pH of the dialysis solution in a safe
3 range. So, what he says is 2.4 is what it should be, and
4 anything over 2.4 is excess.

5 Now, a couple of problems with that. First, this is
6 just an *ipse dixit* by him. He doesn't give any source for
7 this. He doesn't say what the basis for his understanding is.
8 We think the basis of his understanding, and I think he spelled
9 this out a little bit later, was that there is a
10 citric-acid-based acid concentrate that has 2.4 acetate. So,
11 he concludes that, if it's good enough for that, then anything
12 above that is unnecessary, but he doesn't cite to any studies
13 or doesn't cite to any analysis as to why 2.5 or 2.6 or 2.7
14 wouldn't be appropriate. Nor does he address anywhere, and
15 this is one fundamental problem with his opinion here, is that
16 it's an industry standard to have 4. Numerous manufacturers,
17 Rockwell, Fresenius, others, all have an acid concentrate
18 product that has 4 acetate. He doesn't address how it could be
19 excess, when, in fact, it appears to be an industry standard.

20 And, indeed --

21 JUDGE WOODLOCK: It is interesting, but industry
22 standard really does not make a difference. To go back to
23 T.J. Hooper, there can be a standard and it is not a good
24 standard.

25 MR. MELSHEIMER: The standard could be wrong,

1 absolutely could be wrong. But what he doesn't address, your
2 Honor, and I think one of the requirements is, and that he at
3 least be forced to address this, the *Handbook of Dialysis*,
4 which is the leading treatise, talks about the customary acid
5 concentrate containing 4 acetate. So, I agree, the industry
6 standard could be dead wrong, but he has at least got to
7 grapple -- if he is going to say that anything above 2.4 is too
8 much, he ought to have to address why everyone else is doing 4,
9 why the *Handbook of Dialysis* says it's common and customary to
10 use 4.

11 JUDGE WOODLOCK: Does he have to do all the rest of
12 it, or does he simply have to show that there is a basis for
13 saying 2.4 is excess?

14 JUDGE KIRPALANI: Why does he have to address what
15 contradicts him? Doesn't he have to address what supports him?

16 MR. MELSHEIMER: I think he has to do both, your
17 Honor, respectfully. I think the Daubert line of cases say
18 that experts who ignore -- and we cite some of these cases in
19 our brief -- ignore contrary evidence, that that makes their
20 methodology not reliable, because they are supposed to take
21 everything -- they don't have to agree with it. He can
22 certainly say, "Well, I disagree with the 50-year-old *Handbook*
23 *of Dialysis*. I think that's wrong." He can certainly say, "I
24 think all these other companies that offer 4 acetate, that
25 they're wrong, too." But he's at least got to grapple with

1 that. Instead, what he does is, he picks a number somewhat out
2 of the air based on this one citric-acid-based acid
3 concentrate, and says, "Well, 2.4 is really all you need, so
4 anything above that is too much."

5 Now, your Honor, he struggles with this in depositions
6 in other matters, and we have cited this in our brief. In the
7 DaVita litigation, which is a class action pending out in
8 Colorado, he was asked questions about what the appropriate
9 amount of acetate was, and he's asked, Question: "When you're
10 talking about excess acetate, you're talking about the
11 additional 4 milliequivalents that GranuFlo has beyond the
12 other typical acetates?" And he says, "Yes, that's correct,"
13 because in that case he was talking about GranuFlo and not
14 NaturaLyte. So, he's calling "excess" there anything above 4.

15 JUDGE WOODLOCK: Well, it is excess above 4, according
16 to his analysis. It's also excess above 2.4.

17 MR. MELSHEIMER: Correct.

18 JUDGE WOODLOCK: So, this is not necessarily
19 contradictory.

20 MR. MELSHEIMER: Well, your Honor, except we'll
21 continue with his testimony here, where he says that there is
22 an acid concentrate that does not contain excess acetate, and
23 he says, "Yes, that would be solutions that contain 4
24 milliequivalents of acetate, rather than 8." In other words,
25 he's defining it there.

1 Now, you might say, "Well, wait a minute, isn't this
2 just an inconsistency that can be explored through
3 cross-examination?" The reason why it's not merely that -- it
4 certainly is that -- but the reason why it's more than that is
5 that in the real world, when Dr. Borkan is being Dr. Borkan and
6 not being "Expert Borkan" he treats his patients differently.
7 He's asked, "Have you done anything to advise your patients
8 that they were being treated with NaturaLyte?" And he says, "I
9 don't believe that advising them is necessary, because the
10 solutions contain an amount of acetate that is acceptable."
11 Question: "Which is what, just so I'm clear? Is that 4
12 milliequivalents or less?" He says, "Yes, that's correct."

13 So, this testimony and this practice of his creates an
14 inconsistency that the Daubert cases do not tolerate. As a
15 treating doctor he views NaturaLyte with 4 acetate as
16 acceptable, so acceptable, by the way, that he doesn't even
17 feel the need to advise his patients when he's treating them
18 for End Stage Renal Disease that they are being treated with
19 NaturaLyte, but when he's here as an expert he takes a
20 different approach and all the while never citing a study that
21 says that 4 acetate is problematic, that 4 acetate creates risk
22 in the acid concentrate. And so, that's fundamentally why we
23 think his opinion on that subject should be excluded.

24 Now, this has practical implications, and I'm just
25 pointing this out just for the Courts' benefit. At least half

1 of these cases, roughly half, maybe a little bit more than
2 half, do not involve GranuFlo. So, you've got some 12,000
3 cases. We have estimated that about half of them don't involve
4 GranuFlo. So, the implications are that there is not a proper
5 general causation opinion for half of the filed cases.

6 JUDGE WOODLOCK: Is there no one else who uses a
7 figure like 2.4 or something under 4, no other expert who
8 speaks about that?

9 MR. MELSHEIMER: I'm not aware of any, your Honor, on
10 this particular issue.

11 Borkan Opinion Number 2 which we seek to exclude:
12 "All dialysis patients, including those with low or high
13 predialysis bicarbonate levels, are at risk of cardiopulmonary
14 arrest because of GranuFlo or NaturaLyte." Where is this
15 coming from? Well, remember, the genesis of this was people
16 that were presenting with, quote, high, however you define
17 that, predialysis serum bicarb levels, and what Dr. Borkan says
18 is, "It doesn't matter; if you're low, if you're high, you're
19 still at risk because of GranuFlo or NaturaLyte."

20 This opinion also is inconsistent with prior
21 testimony, prior opinions he has given, but also, again,
22 inconsistent with his own clinical practice.

23 So, we have this testimony. He's asked: "You
24 mentioned that if a patient is over your target range for
25 predialysis serum bicarb, that would affect your bicarb

1 prescription. What is your target range?"

2 And he says -- and this was a deposition taken in the
3 Massachusetts State cases -- "I try to keep my dialysis
4 patients between 22 and 24..."

5 Question: "And have you ever heard of a KDOQI
6 guideline" -- we talked about that earlier this morning --
7 "that indicates that serum bicarbonate levels should be kept at
8 greater than or equal to 22...?"

9 Well, "To answer your question accurately, since 24 is
10 higher than 22, I believe that KDOQI has a range of 22 to
11 24..."

12 So, two implications here. The first testimony is
13 talking about his own practice, that he tries to keep his own
14 patients between 22 and 24. In the second set of questions is
15 really the medical standard. Now, it's not just his medical
16 standard or his practice. There are other standards that
17 support it. The DOPPS Study, for example, which we have cited
18 in our PowerPoint presentation, which is a study -- Ms. Brooks
19 talked about DOPPS 1. DOPPS 2 came out in 2014. It indicates
20 a safe range of predialysis serum bicarb levels of around 22 to
21 24, and I don't think there's any study anywhere that suggests
22 that something that is within the patient who presents within
23 that range is not exactly where they're supposed to be.

24 Now, of course, every patient is a little bit
25 different. It's hard to keep individual patients at a certain

1 range all the time. Maybe they are a little bit higher, maybe
2 they are a little bit lower. But that's why these guidelines
3 say, Hey, shoot for a predialysis serum bicarb range of about
4 22 to 24. That's going to prevent both the acidosis on the low
5 side and the alkalosis on the high side. That's where they
6 should present when they come in for treatment.

7 Well, again, the implications here for these cases are
8 serious as well, because here there is about 27 percent of
9 these filed cases, roughly, where the patients are presenting,
10 according to the fact sheets that we've gathered, with a
11 bicarbonate, predialysis serum bicarb range of 22 to 24. And
12 he refuses in his opinions to acknowledge that anyone is --
13 that there is a safe range, basically; that anyone, whether
14 you're low or high, if you have been treated with NaturaLyte,
15 he's going to come in and opine that that's unsafe, even though
16 he treats his own patients to try to get them to present at 22
17 to 24, and, indeed, acknowledges that the KDOQI standard and
18 the DOPPS 2 standard suggest an identical range.

19 The final opinion we seek to exclude with respect to
20 Dr. Borkan is this notion of a spike. So, he describes this
21 idea that, if you are treated with an acetate containing acid
22 concentrate -- which we know that acetates in all these acid
23 concentrates, it may be as low as 2.4 in a citric-acid-based
24 one, but the standard one is basically 4 -- if you're treated
25 with that, he suggests that that is going to create a spike for

1 some defined period of time that's going to create a risk to
2 that patient, because the acetate is going to create a risk to
3 that patient for cardiopulmonary arrest.

4 And this is the testimony he gave to another judge in
5 the class-certification hearing out in Colorado, just to
6 explain what he's talking about and give some context:

7 The judge asked him, "But you're not talking about 10
8 percent of all the people who got GranuFlo had a stroke or a
9 heart attack."

10 "No, sir, I'm not."

11 The Court says, "It's 1 or 2 or 3 percent, maybe.
12 Maybe."

13 Then Dr. Borkan says, "Yes, sir, and it would be" --
14 so, he's just talking about GranuFlo out in Colorado. This is
15 the other point that I made earlier, which is, he has now
16 jumped on another horse and said NaturaLyte is also unsafe.

17 But he describes it is this way: He says, "It would
18 be within a defined period when it would be biochemically
19 feasible to ascribe the untoward event to that spike in
20 bicarbonate caused by GranuFlo exposure."

21 So, the theory is, is that there's something called a
22 "spike," that it is the result of the acetate in GranuFlo, and
23 he says that there is some defined period where that spike
24 could occur that's going to cause you to have a risk of
25 cardiopulmonary arrest.

1 Now, the plaintiffs in their brief in response --

2 JUDGE WOODLOCK: Can I just ask one thing about
3 DaVita, just so I understand? Where does it stand now?

4 MR. MELSHEIMER: I believe the class certification was
5 denied in the DaVita case, and I think the cases are still
6 pending in Colorado.

7 JUDGE WOODLOCK: And no particular action in DaVita
8 has been taken with respect to what you say is an
9 inconsistency?

10 MR. MELSHEIMER: I don't believe so, your Honor.

11 So, in their briefing, your Honor, on Pages 30 to 31,
12 they actually address this, and they say, Well, there's no way
13 to define this spike with any period of time, because, quote,
14 it has not been subjected to rigorous study in a sufficiently
15 large patient population to more precisely delineate patients
16 at specific risk.

17 Now, I'm not suggesting that by that they are
18 admitting to the Daubert motion of Dr. Borkan, but they are
19 admitting that there's no study out there, and Dr. Borkan cites
20 none -- and I'll talk about what he does cite in a minute --
21 cites none that can define what this spike means. And it's not
22 just an academic exercise, because, according to Dr. Borkan,
23 the spike could occur 3 hours after dialysis in the Dickson
24 case, 10 hours after dialysis in the Dial case, more than 14
25 hours after dialysis in the Gaston case and, goodness, 37 hours

1 in the Frans case.

2 So, what he calls a "spike," what he told the Federal
3 Judge in Colorado was, there's a defined period of time and
4 there's going to be a spike that could occur that could create
5 risk, but then he gives no definition to that at all; and,
6 again, his definition appears to be limited only by the number
7 of hours after which a plaintiff has died after receiving
8 dialysis with NaturaLyte.

9 JUDGE KIRPALANI: Mr. Melsheimer, why isn't this a
10 specific causation issue? Why is it a general causation issue?

11 MR. MELSHEIMER: It's a general causation issue, your
12 Honor, because he opines generally that there is a risk of a
13 bicarbonate spike with GranuFlo and NaturaLyte, and it's only
14 manifest in the specific cases for us to figure out, okay,
15 well, what does that actually mean? How is that defined? Is a
16 "spike" 1 hour, is it 10 hours, is it 30 minutes? So, I'm
17 merely --

18 JUDGE WOODLOCK: Well, but his opinion is, as I read
19 it in your Slide 20, "an undefined period of time." That is to
20 say, it has not been rigorously defined at this point. But
21 there is a period of time, he says, I guess, during which the
22 spike can manifest itself, and it turns out that it is quite a
23 long period of time, and it still does not have a definition.
24 But that does not strike me as being necessarily anything other
25 than a kind of flabby opinion.

1 MR. MELSHEIMER: Your Honor, respectfully, here is why
2 it's more than just flab. It's flabby because the scientific
3 evidence would not support any time period longer than 4 hours,
4 and that's being extremely generous, and I'll get to that --
5 that's laid out in our brief, and I'll get to that now. It's
6 not just that there's a problem with a "flabby opinion," as you
7 say. It's the fact that not defining it with any delimiter at
8 all contradicts the weight of scientific evidence. So, let's
9 talk about that.

10 These are several studies, your Honor, which we cite
11 in our report. They are relied on by Dr. Borkan, the Desch
12 study, the Vreman study and the Richards study, and they are
13 relied on by Dr. Borkan to say something different than what
14 his opinion is. They're relied on by him to show, and you can
15 see this, I think, from looking at them, that acetate can make
16 its way into the blood plasma during dialysis.

17 Now, all three of these studies were back in the '60s
18 and '70s, when it was acetate-only dialysis. You heard I think
19 Ms. Brooks talk about this for a little bit, where you had,
20 compared to today, massive quantities of acetate, up to 30 to
21 40 milliequivalents per liter of acetate. And these are all
22 studies that show that during the time period of dialysis that
23 you could have some acetate make its way into the blood plasma.
24 And so that's what the Desch Study shows, that's what the
25 Vreman Study shows, and that's what the Richards Study shows.

1 In the Desch Study I think it's a dialysis period, you can see
2 there on the bottom line, of about 5 hours; in Vreman it looks
3 to be about 4 1/2 hours; and in the Richards Study it appears
4 to be about 6 hours of dialysis.

5 But if you look at what we've highlighted, this shows
6 that from the end of dialysis there's no acetate at all showing
7 up in the blood serum within, in the case of the Desch Study,
8 about 80 minutes, in the case of the Vreman Study, a couple of
9 hours, and in the case of the Richards Study, an hour.

10 So, he relies on these studies to state the
11 unremarkable proposition that, when you're using 30 to 40
12 acetate acid concentrate, that some of that acetate can make
13 its way into your blood system. Okay, fine. But his opinion
14 in this case is that the much lower acetate, quantumly lower
15 acetate in GranuFlo and NaturaLyte, for example, can cause this
16 bicarbonate spike, but the problem is the studies he relies on,
17 you can see the acetate is completely diminished within
18 2 hours, even with his own studies.

19 The study that we cite in our brief, it's extremely
20 generous. It's not cited by Dr. Borkan. It's the so-called
21 Tolchin Study. It is also in the late 70s. It is also
22 acetate-based dialysis with these huge levels of acetate in the
23 acid concentrate. And the Tolchin Study shows definitively
24 that there's no circulating acetate in the blood serum of any
25 patient 4 hours after dialysis. Now, that's with extremely

1 large acetate content acid concentrates. Here, we're talking
2 about 4 or 8.

3 Our position is, at the very least, at the very least,
4 Dr. Borkan's opinion should be circumscribed to 4 hours. I
5 think that if you went on Desch or Vreman or Richards you could
6 come up with an even shorter time period. But certainly under
7 the Tolchin Study, which we cite, with no circulating acetate
8 beyond 4 hours, that that ought to be in some way limiting what
9 he can do, because for him just to be able to say on general
10 causation that this spike can happen -- so, even the use of the
11 term "spike" is sort of an interesting term. A "spike" you
12 think of as something sudden, quick, something happens, then
13 goes away. If you can define a "spike" as being up to two days
14 later, that's not really a spike. If you can define it as
15 being a couple of hours later, comparing that to 37 hours, that
16 just seems inconsistent in a way that is not scientifically
17 validated. So, we submit that the 4-hour limit --

18 JUDGE WOODLOCK: The real issue is not the label
19 "spike" but how long acetate remains in the system. So, call
20 it a "spike" or call it a "lump" or call it a "mountain,"
21 whatever you want to call it. It is the question of how long
22 you have got circulating acetate.

23 MR. MELSHEIMER: Your Honor, that's exactly correct.
24 I think the word "spike" has some rhetorical value to the
25 doctor to make it -- "spike" sounds more dangerous than a

1 "bump," perhaps. But, in any event, the Court is exactly
2 right. The question is what scientific data supports or
3 validates the notion that that can be in your blood system up
4 to 37 hours later. The answer is nothing, and we submit that
5 his opinion should be so limited to no more than 4 hours.

6 Again, your Honor, just as a practical matter, and I
7 looked at these last night, I don't have a slide on this, but
8 of the ten MDL cases for bellwether purposes, six of them are
9 outside this 4-hour window. Four of the cases chosen are
10 within this 22 to 24 --

11 JUDGE WOODLOCK: Maybe you cannot do it as a pop quiz,
12 but are any of the two that I have set down for trial in that
13 setting? Do you know?

14 MR. MELSHEIMER: May I consult one moment, your Honor?

15 JUDGE WOODLOCK: Sure.

16 (Counsel conferred off the record)

17 MR. MELSHEIMER: The group consensus, your Honor, is I
18 think that the Lastorka and Dial cases are both within that
19 window.

20 JUDGE WOODLOCK: So, they would not be --

21 MR. MELSHEIMER: They would not be affected by this.

22 Judge Kirpalani, with respect to --

23 JUDGE WOODLOCK: I think there may be another precinct
24 to be heard from.

25 MR. MELSHEIMER: Okay.

1 MS. BROOKS: I apologize, your Honor. Actually, Dial
2 is 10 hours. It's hard keeping all these cases straight. Dial
3 is a NaturaLyte case, and it's 10 hours, so it's two out of the
4 three of these Borkan opinions.

5 MR. MELSHEIMER: And, Judge Kirpalani, in the
6 Massachusetts cases, the bellwether cases, three of the cases
7 fall outside the 4-hour window. Three cases are within the
8 22-to-24 range. We actually think Ogburn is actually within
9 that range, although there's some dispute about that.

10 So, to answer one other question that you raised,
11 Judge Woodlock, is that Dr. Borkan, I believe, is the only
12 nephrologist opining in connection with the NaturaLyte
13 bellwether cases. There is no other nephrologist opining on
14 the bellwether cases with respect to NaturaLyte, and so he is
15 the shooting match, really, for the plaintiffs on that.

16 So, your Honor, that's really all I've got. If the
17 Court has any specific questions -- I think the opinions are --
18 I obviously started out by suggesting that these opinions were
19 formed to match the reality of the litigation. I think that is
20 what happened. That, of course, in and of itself would not be
21 grounds to exclude them, but the reality is all three of his
22 opinions do not have the kind of scientific validation that the
23 Daubert and Lanigan cases require, and we submit that they
24 should be excluded.

25 JUDGE KIRPALANI: Thank you.

1 Mr. Ketterer.

2 MR. KETTERER: Your Honors, good afternoon.

3 So, I'm going to need to take a step back again in
4 terms of going over some of the basic science from the
5 plaintiffs' perspective and in order to inform some of the
6 discussion that we are going to have about Dr. Borkan's
7 opinions, because I want to go straight to the science and talk
8 about the clear refutation, because there is clear data that
9 was left out in terms of scientific study that Dr. Borkan cites
10 to found his opinions. But the problem is that the premise on
11 which they are approaching the argument is even false. So, for
12 instance, to make it sound like the question --

13 Oh, can we be switched back?

14 JUDGE WOODLOCK: Oh, yes.

15 MR. KETTERER: Sorry. So, the very premise is, well,
16 Dr. Borkan is somehow saying -- they are defining what
17 Dr. Borkan is testifying as to what the spike is. Well, they
18 are already misrepresenting what Dr. Borkan's opinions actually
19 are. Dr. Borkan is not opining that acetate resides 4 hours
20 and is continuing to circulate well into the body after 4
21 hours. There is no expert who is going to testify to that,
22 because, I agree, there isn't actual evidence that acetate is
23 continuing to reside unless there is a failure in a patient to
24 properly metabolize the acetate. There's not going to be
25 continuously circulating acetate. That's not what Dr. Borkan

1 says.

2 When Dr. Borkan is referring to a "spike," Dr. Borkan
3 is referring to what happens immediately as a result of the
4 infusion of acetate into the body.

5 Ms. Brooks talked this morning about the concentration
6 gradients and about how acetate will move into the body. What
7 happens is, is that conversion -- there is a rapid movement.
8 There is 4 or 8 of acetate in the dialysate. It's moving into
9 the body continuously, because, as she also noted, there is a
10 rapid conversion. She called it "immediate." I'll call it, on
11 the outset, 45 minutes or so. And there is a constant
12 conversion. What is that doing? That acetate will convert to
13 bicarbonate, and it adds to the total bicarbonate load that's
14 in the patient. And it's constantly happening. Now, the
15 dispute between the two parties is how much of their product,
16 the acetate, is moving over into the body, and how is that
17 contributing to the overall bicarbonate load in the individual
18 patient.

19 That is the spike (indicating) which Dr. Borkan is
20 talking about. He's talking about the immediate effect, and
21 then what he says, when he relates it to these hours after
22 dialysis -- and this is, by the way, very clear in his reports
23 and in the depositions -- when he talks about this residual
24 bicarbonate, that's true, and there is a study he cites. He
25 cites the Graham Study.

1 Actually, if we could just put this up for the Court,
2 if we put up GFPL4176, for a moment, and if we could go to Page
3 29 of that exhibit -- all right.

4 JUDGE WOODLOCK: I guess a question I have is, is
5 Graham an acetate study?

6 MR. KETTERER: I'm sorry. What's that?

7 JUDGE WOODLOCK: Is Graham an acetate study?

8 MR. KETTERER: Graham is a bicarbonate study, your
9 Honor. And let's just be clear about this for a second. What
10 the issue is, is how does acetate, which converts into
11 bicarbonate -- it's the bicarbonate's effect which is really at
12 issue in the case, right? Because the bicarbonate is what
13 leads to the metabolic alkalosis.

14 JUDGE WOODLOCK: At this point we are talking about
15 whatever enhancement of the bicarbonate is brought on by
16 acetate, and that's why I ask whether Graham is an acetate
17 study that would tell us something about that relationship.

18 MR. KETTERER: It's not being looked at for that
19 purpose. It's being looked at for the purpose of how long
20 residual bicarbonate can last in the body, okay? So, what
21 we're trying to say is, or what Dr. Borkan is trying to express
22 is, look, the acetate has converted to bicarbonate already.
23 That's what's gone on in the body. It happens at a rapid
24 conversion.

25 Now the question is does the residual bicarbonate

1 continue on in the body for a period of time? And what he
2 testified to at the DaVita litigation is, Look, there is a
3 fixed time period. So, to say there is no fixed time period at
4 which it can represent, he did. He testified 48 hours. If you
5 go beyond 48 hours, there's no more residual bicarbonate that's
6 going to be as part of the effect.

7 JUDGE WOODLOCK: He said "48 hours"?

8 MR. KETTERER: "48 hours." That was his testimony,
9 and I can give you the citation to that as well, your Honor.
10 But he testified very clearly that that's the threshold outset,
11 okay?

12 And they put up the four cases that he's a
13 case-specific expert in, and they're welcome to challenge
14 whatever it is through whatever means, but in the context of
15 this motion what he is saying is, Look, at these different
16 defined intervals when the patient undergoes dialysis there is
17 going to be a residual run-up and a spike. There's going to be
18 an escalation of acetate that's moving into the person. That
19 acetate is going to convert to bicarbonate. The bicarbonate
20 goes up. Here's the window of time that we've got. And that's
21 what he says in his report very clearly. And that's the
22 testimony that's consistent at the DaVita litigation,
23 consistent in the testimony that's here.

24 And that's one of the problems with the way that they
25 are attacking this NaturaLyte versus GranuFlo issue. What they

1 are saying is, and what the goal is here, when we are speaking
2 about litigation goals, is, they want to say, Well, 50 percent
3 of the cases are NaturaLyte, which, by the way, we don't buy
4 into, primarily because they are claiming that they converted
5 all their clinics, essentially, to GranuFlo, on one hand, and,
6 on the other hand, when they come into court, they're saying,
7 Well, 50 percent of the cases you don't have product ID on, so
8 it must be NaturaLyte. That's not something that we are
9 conceding, number one, that fact.

10 But, number two, forget that for a second. It isn't
11 litigation-driven. It's science-driven. The theory of the
12 case --

13 And can we go to my PowerPoint and actually go to
14 Slide 7, please.

15 MR. MELSHEIMER: Might I get a copy of the PowerPoint?

16 MR. KETTERER: Sure, I will give you my copy.

17 MR. MELSHEIMER: I don't want your copy. I don't want
18 to impair you.

19 JUDGE WOODLOCK: Tomorrow we will have copies for
20 everyone?

21 MR. KETTERER: We have one now, and we will have
22 copies.

23 THE COURT REPORTER: And for the court reporter,
24 please.

25 JUDGE WOODLOCK: All other people being equal, most

1 important of all is that the court reporter gets that, because
2 the dictionary for this case is rather demanding.

3 MR. KETTERER: I understand, your Honor. That's my
4 fault and responsibility for that oversight. So, I apologize
5 to defense counsel and the Court.

6 This is what I handed up, and I have an extra copy
7 that --

8 JUDGE WOODLOCK: Over there, first.

9 MR. KETTERER: May I approach?

10 JUDGE WOODLOCK: Yes, please.

11 MR. KETTERER: I apologize again, your Honor.

12 If we could go to Number 7. And you will see here,
13 your Honor, one of the things I didn't get to this morning,
14 because it wasn't really relevant to your inquiry right at the
15 time, was sort of a basic layout of causation from the
16 plaintiffs' standpoint, and it feeds into this issue in terms
17 of NaturaLyte.

18 The only difference between NaturaLyte and GranuFlo is
19 the amount of acetate which is present in the product. One has
20 4. They actually have a product in Europe that we are going to
21 talk about a little bit later, Granudial, which has 6, and
22 GranuFlo, which has 8. They are all essentially there to do
23 the same thing, and there's nothing in and of itself -- it's
24 not like if I wheel in the NaturaLyte or I wheel in the
25 GranuFlo and I say to you, "Judge, this is just dangerous

1 sitting here." It's not. But it's how it's used, and whether
2 it's accounted for, and whether the physician has the proper
3 information, and whether the proper information has been
4 communicated that makes the product potentially dangerous or
5 not.

6 JUDGE WOODLOCK: So, where do we get the 2.4?

7 MR. KETTERER: The 2.4 actually comes from -- let me
8 just say that there's a Borkan cite for this. I was going to
9 get to that, your Honor, but that's not something that was
10 produced out of thin air.

11 And I hate to go back and forth between the exhibits,
12 but can we do that? Can we go back to Dr. Borkan's report and
13 go to Page 21. Let me just make sure that's the right page.
14 And if we could blow up that second paragraph, please.

15 And if you look at that, your Honor, the bottom line
16 is, "Dialysis patients in the U.S. are exposed to highly
17 efficient dialysis equipment and some of the highest
18 bicarbonate dialysates on the planet between 2002 and 2011."
19 He cites a study. The study that he's citing is the second
20 DOPPS Study from Francesca Tentori. It says, "In the U.S. the
21 average dialysate bicarbonate content, 37.0, was plus or minus
22 2.6." Now, that doesn't have to do with the actual content
23 that he looked at. That doesn't mean 2.6 was the amount of
24 acetate, is what I should say. 45 percent of the ESRD
25 populations received greater than or equal to

1 38 milliequivalents, and 50 percent of the DOPPS reporting
2 facilities used a single dialysate bicarbonate concentration.

3 And when Dr. Borkan was asked about this, what he's
4 referring to is, he's looking at most of them are using 4.
5 There is a possibility he looked at all of the acetate
6 concentrates that were available in the United States at that
7 particular time. The lowest concentration that exists that's
8 available was 2.4.

9 So, when he goes to the United States and he's looking
10 at what are the dialysate concentration compositions that are
11 available and sold within the United States, he looks at all of
12 the different compositions. There's 8, there's 4, there's 2.4,
13 and I'm sure there's some other products, but they all fit into
14 one of those three categories. So, when you are looking at --

15 JUDGE WOODLOCK: So, anything that is produced is in
16 this range?

17 MR. KETTERER: It is 2.4 in the United States. It's
18 available as either 2.4, which is Citrasate, a product with 4
19 -- now there are different iterations. There's NaturaLyte,
20 which is made by Fresenius. There's a Minntech product which
21 has 4, potentially. There's a whole other range of products
22 which are made which contain 4, and there's one product that
23 contains 8. That's GranuFlo.

24 JUDGE WOODLOCK: Where is the 2.4?

25 MR. KETTERER: The 2.4 is in Citrasate, your Honor.

1 That's manufactured here, and that's also now owned by
2 Fresenius.

3 JUDGE WOODLOCK: And it is used for this purpose?

4 MR. KETTERER: It's used for the same purpose.

5 JUDGE WOODLOCK: So, anything that is manufactured is
6 in the red zone?

7 MR. KETTERER: No, not anything that's manufactured.
8 Because 2.4 may not be -- is not what we're saying is in the --
9 when you say the "red zone," your Honor --

10 JUDGE WOODLOCK: Greater than 2.4 --

11 MR. KETTERER: Right.

12 JUDGE WOODLOCK: -- is what he --

13 MR. KETTERER: Perhaps he should have said more
14 than --

15 JUDGE WOODLOCK: "Anything above 2.4 milliequivalents
16 per liter of acid will enhance bicarbonate delivery."

17 MR. KETTERER: That's correct.

18 JUDGE WOODLOCK: And presumably anything in excess of
19 that is --

20 MR. KETTERER: That's correct.

21 JUDGE WOODLOCK: -- in what I call the "red zone."

22 MR. KETTERER: That's correct. And the 2.4, your
23 Honor, is the one product which he is assigning, because that's
24 the only other product in the United States.

25 JUDGE WOODLOCK: What is his basis for saying that?

1 MR. KETTERER: Let me just make sure I understand this
2 before I come out of the box and say it to you.

3 JUDGE WOODLOCK: All right.

4 MR. KETTERER: When you say his only product that he
5 is saying is safe, what is his basis for saying the 2.4 would
6 be safe? The reason why is that there's an overall philosophy
7 that the lower the amount of acetate that's in the product, the
8 safer it will be for the patient, because the patient has a
9 lowered risk, and this is consistent throughout all of the
10 experts, that the lower the amount of the acetate, the less
11 there is for a rate of error, which is what happened in this
12 case, for the physician to have. So, if we can reduce the
13 risk, and the more we can reduce the risk by having less
14 bicarbonate converted or accounted for -- and the best way is
15 to account for it -- but let's say that there is going to be an
16 error rate. The best way to do that would be to use the least
17 amount of acetate in order to keep the product chemically
18 stable, and that's based on the fact that the belief is that
19 the more -- or the proof is that the more acetate you use the
20 more it will convert to bicarbonate, the higher the bicarbonate
21 goes in the person's blood.

22 JUDGE WOODLOCK: This comes down to a statement,
23 doesn't it, that anything over 2.4 is not necessary to maintain
24 the pH of the dialysis solution in a safe range?

25 MR. KETTERER: That's a factual statement in the sense

1 of --

2 JUDGE WOODLOCK: Well, but I could make that
3 statement, but nobody would believe it, and so there has to be
4 some foundation for it.

5 MR. KETTERER: The foundation is the actual product.

6 JUDGE WOODLOCK: Isn't that circular?

7 MR. KETTERER: No, no, no. Let me just make sure I'm
8 understanding, and I will tell you why -- it may be circular,
9 but I will tell you why it's true. What you are saying, is,
10 look, how do you know that 2.4 is all you need? You know that
11 2.4, at least of the existing products, is the minimum we know
12 about in order to keep the chemical stability to have it for
13 the product, right? Because that's the product that exists.
14 It's chemically stable, right? This is where you get into the
15 circuitous reasoning. But it is, in fact, a real product.
16 It's used in dialysis patients, it's actually there, the 2.4
17 works. So, we know that that minimum amount, 2.4, is all you
18 would need. No other product exists that is less than 2.4
19 that's available to be bought or sold.

20 JUDGE WOODLOCK: But that doesn't make everything else
21 excess.

22 MR. KETTERER: When you say "excess," what he's saying
23 as being excess is you don't need any more than 2.4 to make it
24 chemically stable. Obviously, if you can do it with 2.4,
25 anything more than 2.4, in his opinion, is what he's saying is,

1 you don't need that extra acetate, because the product exists.

2 Let me see if I can -- your Honor, do you mind if I
3 use the flip chart for a minute?

4 JUDGE WOODLOCK: No.

5 MR. KETTERER: I'll just bring it back, if I may, for
6 a second.

7 There's three products, primarily, and let's just talk
8 about them in numerical values. We have citric acid, and
9 that's 2.4. We have a -- and that's 4. And we have GranuFlo.
10 That's 8. All right?

11 JUDGE WOODLOCK: All right.

12 MR. KETTERER: And the actuality is there's only these
13 two that exist in these iterations (indicating). GranuFlo is
14 the only 8, as far as I know. There may be another product.
15 There actually may be another dry citric acid product that's
16 2.4. But that's the lowest in terms of the citric acids. So,
17 the question is why is this automatically excess, right
18 (indicating)? Because if I have this, how can he say, what's
19 the foundation to say anything more than this is extra
20 (indicating)?

21 JUDGE WOODLOCK: That's not what he is saying,
22 "extra." He's saying "excess," and he's saying that the excess
23 has an intimate relationship between bicarbonate and other
24 critical electrolytes.

25 MR. KETTERER: That's true.

1 JUDGE WOODLOCK: It is. But the question that we are
2 trying to deal with is at what point do we have a tip on this,
3 and what you seem to be saying is anything above the minimum is
4 a tip, and I guess I want to understand where we can say that
5 in light of the increase in peri-dialysis deaths due to
6 exposure to excess.

7 MR. KETTERER: So, his argument is that any time you
8 add more acetate beyond -- this is a minimum standard for a
9 chemically stable product. I agree with what FMC has
10 presented, which is, you have to have some acid contained in
11 the dialysate in order to maintain chemical stability. That's
12 true. And to prevent precipitation. That's essentially what
13 it is preventing. So, what Dr. Borkan is saying, is, Look, if
14 you are going to get more than what you absolutely have to,
15 when you add anything more you are raising the risk. Now, the
16 risk --

17 JUDGE WOODLOCK: I understand the principle that 4 is
18 more than 2.4.

19 MR. KETTERER: Right.

20 JUDGE WOODLOCK: I have got that one. The question is
21 whether or not that relates in some fashion to increased risk
22 for peri-dialysis patients. Is there a study, something that
23 says that, other than saying "4 is greater than 2.4"?

24 MR. KETTERER: Sure. If you look at the litany of
25 literature which we cited in the Omnibus Brief, your Honor,

1 which all covers this basic principle -- and so I hate to go
2 back to move around from slide to slide.

3 JUDGE WOODLOCK: Then, more specifically, can I look
4 at something in the literature that says at 2.9 you have got an
5 increase?

6 MR. KETTERER: No.

7 JUDGE WOODLOCK: Or is it simply that --

8 MR. ROTMAN: Brian.

9 MR. KETTERER: Sorry, your Honor.

10 (Counsel conferred off the record)

11 MR. KETTERER: So, your Honor, what you are looking
12 for is, you're asking is there a number, right, this number,
13 you used 2.9, correlates, and if you add that number onto the
14 total that puts you at a higher risk (indicating)?

15 JUDGE WOODLOCK: Yes, studies that would show, "We
16 have had use like this in this number of patients or this
17 number of clinics --

18 MR. KETTERER: Right.

19 JUDGE WOODLOCK: -- and when you go to 2.9 they start
20 dropping off more frequently than they did at 2.4."

21 MR. KETTERER: They don't, and let me explain to you
22 why. That's because the acetate in almost all these studies is
23 never controlled for. The acid concentrate is not a
24 controlled-for factor. It's the total bicarbonate.

25 JUDGE WOODLOCK: But doesn't that mean there is not

1 sufficient evidence to make a statement like that, other than
2 to say the basic arithmetic statement of 4 is greater than 2.4?

3 MR. KETTERER: No, because you can't take out or
4 remove. What Tentori does show is the higher the bicarbonate
5 -- and a whole host of other studies -- the higher the
6 bicarbonate the greater the risk. And this isn't about --

7 JUDGE WOODLOCK: Does any other expert say that?

8 MR. KETTERER: Oh, yeah, every --

9 JUDGE WOODLOCK: No, no. Does any other expert say
10 that 4 is a greater risk than 2.4?

11 MR. KETTERER: 4 is a greater risk than 2.4?

12 JUDGE WOODLOCK: Right.

13 MR. KETTERER: I don't know that they explicitly say
14 it that way, your Honor.

15 JUDGE WOODLOCK: That is how people say things,
16 explicitly, for purposes of testimony, one hopes.

17 MR. KETTERER: Well, let me just explain the nuance.
18 I get what you are saying about -- you're asking me a very
19 direct question, and my direct answer is no, okay? So, I don't
20 want to skirt the issue.

21 But what I do want to tell you is that I think there's
22 some nuance to actually saying that, and the nuance that I
23 would say to that is the theory of causation is not that you
24 have to compare these two numbers in order to reach a causation
25 conclusion, okay (indicating)? But the theory is that more

1 acetate and more bicarbonate is worse for the patient. So,
2 they may not say, "4, more than 2.5, is a problem,"
3 specifically, but what they would all agree with is the more
4 acetate you have the more that will convert to bicarbonate and
5 the greater the risk. That is something that all of them would
6 agree with.

7 So, to answer your question, this is where my nuance
8 would come in, "Is it true that you don't have an expert that
9 says this exact same thing the same way Dr. Borkan does?", I
10 agree with you.

11 JUDGE WOODLOCK: But you have got somebody who says it
12 for 8.

13 MR. KETTERER: Yes -- no, not necessarily in a
14 comparative way, your Honor. No, they don't put it that way.
15 They don't say that 8 is necessarily per se the reason. See,
16 it isn't about a comparison in these two instances. Dr. Borkan
17 may say that 8, of course, because 8 is more than 4, 8 is even
18 riskier, but it isn't that 4 is somehow automatically per se,
19 just because it's 4, safe. Is it safer than 8? Of course,
20 because it's less. I mean, that's the simple math.

21 JUDGE WOODLOCK: Well, but simple math is not the only
22 issue here. I suppose if you get some sort of critical mass,
23 and you say it is above 2.4, aren't there some studies that
24 show some sort of slope for the increased risk?

25 MR. KETTERER: Sure, with respect to bicarbonate, and

1 that's where -- it's not measured by acetate, your Honor.
2 That's one of the fundamental differences in terms of the way
3 the studies are. Because all this is -- the acetate in and of
4 itself isn't the risk. It's only when it comes to bicarbonate
5 that it's the risk.

6 JUDGE WOODLOCK: Right, but you still have to make the
7 transformation. You have to say, by introducing acetate, you
8 are introducing an increased amount of bicarbonate.

9 MR. KETTERER: Right.

10 JUDGE WOODLOCK: And then the further step, that it is
11 risky; that increased delta of bicarbonate created by the
12 increased amount of acetate is risky.

13 MR. KETTERER: Yes, and that's the dispute factually
14 in the case, and there's plenty of science behind how much
15 acetate is converted. Actually, we are going to talk about
16 this in a little bit with respect to the Lipps and some of the
17 Colton and Zidney motions, how much acetate is converting and
18 how much total bicarbonate is there. The question, your Honor,
19 is that there are plenty of studies that talk about the total
20 amount of bicarbonate raising the risk from both sources, from
21 both the acetate and the bicarbonate. That's two potential
22 sources of buffer or bicarbonate, the one that will convert in
23 the human body and the other that's crossing over the membrane
24 and is directly infusing into the body. So, both are sources
25 of bicarbonate that are raising the person's bicarbonate in

1 their body, when it converts in the liver and when it transfers
2 over from the bicarbonate in the dialysate.

3 MR. ROTMAN: Brian.

4 (Counsel conferred off the record)

5 MR. KETTERER: So, what my colleague has handed me is
6 a paper that just illustrates that point about, as the
7 bicarbonate is going up, then the risk is going up, so, for
8 every 4 milliequivalents of bicarbonate that's being raised,
9 the concomitant death -- or the concomitant hazard ratio is
10 also going up at the same time. And that's just one of several
11 studies that show that, that as bicarbonate goes up -- if you
12 are asking the fundamental question can we show that as
13 bicarbonate goes up the risk goes up? Absolutely.

14 JUDGE WOODLOCK: But it is a compound question, and it
15 really is what is linked to what, and the increase caused by
16 acetate, the increase in acetate transforming itself into
17 bicarbonate is really the question, and when do you reach with
18 acetate a critical mass that would increase the bicarbonate
19 enough to cause --

20 MR. KETTERER: You can't look at it separately.
21 That's the issue, your Honor. You can't look at did the
22 acetate specifically -- we know that the acetate contributed to
23 the overall bicarbonate level, okay? And what we know is from
24 the comparison data, that if you use a product with 4 or a
25 product with 8, your bicarbonate goes up more with the 8

1 product. Okay? That's the comparison of the data.

2 JUDGE WOODLOCK: Well, but this seems like an exercise
3 in pure reason rather than some sort of scientific evaluation
4 of existing data that tells us something about correlations.
5 That's my problem with it.

6 MR. KETTERER: Well, it's not just reasoning, no, no,
7 no. There's data behind -- if you're asking for is there data
8 that shows if you use the higher acetate product your
9 bicarbonate goes up more? Yes.

10 JUDGE WOODLOCK: No. I am asking you when you reach
11 that risk point, that inflection point, whatever it is that
12 means that you have gone too far, that the increase --

13 MR. KETTERER: That your bicarbonate's too high?

14 JUDGE WOODLOCK: Right. That the use of excess
15 acetate, whatever that means -- and now I gather it means
16 Above 2.4 -- is sufficient to create this intimate relationship
17 of increase in peri-dialysis deaths.

18 MR. KETTERER: What's going on right now, your Honors,
19 is that -- and I just want to make sure, again, I'm being clear
20 on this, because I am not sure that I am. Because I think that
21 there's some disconnect about what the issue is for Dr. Borkan
22 versus what the overall data points are. The overall data
23 points are that there's plenty of data out there and scientific
24 study which shows that, when you have both things together, the
25 higher the bicarbonate is, the greater the risk. What's the

1 point at which you have to infuse the acetate? Well, there's
2 only a couple of acetate products that are available. So, when
3 you use this acetate (indicating), has there been a greater
4 increased risk of higher bicarbonates? Absolutely. When you
5 use NaturaLyte can people have bicarbonates that are too high?
6 We're going to actually look at a bunch of data from the
7 company that suggests the answer is yes, that even using a
8 lower product that you can still have too high a pH and too low
9 a potassium and have that risk.

10 So, then the question is, then your next part of the
11 compound question is, well, wait a minute. How is Dr. Borkan
12 saying that -- and let's say that these two could theoretically
13 happen (indicating). How does he know that this, between this
14 and this and any modular increase, 2.5, 2.6, 2.7 -- let's say
15 you have data on this, and you have data on this (indicating).
16 Where is your data to say between the 2.5 and 4 that there is a
17 specific data point? And the answer is that there's not a
18 specific data point between -- that says that 2.5 is worse than
19 2.4. What he's saying is that this 4 (indicating) is still a
20 risk, and this 8 (indicating) is still a risk, and that's based
21 on the available data.

22 If you're saying he can't testify or shouldn't be
23 allowed to say that 2.5 or 2.6 or 3 or 3.2 are all risky, I
24 would say that that's based on his overall look at all of the
25 data that says that more has been proven to be bad, the more

1 you add acetate, the more that converts to bicarbonate, the
2 greater that risk. That's what he's saying. So, he's not
3 drawing on, "I have a number from 2.5." That doesn't exist.
4 There's no data point that exists.

5 JUDGE WOODLOCK: So, why do we let him testify about
6 this? Why don't we let the existing actual evidence-based
7 examinations of risk apply here?

8 MR. KETTERER: Well, he's not going to say 2.5 is
9 automatically worse than 2.4. That's not what he's going to
10 say. And if you want to restrict him from saying anything in
11 excess of 2.4 is not accurate because you don't have any data,
12 I'm actually not arguing with you based on the data point.
13 What I'm saying is he has data on this (indicating), because it
14 exists, and he has data on this (indicating), which is 8, and
15 every expert on both of these products would be able to tell
16 you based on the theory of causation that that's true. If
17 we're arguing about 2.5 to 3.9, I don't really have an argument
18 with you. Because the bottom line is, is that there are no
19 such products that are 2.5 to 3.9, so obviously no data exists
20 on 2.5 to 3.9. So, it would be an impossibility. So, asking
21 him to opine on 2.5 to 3.9, that's fallacious. I agree with
22 that. But if we are arguing about is there data on 4 or is
23 there data on 8, the answer is yes.

24 JUDGE WOODLOCK: And that data is pronounced by some
25 other experts?

1 MR. KETTERER: Well, not only other experts, but I
2 would say the litany of literature.

3 JUDGE WOODLOCK: Well, "litany" I am less concerned
4 about. I am concerned about some live person who gets up on
5 the stand and says, "4 is danger."

6 MR. KETTERER: I would argue that Dr. Borkan would say
7 that 4 is danger. I would argue that any of the other experts
8 would argue in the theory that it's the same thing, that they
9 all use -- a lot of them use 4, a lot of the experts do. But
10 that's when I was talking about, if you wheel it in and you
11 have the product, that it's automatically unsafe, that's not
12 it. It's how it's being used. And Dr. Borkan's -- I know that
13 they like to cite to that testimony out of Colorado where he
14 said, well, 4 is what he used, but when he got into his
15 deposition in this litigation, what he explained is that it's
16 the context of how it's being used that either makes it safe or
17 unsafe.

18 One of the things that you heard in FMC's history
19 about the dialysate products was the dialysate prescriptions
20 have been recommended to go up. The more bicarbonate, the
21 higher the bicarbonate prescription that's being used, when you
22 add this (indicating) makes it more dangerous. How do you know
23 that? Because when you add to the total bicarbonate load
24 through either source you are raising the patient's serum
25 bicarbonate. That's provable in the data, in the science, that

1 the higher the bicarbonate's being raised through both sources
2 -- because this isn't the only source (indicating). So, you
3 have two sources, and if you add -- there is a difference
4 between -- I know this seems obvious, but if you have 40 or you
5 use 35, there is a difference between those two numbers, right?

6 JUDGE WOODLOCK: Maybe this is more fundamental, but
7 you go back to Paracelsus who tells us that there are no
8 poisons, there are just bad doses.

9 MR. KETTERER: Sure.

10 JUDGE WOODLOCK: And so, the question is when does a
11 bad dose lead to poison on this? And that's where I am trying
12 to figure out what that is, and if it is very fact-specific,
13 well, then we are back to Judge Kirpalani's question, which is,
14 why isn't this a specific causation question?

15 MR. KETTERER: Well, I actually agree that it could be
16 a specific causation issue.

17 JUDGE WOODLOCK: Well, but that, then, says why do we
18 need him with unanswered questions speaking to general
19 causation?

20 MR. KETTERER: Because it's not purely about -- well,
21 you do need someone speaking about general causation.

22 JUDGE WOODLOCK: Oh, you do, but this one may not be
23 the fellow.

24 MR. KETTERER: Right. But what I am saying is -- and
25 I think there are other answers on what and how he's answering

1 some of these other objections that they have. So, the general
2 causation opinion, he's not out on general causation with
3 respect to everything, and his general causation opinion on
4 NaturaLyte is not wrapped up in whether or not he believes
5 anything 2.4 or excess is the only opinion. That's not the
6 basis of his opinion. What they are suggesting is that the
7 spike or the rise in bicarbonate that you get from 4, as I
8 started the argument with, that's a misinterpretation of what
9 the spike actually is. He's not alleging, nor does he actually
10 ever say the spike is in the acetate. That's not what he's
11 saying. So, if that's not the argument and the argument is,
12 well, it's the spike in bicarbonate that happens initially and
13 then resides, I would say look at his report and look at what
14 we stated in the brief. It's absolutely clear. I don't know
15 if that page is up, your Honor.

16 JUDGE WOODLOCK: It is.

17 MR. KETTERER: Okay. What's absolutely clear is he
18 does say what the source is for why bicarbonate goes up and how
19 it can go up, and he has a study that says that, when the
20 bicarbonate goes up, that's at a greater risk. And there's
21 more than just one study. He cites to a litany of studies on
22 that particular area.

23 The other thing, your Honor, is that, and I want to
24 get away from this one point that seems to be kind of going
25 back and forth here, which is that somehow there is a numerical

1 number at which you cross a threshold and that's the danger
2 zone. I will tell you why I want to get away from that. It's
3 because that's not really what is going on for every individual
4 patient.

5 If we were to look at this in a case-specific context,
6 what we would be talking about is a spectrum about what happens
7 during the dialysis process, right? Different people come in
8 at different levels. And so, what the process is -- we talked
9 about alkalosis being a process. We are not saying that every
10 one of our clients got alkalemia or that they became
11 metabolically alkalotic, nor do we have to prove that. What we
12 are saying is that, when you raise a patient's serum
13 bicarbonate, their blood bicarbonate, and you do it too
14 rapidly, that you can cause electrolyte shifts. And do you
15 know who says that? All of the defense experts.

16 So, the argument is, if you take it up too fast and
17 both the amount of the shift and the volume of the shift is too
18 high, then that patient can have a sudden cardiac arrest.
19 That's not in disagreement here.

20 JUDGE WOODLOCK: Then, you do not need this.

21 MR. KETTERER: I do not need which part of it?

22 JUDGE WOODLOCK: What is problematic is the use of
23 someone who introduces issues that are somewhat extraneous and
24 somewhat misleading.

25 MR. KETTERER: What I want to clarify is what is it

1 that you think that what Dr. Borkan is saying is misleading?
2 Because the spike is not anything really -- there's different
3 terminology that's used, but everyone agrees, including
4 Dr. Maddux, that the greatest infusion of bicarbonate is at the
5 beginning of dialysis. So, if that's the largest point or the
6 largest run-up or the steepest amount of gradient, then what's
7 the difference between what that's being said and what
8 Dr. Borkan was saying?

9 JUDGE WOODLOCK: I guess this: that there are three
10 opinions that they object to. The first one has to do with
11 saying that greater than 2.4 milliliters is the red zone. That
12 is really what he is saying.

13 MR. KETTERER: Okay.

14 JUDGE WOODLOCK: And there does not appear to be
15 anything other than this mathematical relationship, no studies,
16 nothing, just, that is the way, if you have got more, that is
17 greater than less, and I am not sure that that adds to the sum
18 of human knowledge.

19 MR. KETTERER: I guess what I would say, and I do not
20 want to keep going back and forth on just this one point, but I
21 do want to respond, and it is what it is, is that the
22 correlation is not based on a data-less sort of viewpoint. If
23 it's true that the only points that we have to compare are
24 these points (indicating), and we know that the risk goes up
25 with the higher the bicarbonate, i.e., you add more bicarbonate

1 through acetate or you add more bicarbonate through the
2 dialysate or a combination of both, which is what we are
3 alleging here, and if those things are true, then why isn't it
4 also reasonable -- based on that data, why isn't it also
5 reasonable to opine that more is more dangerous than less?
6 Because that's what all the data suggests. I mean, that's the
7 logical syllogism which I'm presenting. And it's not
8 data-less. It would be data-less if I didn't know what
9 happened here (indicating) or I had no evidence. Let's say I
10 don't know what happens, that's the point of a trial, but
11 that's what happens here (indicating).

12 JUDGE WOODLOCK: I think I understand the argument.

13 MR. KETTERER: I know, your Honor.

14 So, let me turn to the other arguments, which were the
15 use of GranuFlo and/or NaturaLyte risk of dangerous bicarbonate
16 spike, and we are talking about that result in cardiopulmonary
17 arrest, and here we are no longer talking about the difference
18 between these two (indicating). What I would relate to simply,
19 your Honor, on both of these points is that the implication was
20 somehow, Well, there's just no evidence about NaturaLyte, which
21 just isn't true, that NaturaLyte just came out of nowhere. And
22 I don't want to cite to the FDA as authority. I'm not doing
23 that.

24 But when you are talking about a review of data and
25 what's the data that's out there, all of the data relates to

1 how acetate itself converts to bicarbonate, how much acetate
2 exists, how much acetate will convert, and then with that how
3 much total bicarbonate ends up in the patient, and the studies
4 are about the total bicarbonate that's in the patient. So, if
5 these add to the risk (indicating), what he's saying is, when
6 you add either of these products (indicating) and you have the
7 dialysate bicarbonate, there is a run-up at the beginning of
8 dialysis. That's the spike. The more the gradient or the
9 steeper the movement along this line (indicating), the higher
10 the risk. That's what's being referred to in point one, or, at
11 least as Dr. Borkan's concerned, that's what he is referring
12 to. He is not suggesting that there is a spike which lasts
13 forever, that we never know what time it's going to be. He
14 said very clearly 48 hours, that's the risk window. Now it's
15 up for debate whether he's right or wrong. But it's not some
16 limitless value. That's not what he's saying, and nor has he
17 ever said that, that there was no way to put it on.

18 I think I've addressed those points. I know that this
19 was the most significant difference of opinion on this. I
20 understand where the Court is coming from, and I am not
21 suggesting -- all I'm suggesting is that, even if your Honors
22 should find that he shouldn't be allowed to say this, I would
23 argue that his opinions on NaturaLyte and GranuFlo are still
24 valid, with the exception of him being stricken or restricted
25 from using that specific language with respect to that 2.4

1 being automatically safer.

2 So, I would absolutely concede that, if your Honor
3 rules that way, I understand, I presented my syllogism on that,
4 but I don't think it affects these other opinions or any of the
5 other opinions that they have complained about, because there
6 is a litany of data and also clear testimony where he has
7 explained the other opinions, and there's nothing that they've
8 presented which suggests that, when you look at the totality
9 again of all of the information and the weight of the evidence
10 and the manner in which Dr. Borkan weighed it, that he's
11 restricted on either of these two products (indicating).

12 MR. MELSHEIMER: May I be heard, just briefly, your
13 Honor, on rebuttal?

14 MR. TARRICONE: Your Honor, I just want to add one
15 thing on this issue. Because the motion, the second point
16 was --

17 JUDGE WOODLOCK: There are two of us, so this is
18 really Australian Doubles.

19 MR. TARRICONE: I can't help myself.

20 JUDGE WOODLOCK: Right.

21 MR. TARRICONE: But the second point that
22 Mr. Melsheimer made had to do with NaturaLyte plus 4, that
23 should be stricken. Ms. Brooks used 35 as the dialysis
24 prescription in the examples she was giving. Well, 35 plus 8
25 is 43. That's the total amount of bicarb. But 39 plus 4 --

1 JUDGE WOODLOCK: If you have that, call it
2 transformation -- you can call it "diffusion" and "infusion,"
3 but I will just call it "transformation" -- all of a sudden the
4 acetate becomes bicarb *ipse dixit*, to use a turn of phrase,
5 then that's right. The question is the biomechanics of this
6 undertaking.

7 MR. TARRICONE: But the point is that 35 plus 8 is 43.
8 That's using GranuFlo. Well, 39, if a patient is dialyzed at
9 39 plus 4 with NaturaLyte, it's also 43. So, you can't just
10 look at the product, the acetate in the product in isolation,
11 and the prescriptions matter here, and at these clinics, at the
12 Fresenius clinics, patients were routinely being dialyzed with
13 very high numbers. So, this really is an issue for specific
14 causation --

15 JUDGE WOODLOCK: That, I guess, is what we were
16 touching on, Judge Kirpalani more precisely, but why this
17 should be viewed as a general-causation kind of question that
18 can be offered. Now, it may be that Borkan shows up for both;
19 he is both general and specific.

20 MR. TARRICONE: Well, the examples that were used in
21 Mr. Melsheimer's presentation were his specific causation
22 opinions, so that's how we got into that today.

23 JUDGE WOODLOCK: So, if he does not have testimony
24 that is specific on some particular case, then he does not
25 testify in that particular case.

1 MR. TARRICONE: Well, I am not sure I understand.

2 JUDGE WOODLOCK: If this is specific causation, and he
3 has got opinions on specific causation because he has looked at
4 various things in the various cases that he has been testifying
5 about, if he does not have a specific opinion, then it cannot
6 be offered as a general opinion. Now, that may apply to other
7 cases. I do not know what he is going to be used for.

8 MR. TARRICONE: Well, except for this, your Honor:
9 The principle that can't be disputed is that the higher bicarb
10 is more dangerous. What amounts to the higher bicarb, how much
11 comes from the acetate and how much comes from the bicarbonate
12 prescription, you have to look at both. And to simply say if
13 it's NaturaLyte that it can't be in play because one is plus 8
14 and the other is plus 4, which is what the defendants' motion
15 is for point two, just doesn't add up. It can't be looked at
16 in a vacuum like that.

17 JUDGE WOODLOCK: I think it is point one.

18 MR. TARRICONE: Point one.

19 JUDGE WOODLOCK: Thank you.

20 MR. MELSHEIMER: Your Honor, might Ms. Brooks just
21 address the point that he just addressed with respect to a
22 particular study, and then I will finish up?

23 MS. BROOKS: So, if I might join the game of
24 Australian tennis, your Honor, with the Court's permission.

25 JUDGE WOODLOCK: All right.

1 MS. BROOKS: Just very briefly, because your Honor has
2 been asking, "Let's talk about the science, let's talk about
3 studies" -- and if I might approach here?

4 JUDGE WOODLOCK: Yes.

5 MS. BROOKS: What Mr. Tarricone just said is that, if
6 you have a 35 bicarbonate dialysate and you have 8 NaturaLyte,
7 you have 43 bicarbonate. Wrong. You have 35 bicarbonate and
8 8 acetate. And everything that Mr. Ketterer was talking about,
9 all these studies about the bicarbonate in the dialysate
10 driving the serum bicarbonates, that is true, but that's not
11 the acetate.

12 So, a study came out earlier this year in March, I
13 believe, called Yamamoto, was the lead author, from a group in
14 Japan, and here's what they did: They had two different
15 dialysates. One of them had 30 bicarbonate in the dialysate
16 and 6 acetate, or, to use Mr. Tarricone's words, a total buffer
17 or bicarb of 36. The other dialysate they used had 34
18 bicarbonate in the dialysate plus 2 acetate for a total of 36.
19 Under the plaintiffs' theory, then patients receiving either
20 one of these dialysates (indicating) should have the same serum
21 bicarbonate at the end of dialysis, because this is supposedly
22 the total bicarb load, and they have the same.

23 What Yamamoto proved effectively and clearly was the
24 patients who had the 34 bicarb in the dialysate ended up with
25 significantly higher post-dialysis serum bicarbonates than the

1 patients who had the 30 bicarb. And that shows that it is the
2 bicarbonate that's in the dialysate, not the acetate, that is
3 driving post-dialysis serum bicarbonates.

4 So, your Honor's question about is there any study
5 that shows that 2 acetate is safe but 6 acetate is dangerous,
6 the answer is, not only is there no study showing that, there
7 is a study showing exactly the opposite, and that is the
8 Yamamoto study that came out in March of 2015.

9 MR. MELSHEIMER: Just very briefly, your Honor. May
10 it please the Court --

11 Jason, if you would go to Slide 25.

12 There was a question about the evidence, and I believe
13 your Honor raised a question about the Graham Study. There are
14 two studies cited by Dr. Borkan. One is this MiD Study, which
15 is on Slide 26 in your slide deck, and one is the Graham Study.
16 Critically, neither one of these involves really what's the
17 gravamen of Dr. Borkan's opinion, which is that acetate, this
18 excess acetate -- and I can't imagine more of an *ipse dixit*
19 than what he has done, which is, all he's done is, he's looked
20 for all the different acetates -- all the acid concentrates out
21 there. He has found the lowest one, and he said, "Okay, by
22 definition, everything that's higher than the lowest one I've
23 found is going to be excess." And that's how he's able to
24 capture NaturaLyte as being excess, even though, when he is
25 "Dr. Non-Testifying Borkan" he uses NaturaLyte on his own

1 patients, doesn't tell them he's using it, uses a 35 bicarb
2 setting, I believe that's in his deposition, and doesn't feel
3 the need to dial it back or adjust it in any way. So, that's a
4 classic *ipse dixit*.

5 But both of these studies show -- so, the MiD Study is
6 very unremarkable. It says, "Look, if you're an End Stage
7 Renal Disease patient, you're at an increased risk for
8 arrythmia following dialysis." That's true. People that have
9 End Stage Renal Disease, they're sick, dialysis is stressful,
10 so you are going to be at an increased risk. It doesn't talk
11 one word about acetate or bicarb levels. That's the MiD Study.

12 The Graham Study was not an acetate study. It didn't
13 purport to study acetate. I think I heard Mr. Ketterer say
14 that none of these studies do, that none of these studies
15 actually consider acetate. And, of course, that's the
16 fundamental problem with Dr. Borkan's opinions trying to link
17 the danger. They went out and hired a fellow that they want to
18 link the danger of NaturaLyte to its acetate content. He stuck
19 with his prior testimony in his treating practices.

20 But even if that weren't enough to exclude him under
21 Daubert as acting differently outside the courtroom than inside
22 the courtroom, he doesn't have any scientific data to suggest
23 this notion that anything above 2.4 is, quote, excess and is,
24 therefore, dangerous. That's why we think he should be
25 excluded.

1 Thank you, your Honor.

2 JUDGE WOODLOCK: I just want to be sure that all of
3 the studies that we should rely on are in the briefing.

4 MR. KETTERER: Yeah, I believe so. Yes, your Honor.

5 JUDGE WOODLOCK: Including Yamamoto?

6 MR. KETTERER: Well, I don't know if Yamamoto is in
7 their briefing. I would just say that, just for the sake of
8 brevity, that you ought to look at Table 2 from Yamamoto before
9 you buy into that particular conclusion.

10 JUDGE WOODLOCK: Can I suggest that we take a break
11 of, say, 10 minutes now --

12 MR. KETTERER: Sure.

13 JUDGE WOODLOCK: -- and adhere to a schedule that gets
14 us out a little bit before 5:00? I think the two upcoming
15 motions are inextricably intertwined.

16 MR. KETTERER: I'd agree with that, your Honor.

17 JUDGE WOODLOCK: So, we can talk about both of them
18 together at the same time.

19 MR. KETTERER: Sure.

20 THE CLERK: All rise.

21 (Recess taken 3:30 p.m. to 3:40 p.m.)

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

24 JUDGE WOODLOCK: I guess you are going after
25 Dr. Lipps.

1 MR. KETTERER: I am, your Honor. And there is -- you
2 had mentioned whether there was some blend-over between what
3 Drs. Colton and Zydney did and Mr. Lipps or Dr. Lipps, or
4 however we are going to refer to him. The essence of the
5 reason for the blend-over is because the motion that we filed
6 against Mr. Lipps is that essentially he has methodologically
7 done a very similar thing, only with far less rigor than
8 Drs. Colton and Zydney did. What Dr. Lipps did was, he
9 essentially testified as a fact witness -- and by the way -- of
10 course he would be allowed to testify as a fact witness, no
11 dispute about that, but he came in and said -- well, he
12 testified at his fact deposition, then he drafted an expert
13 report, and what he did in drafting the expert report is, he
14 had the lawyers go back -- and this is his own testimony, and I
15 can put that up. It's 4573.

16 Can we switch over again. Sorry.

17 And if we could go to Page 10, and it's Line 21.

18 I'm not going to read it just laboriously. There is
19 one section I want to direct you to, your Honor. But,
20 basically, the setup behind this is, he was giving his expert
21 deposition, and he was asked about how his report had been put
22 together.

23 And if we could go, then, to Line 19 and the answer.
24 And it says, "After the deposition for two days in January,
25 where you obviously know all the material -- "

1 JUDGE WOODLOCK: Do you mean Page 19?

2 MR. KETTERER: It should be Line 19. That's what I
3 had asked for.

4 JUDGE KIRPALANI: Page 10?

5 JUDGE WOODLOCK: Page 10?

6 MR. KETTERER: Page 10, Line 19? All right. How
7 about let's go to Page 11, Line 19.

8 JUDGE WOODLOCK: I think that is the same one.

9 MR. KETTERER: All right. Sorry, your Honor, my
10 fault.

11 It says, "After the deposition for two days in
12 January, where you obviously know all the material from that,
13 it was summarized by the legal staff. I then reviewed it and
14 made modifications where I thought there were things that
15 should be added or something was basically not the way I wanted
16 to say it. So, I basically modified, rewrote it and then came
17 to an agreement on it."

18 And then the question is, "Okay. So you asked -- or
19 as part of the typical protocol, you gave testimony in January
20 in this case, correct?"

21 "Yes."

22 "Someone from the legal team gave you a summary of
23 what was testified in that deposition -- what you testified to
24 in that deposition, correct?"

25 "I had a copy of the deposition, so I'm also familiar

1 with it."

2 And then we go on, and basically what its says is that
3 he reviewed the draft and he made some changes based on that.
4 But the sum total of the entire expert report is based on what
5 he testified to. There's no other allegation he went through
6 any sort of literature. There's no analysis, there's nothing
7 else.

8 JUDGE WOODLOCK: Is this just a question of how we
9 characterize what testimony he is going to give in this case?
10 That is to say, is there something that has no basis for being
11 admitted in the case?

12 MR. KETTERER: Well, I'd argue the answer to that is
13 yes, and I'll tell you why. Beyond the methodological flaw of
14 him being an expert or not, what he is testifying about that's
15 flawed, and we're going to go right to a data set that I know
16 wasn't considered by him, but what he did and what he testified
17 he did in forming his opinions was, when he got wind of the
18 litigation -- and this is all laid out in our brief -- but when
19 he got wind of the litigation, what he testified to is, he went
20 back and he had Dr. Frank Gotch, who works in a related company
21 to them, go back and do some kinetic modeling, incidentally,
22 the same kind of modeling that Drs. Colton and Zydney did. And
23 he went and he dusted off some -- this is his words -- he
24 dusted off some data from the '70s, again, the same thing they
25 complain that Drs. Colton and Zydney did in looking at their

1 patients.

2 He dusted off the data from the '70s, he has the
3 numbers rerun, and they suddenly realize in April of 2013 that
4 they had had this all wrong and they had been missing the
5 diffusion gradient, and they hadn't been accounting for that it
6 works both ways, okay? And he readily admits that the reason
7 he even looked at it was because of litigation, which, again,
8 in and of itself isn't a problem, except it impacts the
9 reliability of the results in the sense of he didn't do any
10 further confirmation of that, right? There's no look to see
11 if, "Does the data confirm what I'm saying?"

12 And one of the things that the data says, and you
13 heard this today extensively, was, well, the dialysate
14 bicarbonate controls and it acts as a delimiter. And this is,
15 by the way, a founding principle which runs through a lot of
16 the critiques that they've made of Dr. Borkan and the Hakim
17 Study and all these foundation principles, except, and we are
18 going to look at this right now, there is a data set from FMC
19 themselves which shows that four patients of the 16 in the
20 study -- there are 186 total, but I know they are going to
21 address this in a second -- exceeded the dialysate bicarbonate,
22 and we are going to look even closer at what it says.

23 So, this is something that was clearly available to
24 them, because it's their data, it's something that Mr. Lipps or
25 Dr. Lipps could have absolutely considered and should have

1 considered. In addition to -- forget if they didn't even have
2 this data. Let's put this data aside. Let's pretend like it
3 didn't exist. He doesn't run the model any further. He
4 doesn't test the model. He doesn't do anything with it, other
5 than he looks at the conclusions, which is exactly what we were
6 talking about as potentially problematic this morning, which he
7 does even less. He looks at the conclusions, he then goes to
8 Ms. Brooks and Mr. Castle, the lawyers, and asks them to
9 disseminate the information that the theory that they had
10 thought about total buffer not adding 35 plus 8 is now wrong.
11 So, that is the information. And, in fact, one of the
12 phlegmatic clips that we had actually wanted to play -- I know
13 this came up before Judge Kirpalani, I don't know that it has
14 come up before you yet, Judge Woodlook, is we would put
15 together all of the witnesses who testified at FMC, and
16 universally they all testified, "When did you learn about
17 this?" "Oh, three days ago or two days ago, or however long
18 ago." "Well, who was that from?" "Well, I learned about it
19 from the lawyers."

20 And that's the way in which the information and the
21 testing was done in this case that he wants to offer an opinion
22 about. So, what he says is, "Well, it doesn't matter. The
23 acetate just doesn't matter. It doesn't matter whether it's 2
24 or 4 or 6 or 8 or 10. It doesn't matter." Well, what's that
25 based on? Well, one, it's kind of based on modeling from at

1 least Lipps, that's his only basis, and then he doesn't -- if
2 he has any other basis, he certainly didn't say it in his
3 deposition, either deposition, nor does it appear in his
4 report. He has two literature sources in his report. So, he
5 doesn't cite to data, he doesn't cite to FMC documents.

6 And when I was talking about the totality of the
7 evidence and how this kind of blends over a number of the
8 defense experts, this is what I was referring to, is, the
9 defense experts take the notion, and Mr. Lipps is an example of
10 this, of, "Well, I want to look at what I want to look at, and
11 that's the only thing that's relevant, and I'm not going to
12 look at whatever the plaintiffs said, and I'm not going to look
13 at any other data set that might exist out there," and if he
14 did, I just don't know about it, because it's not in his report
15 and he didn't tell me that, and I took his deposition. So, how
16 am I to know what it is he used to analyze, or how can I
17 appropriately question him, and how do I know what his
18 methodology is, and how reliable are those conclusions if he
19 doesn't look at any of this other material, which is clearly
20 something he neglected?

21 JUDGE WOODLOCK: I think I understand the argument,
22 but what does it mean to say, "Of course he can be a fact
23 witness"? Will it come in, "There is this data set, and one
24 could look at the data set and say this"? Will it come in that
25 way?

1 MR. KETTERER: Well, I think he can factually testify
2 as to what he actually did. I mean, I don't know how I could
3 possibly say to you, your Honor, like, "Oh, you can't have him,
4 he can't -- "

5 JUDGE WOODLOCK: So, what are you excluding, then? An
6 opinion, some words? What is it that you want to keep out?

7 MR. KETTERER: Two things are excluded. One, the
8 opinion that the 2, the 4, the 6, the 8 or 10 acetate doesn't
9 matter. That's an opinion, okay? That should be excluded.
10 And also -- and anything where he testifies about understanding
11 or knowing anything about acetate transport specifically should
12 be excluded. What he can say is, factually, "Here is what I
13 did. I ran this. I got these results, and then I went and I
14 had a meeting with my lawyers, and they told everyone else."
15 That's a fact. Those are facts.

16 JUDGE WOODLOCK: I am not sure the letter facts are
17 going to be material in this case. Big surprise that lawyers
18 become diffusion agents for information in the course of
19 litigation?

20 MR. KETTERER: It's not, but it goes to bias, your
21 Honor, and I think that's something for a motion *in limine*
22 later on. If every witness first learned of a change in
23 theory -- your company believes one thing for a decade, and
24 then the reason that you changed your mind, that every witness
25 changes their mind, is because of a conversation with the

1 lawyers, is that not impact of bias on every one of those
2 witnesses?

3 JUDGE WOODLOCK: I am not sure, I guess is my answer.
4 But the core of it is he would be able to testify that he ran
5 these numbers on this data set --

6 MR. KETTERER: Right.

7 JUDGE WOODLOCK: -- and he came to what?

8 MR. KETTERER: To "X."

9 JUDGE WOODLOCK: He came to the end and the end was --

10 MR. KETTERER: He didn't run the data. He got someone
11 else to run the data.

12 JUDGE WOODLOCK: But he is competent to look at data
13 and say, "I saw this data and this data suggests something," or
14 what?

15 MR. KETTERER: What he can say is what the end result
16 was of the data. The data said whatever the data said.

17 JUDGE WOODLOCK: So, is there someone else from the
18 defendants who is going to interpret this data or deal with --

19 MR. KETTERER: Sure. They hired John Sargent.

20 JUDGE WOODLOCK: Colton and Zydney?

21 MR. KETTERER: Yeah. They hired John Sargent. And
22 the reason why Colton and Zydney got originally hired was
23 because Dr. Lipps, Mr. Lipps, had put this information out
24 there, and the problem was it was run by a man named Frank
25 Gotch, who, by all accounts, is a very well regarded, well

1 esteemed guy. The problem is he has Alzheimer's.

2 JUDGE WOODLOCK: I'm sorry?

3 MR. KETTERER: He has Alzheimer's, so we couldn't
4 depose him, and it was questionable that, based on the
5 progression of Alzheimer's, when he ran the data whether or not
6 that would have been accurate data to rely on or not, and
7 that's the calculations that Mr. Lipps relied on. So, we
8 wanted to go talk to Dr. Gotch. They told us, "Well you can't
9 talk to Dr. Gotch, because he has Alzheimer's," or late stages,
10 or whatever it is, that he wasn't available. Okay. I mean,
11 you know, that's tragic for Dr. Gotch.

12 So, we're in the position of having to look at
13 whatever data we have and have someone else analyze it. That's
14 how Drs. Colton and Zydney got involved, is, they looked at
15 that, they found a flaw, and they said, "Look, we should run a
16 much more detailed model." That's what they did, they ran a
17 much more detailed model. Then they complain in their
18 briefs -- well, they have a litany of things that they complain
19 about, and I've already addressed these -- the model relies on
20 some of these other factors, the same things that Mr. Lipps
21 relied on, only they went and looked at the literature much
22 more exhaustively. They set up different parameters for it.

23 So, the idea that methodologically this isn't accepted
24 testing, well, that's kind of a two-faced argument, because
25 they are trying to offer it, and they're using it all over

1 their company, but somehow it's not good enough for these
2 experts.

3 JUDGE WOODLOCK: If I may, just so I understand what
4 the defendants' view is, why isn't Lipps frosting on the cake?

5 MS. BROOKS: Your Honor, Dr. Lipps is the founder of
6 Fresenius USA.

7 JUDGE WOODLOCK: As I listen to it, it is fairly hard
8 for me to say that he is not being offered for expertise of a
9 particular type, and it sounds to me like he did not do the
10 full analysis that one might otherwise expect from an expert,
11 and it sounds to me like Dr. Sargent did, and so what do we
12 need Lipps for?

13 Part of this is, it is always nice to make new
14 friends, but parading people into the courtroom, lots of them,
15 is not necessarily to be valued.

16 MS. BROOKS: Understood, your Honor. So, first of
17 all, I can clear this up. I am not sure plaintiffs actually
18 read Dr. Lipps' expert report. He doesn't rely on Dr. Gotch's
19 model for anything, for any of his opinions. He has no
20 intention of discussing Dr. Gotch's modeling as part of his
21 expert opinion. So, that should allay whatever concerns the
22 plaintiffs have about that.

23 JUDGE WOODLOCK: Well, let's put the Dr. Gotch stuff
24 to one side. It sounds to me like they have their own way of
25 dealing with analysis of data. What I guess I am getting at

1 is, why do we need Dr. Lipps on here except for the honor of
2 sitting in the chair in front of the jury?

3 MS. BROOKS: We need him, your Honor, because the
4 plaintiffs are arguing that this total buffer concept, where
5 you add the bicarbonate to the acetate and you come up with 43,
6 for example, is real, and that's reality, and that's
7 scientific, and that the bicarbonate -- if I could approach and
8 put my chart back up -- that the bicarbonate in the dialysate
9 does not act as a delimiter. They are saying that this is not
10 true (indicating). Dr. Lipps is the individual who sat down
11 and looked at -- brought to bear his 50 years of experience.
12 He has a Ph.D in Chemical Engineering from MIT. He was one of
13 the inventors of the hollow-fiber dialyzer, and he brought to
14 bear all of his expertise in how these dialyzers work and the
15 process of diffusion and said, "Hey guys, you missed," "you"
16 meaning other people at Fresenius, particularly Dr. Hakim, "you
17 missed the basic fundamentals of how diffusion --"

18 JUDGE WOODLOCK: Well, why isn't a way to look at
19 Dr. Lipps here is a little bit like Dr. Hakim, provoked a
20 reconsideration but his opinion qua opinion is not fully
21 developed enough to justify putting him on the stand as an
22 expert? So, Dr. Sargent ends up on the stand as an expert, I
23 guess, without taking a position about that. Maybe Dr. Lipps
24 gets to talk about his invention or the kind of hollow-tube
25 diffusion, whatever that is, but he does not get to get up

1 there and provide that full-scale cross-analysis with Colton
2 and Zydney on how what I will call the biomechanics of acetate
3 diffusion becoming bicarbonate works.

4 MS. BROOKS: And he doesn't plan on that, your Honor.
5 Here are the two opinions in their brief the plaintiffs move to
6 exclude: They move to exclude Dr. Lipps' opinion that, "The
7 patient's serum bicarbonate levels cannot exceed the
8 bicarbonate in the dialysate (without regard for the
9 contribution of acetate)."

10 The problem is that is not Dr. Lipps' opinion.
11 Dr. Lipps never said it cannot exceed it.

12 JUDGE WOODLOCK: Well, then, this is an easy one. It
13 is moot.

14 MS. BROOKS: There we go. It's moot, your Honor.

15 The second one they move to exclude is that Dr. Lipps
16 should not be allowed to opine, "That the bicarbonate delivered
17 to the patient is controlled by and cannot exceed the
18 bicarbonate prescription which is entered into the dialysis
19 machine display." And, again, he never said that. He said, if
20 it does exceed it, then it will dialyze back from the blood
21 into the dialysate. That's all he is saying.

22 They are moving to exclude opinions that he never
23 gave. So, you're right, they're both moot, because I'm quoting
24 verbatim from their brief. This new theory about the Gotch and
25 Dr. Gotch's modeling, Dr. Lipps is not discussing that in his

1 expert report and does not intend to discuss it on the witness
2 stand; nor does he intend to discuss Drs. Colton and Zydney and
3 their modeling. That is, indeed, being rebutted by
4 Dr. Sargent.

5 MR. KETTERER: The problem is, your Honors, is that at
6 the deposition what he did is, he started talking about how
7 none of this matters in the same context as these opinions,
8 that the reason why the delimiter, or however you want to put
9 it, this movement of the concentration gradient back and forth,
10 what he said is he's talking about acetate transport throughout
11 all of these things, and they are laden within those two
12 opinions which we are moving to strike. You can't say at your
13 deposition, "Well, it doesn't matter, the acetate doesn't
14 matter." He said it to me multiple times. 2, 4, 6, 8 --

15 JUDGE WOODLOCK: This is not a "gotcha" moment, but we
16 really have to know what the opinion is that you are excluding,
17 and I am told that that is not his opinion, he is not going to
18 state it. Now, if it is he is going to wink, wink, nod, nod,
19 get before the jury some kissing cousin to, that is a different
20 issue. But if he is not going to state it, he is just going to
21 talk -- not just -- but he is going to talk about his
22 background in the machinery that deals with this sort of
23 thing --

24 MR. KETTERER: Well, your Honor, if he's only going to
25 talk about his background in the machinery, I wouldn't qualify

1 him as an expert, then, because I don't know how that's
2 relevant to the case. Then I have a different motion, because
3 that's not what I understand that he's going to come and say.

4 JUDGE WOODLOCK: Well, but if the motion is the most
5 specific version, what opinions do you exclude, and they say
6 they are not going to offer those opinions, then it is moot,
7 formally moot.

8 MR. KETTERER: Right.

9 JUDGE KIRPALANI: I know I have this. So, what is
10 disclosed in his expert report is opinion evidence?

11 MS. BROOKS: Your Honor, what is disclosed in his
12 expert report is, "That the bicarbonate delivered to the
13 patient" -- excuse me -- "That if the serum bicarbonate
14 concentration exceeds the dialysate concentration, the
15 diffusion gradient will switch and bicarbonate will diffuse
16 into the dialysate." He is basing that on his 50 years of
17 experience as a Ph.D chemical engineer from MIT and the
18 developer of the hollow-fiber membrane where that switching and
19 diffusion takes place.

20 MR. KETTERER: How is that any different from
21 Dr. Hakim using all of his experience to build out what he did
22 from November of 2011 --

23 JUDGE WOODLOCK: Are you objecting to that opinion?

24 MR. KETTERER: I am objecting to that opinion, yes,
25 because it is what we objected to in our brief. That is an

1 objectionable opinion.

2 JUDGE WOODLOCK: Well, it may be objectionable. I
3 just want to know what it is that you have, in fact, objected
4 to. And so, it is this statement about what happens in
5 diffusion?

6 MR. KETTERER: Right.

7 MS. BROOKS: And what's interesting is -- I'd like to
8 read from plaintiffs' brief. Here is their description -- and
9 this is their brief regarding Dr. Lipps -- here's their
10 description of this very phenomenon: "Molecules of bicarbonate
11 and electrolytes will diffuse from high concentrations in the
12 dialysate through a semipermeable membrane into the patient's
13 blood, which has a lower concentration of those particular
14 substances. Diffusion works in both directions, and, to the
15 extent that there are higher concentrations of various
16 substances in the blood, there will be diffusion from the blood
17 into the dialysate. Diffusion is, thus, characterized by the
18 movement of molecules from higher to lower concentration, and
19 this differential is referred to as the 'concentration
20 gradient.'"

21 So, for them to say that Dr. Lipps' opinion stating
22 that exact thing that's in their brief is unreliable --

23 JUDGE WOODLOCK: Well, you see, it works both ways,
24 and I am applying what is called "Occam's Razor" to this. I am
25 trying to cut down the number of moving parts to the case and

1 kind of star turns by Ph.Ds from MIT. I assume that that is a
2 higher gradient than, say, Tufts or --

3 MS. BROOKS: Absolutely not, your Honor.

4 (Laughter)

5 JUDGE WOODLOCK: So, it seems to me to be immaterial
6 for my present purposes of analysis.

7 So, we have got Dr. Lipps. You would like to have him
8 show up and say, "Hello," to the jury, but he does not add
9 anything to it. I take it you do not dispute this phenomenon.
10 The guys who are going to fight about it are, if we let them,
11 Colton, Zydney and Sargent. So, why should we let him testify?

12 MS. BROOKS: Well, then, if your Honor is saying why
13 do we need him as an extra expert witness, perhaps we don't,
14 but that, then, is a separate issue, which we discuss at the
15 end of our brief, which is, he is a percipient witness.

16 JUDGE WOODLOCK: I do not think of him as the same
17 issues, that someone who is a percipient witness necessarily
18 becomes an expert, at least in this context, and so if he is a
19 percipient witness, I assume that there is no objection because
20 he is not going to pronounce an opinion.

21 MS. BROOKS: He will simply state the facts as he
22 knows them, and that will include the fact of how his dialyzer
23 works, the fact of how diffusion works. I mean, there's no
24 getting around that Dr. Lipps --

25 JUDGE KIRPALANI: Is there something not generally

1 accepted about what she just summarized as his description of
2 how diffusion works?

3 MR. KETTERER: Not really, your Honor. That's what
4 I'm saying, is that, look -- by the way, if we're trying to cut
5 down witnesses, I don't know if it came through before that
6 somehow Dr. Borkan is coming in general causation in all these
7 cases. He's not. It's an individual witness-by-witness thing.
8 We don't intend to call, like, four general causation
9 witnesses.

10 But to answer, Judge Kirpalani, your question about
11 this, no, there's no reason for him to come and offer testimony
12 about the process of diffusion. Diffusion is a scientific
13 fact. The question is how you apply it, right? If they want
14 to apply it for an opinion and give an opinion, that's where we
15 have an objection, that, as a result of this particular
16 phenomenon, this is what it means in terms of the case. That
17 we should be restricted from doing for the reasons I've stated.
18 There's methodological reasons. He certainly hasn't done a
19 thorough and exhaustive research, and we can go right to some
20 of the points.

21 But, that notwithstanding, it certainly doesn't add
22 anything. But that's kind of a separate question from the
23 expert question. I agree with that. But we are not disputing
24 does diffusion happen in dialysis.

25 JUDGE WOODLOCK: But the ultimate conclusion is one

1 that Sargent will give in this case.

2 MR. KETTERER: Absolutely, and Sargent is basically
3 only offered, as I understand it, as a rebuttal witness.

4 JUDGE WOODLOCK: Where did he go to school?

5 (Laughter)

6 MS. BROOKS: I'm turning to Mr. Denning. He'll know.
7 I know it was not MIT, your Honor.

8 MR. KETTERER: Dr. Sargent is an esteemed -- I would
9 concede that all the people that are involved are extremely
10 esteemed experts.

11 So, your Honor, and with Colton and Zydney only one of
12 them is going to be called. We are not calling both Colton and
13 Zydney to say something that's essentially the same. They've
14 done similar work.

15 JUDGE WOODLOCK: The flip side of this is what is the
16 harm to you if he testifies as a percipient witness without the
17 opinions? And I think I understand, if it is really a
18 percipient witness there is no real harm, except more people in
19 the case. On the other hand, the guy who creates it -- this is
20 something nice to show to the jury, and it is helpful to
21 understand it, so the guy who invented it, or whatever --

22 (Voice from Smartphone)

23 JUDGE WOODLOCK: I hope that that was a concurrence.
24 Siri concurred with that?

25 (Laughter)

1 MR. KETTERER: Judge, we have no objection to
2 Mr. Lipps coming as a fact witness, none whatsoever.

3 MS. BROOKS: Then, apparently, the issue is moot. I
4 will say that this was more of a belt-and-suspenders approach.

5 What we were concerned about, particularly with
6 Dr. Lipps, is he would be testifying as a fact witness, and
7 then the plaintiffs would object that he was getting into
8 expert testimony, when all he was doing was talking about his
9 own knowledge and observations. He's more than just that he
10 was the inventor of the hollow-fiber dialyzer. He actually
11 brought -- Mr. Ketterer referred to a dry acid concentrate
12 product in Europe called "Granudial." Dr. Lipps is the one who
13 decided to bring that from Europe to the United States, and
14 eventually that became "GranuFlo," so he can talk about all of
15 that.

16 JUDGE WOODLOCK: If it is relevant. As I say, this is
17 not an occasion for star turns from people who have
18 distinguished lives generally to come in and present themselves
19 to the jury, but within reason. My only concern is that we are
20 all on the same page about what the opinion is.

21 And I understand this from you to be, from the
22 plaintiff, to be you do not want him saying it does not make
23 any difference how much acetate is there.

24 And I take it you are not going to offer him for that.

25 MS. BROOKS: I'm sorry, your Honor. Pages were being

1 turned. I missed the very last part.

2 JUDGE WOODLOCK: That you are not going to offer him
3 for it does not make any difference how much acetate is
4 included in the GranuFlo or NaturaLyte.

5 MS. BROOKS: I guess there are other experts that
6 could certainly cover that, your Honor.

7 JUDGE WOODLOCK: All right. So, then, he does not
8 testify to that.

9 MR. KETTERER: And anything about this delimiter,
10 mentioning delimiter, I mean, that is the focus, certainly, of
11 our briefing, and that certainly should be out too, because
12 that clearly has not been rigorously tested.

13 MS. BROOKS: But what I do want to make clear is, as a
14 factual witness, Dr. Lipps is the one that realized that
15 Dr. Hakim and others who used this total buffer theory, which
16 Mr. Tarricone just said in this courtroom -- so, it's by no
17 means not debated, it's still debated -- he said that if you
18 had a 35 bicarb and an 8 acetate, you had 43.

19 JUDGE WOODLOCK: I understand that is debated, but
20 that does not mean that somebody who is not competent to
21 testify about it gets to testify about it, and what I am
22 hearing on the basis of what is involved so far is that
23 Dr. Lipps has not done the full kind of analysis that one would
24 require from an expert in this area, and so he will not be
25 testifying with respect to that issue, his opinion with respect

1 to that issue.

2 MS. BROOKS: What I wanted to make clear is, as a fact
3 witness, once he realized that this concept had been missing,
4 he is the one that then brought it to the attention of some of
5 the litigation team, but Mr. Ketterer said that every witness
6 who was deposed about, "Well, you used to believe in total
7 buffer. When did you learn or how did you learn that it wasn't
8 accurate? They said, 'I learned it from the lawyers.'" That is
9 not true.

10 JUDGE WOODLOCK: There is another issue that is
11 presented here, and that is the kind of history of how we got
12 here, and, as fascinating as it is and challenging, I suspect
13 for the defendants, and the desire to write and rewrite history
14 for all parties, I am not sure it is relevant. The relevance
15 is what is the science and how does it work? That this was
16 provoked by a particular memo, or that Dr. Lipps had an
17 epiphany that caused him to strike the entire Fresenius Medical
18 Office blind to the previous understanding about total buffer
19 seems to me to be immaterial.

20 Now, you may say, "Well, bias," and I am not sure that
21 I take a broad view about bias, but now we are dealing with
22 things that are outside of questions of opinion but questions
23 that I think may be framed by motions *in limine*. How much we
24 are going to get into there was a memo and the alternative
25 grounds for admissibility of the memo, how much we are going to

1 get into Dr. Lipps all of a sudden saying, "Wait a minute, let
2 me tell you how this works," and now it becomes clear, that
3 does not strike me as meaningful and potentially misleading as
4 bias.

5 MR. KETTERER: Well, I mean, those are all questions
6 for another day, and I think, your Honor, one of the things I
7 would say is that I do think in ruling on those kinds of
8 motions it is important to have the full history of what's kind
9 of happened, because that's a separate kind of decision, right?

10 JUDGE WOODLOCK: It may be, it may be, but it is not
11 this.

12 MR. KETTERER: Well, I agree with that.

13 JUDGE WOODLOCK: I am just tossing out something that
14 you should be thinking about in terms of my bias about how
15 cases are tried -- I will say it, I have said it, I am sure, to
16 some of the lawyers in this room before -- like a Yankee meal:
17 you serve it cold and you slice it thin, and that means that
18 there is not a lot of, "Look at Dr. Hakim, he worked for them,"
19 or, "All of a sudden our brain had this new idea." I do not
20 see it right now.

21 MR. KETTERER: Again, your Honor, I'm fine with all
22 that, conceptually, except to the extent that any scientific
23 opinion is clouded by bias, and I think that's an important
24 question.

25 JUDGE WOODLOCK: Maybe.

1 MR. KETTERER: I agree with what you're saying. But
2 if the basis for the science is flawed, that's something that
3 we have to explore, even in this context.

4 JUDGE WOODLOCK: Yes. But you do not have to do that
5 with Lipps, because he is not going to be testifying to any
6 opinion.

7 MR. KETTERER: Fair enough.

8 MS. BROOKS: Thank you, your Honor.

9 JUDGE WOODLOCK: And Hakim is not testifying to
10 anything.

11 MR. KETTERER: That's true.

12 MS. BROOKS: Your Honor, would you like to now hear
13 our motion regarding Drs. Colton and Zydney?

14 JUDGE WOODLOCK: Let me just be sure that we have got
15 the proper segue.

16 MR. KETTERER: I don't have any problem with doing
17 that, your Honor. The one thing I would like to do is, since
18 we sort of blended over, is, there is a very specific data set
19 that I want to go to before we talk about anything else, and
20 the reason being is because, one of the things that has been
21 out here is, I don't like when we go to a study and we don't
22 actually look at the study, and then we're sort of talking
23 about these data points in this vacuum, except we really
24 haven't looked at any actual data. And that's been one of the
25 problems I think that has been going on all throughout the

1 hearing.

2 I think I probably made a mistake in terms of the
3 presentation to you in not sort of going over, at least from
4 our vantage point, what some of the specifics are with some of
5 the actual science. And so, what I wanted to --

6 JUDGE WOODLOCK: Let's see if that is relevant.

7 MR. KETTERER: Right. This is a data point, though, I
8 think that is relevant to this motion.

9 JUDGE WOODLOCK: All right.

10 MR. KETTERER: And that's why I want to go to this.
11 And it's because one of the challenges that they say is, "Well,
12 Colton and Zydney and all these people haven't looked at any
13 actual data." So, I want to show you the data that they
14 actually looked at in their Supplemental Report that wasn't
15 turned over to us until the end of July, and I know you are
16 familiar with the ABC Study, which is a study that they did.
17 This is also a study they did. They did it three years ago,
18 and they did it in Portugal in direct response to the
19 November 4th, 2011 memo.

20 So, if we could just put up 4367.

21 May I approach, your Honor?

22 JUDGE KIRPALANI: You may.

23 JUDGE WOODLOCK: Did it really come with a flag?

24 MR. KETTERER: I'm sorry, your Honor?

25 JUDGE WOODLOCK: Did it really come with a flag?

1 MR. KETTERER: I believe it is a Portuguese flag.

2 This is "Blood gas analysis data," and it's from a
3 clinic in Portugal, Vila Franca de Xira, and the woman who is
4 on there, Cacilia -- I'm probably butchering her name --
5 Scholz, is a Fresenius Europe employee. This is a
6 presentation, a slide presentation that she did about the
7 results of this particular study. Now, we didn't just get the
8 slide presentation. We finally got all the underlying patient
9 data so that we could analyze it ourselves. But she actually
10 had done all the analysis for the company already.

11 The parameters of the study, and one of the things I'm
12 sure that will come up, is that this study was done on 186
13 patients, but that there was another form of dialysis called
14 "hemodiafiltration" that was used on some of the patients.

15 JUDGE WOODLOCK: Just so I am clear about this, the
16 attachment of the November 4th, 2011 memo is not a backdoor way
17 of bringing the memo in?

18 MR. KETTERER: No, it's not, your Honor, and actually
19 I don't care if those two pages ever come in, but the reality
20 is they were attached by the company, not by me, so I didn't
21 highlight those or anything else. No. In fact, this is really
22 about purely the data on this, and I don't care if you look at
23 those two pages or not, other than for the information that
24 that was the reason that they did the study.

25 The data itself was that there are two processes.

1 There were some patients who got hemodialysis only; that's what
2 we have here in the United States, some who got
3 hemodiafiltration. That's a higher-infusion form of dialysis.
4 And then there were some who got sort of a blend-over of the
5 two, who had gotten something called "substitution fluid,"
6 which is part of a direct infusion part of the process for the
7 dialysate, along with hemodialysis.

8 I don't want to talk about anyone other than the
9 patients who are hemodialysis, because that's all that's
10 relevant here, is we're comparing like patients to like
11 patients, okay, hemodialysis patients to hemodialysis patients.

12 And, incidentally, we filed a Supplemental Report.
13 Clark Colton and Andrew Zydney both filed Supplemental Reports,
14 and Dr. Sargent actually also just filed yesterday a
15 Supplemental Report responding to the conclusions. And,
16 interestingly enough, Dr. Sargent barely talks about the
17 analysis that Drs. Colton and Zydney did on this particular
18 data. He has a lot of critiques about a lot of other things
19 they said, but this data not as much.

20 And one of other things is that, your Honor, and I
21 will just cite it, is that the defendants in their Omnibus
22 Causation Brief, and I think it's on Page 25, talk about how,
23 "Well, the plaintiffs don't have any evidence of the fact that
24 these patients have alkalemia, and how do we know that the
25 combination of acetate and bicarbonate leads to alkalemia

1 defined as above 7.45? How do we know that? And how do we
2 know whether or not the potassium is really dropping so low in
3 all of these patients? And how do we know that it really has
4 any of this effect?"

5 Now, again, this is data that they have. None of
6 their experts have reviewed it, except for Dr. Sargent in a
7 rebuttal. Not one other expert has reviewed this data.

8 And blood gas data is, by the way, what they say is
9 the best data, because it's done at the chair at the time in
10 realtime. That would be the best data. And, in fact, one of
11 their experts, Dr. McCullough, at a recent deposition said,
12 "That would be the best data." "Did you ever see that data?"
13 "Never saw that data." I don't know if he asked for it, but he
14 didn't see it. It certainly wasn't given to him.

15 And if we could go, first of all, to Page 5 of this
16 exhibit, the data, this is all the underlying information and
17 the type of information that was collected. It's on Page 5,
18 your Honor. It measures a number of different things, and I'm
19 not going to go through them all: bicarbonate, potassium,
20 sodium, glucose, a number of things that are important to
21 dialysis patients.

22 So, this wasn't something that was novel in the sense
23 that they were doing this kind of thing for the first time, but
24 blood gas analysis data, that's very unique, and, in fact, the
25 author concedes that in one of her slides, and she did at

1 deposition. It's not something that's normally seen, it's not
2 normally done, and I don't think even the defendants would say
3 that blood gas and analysis data is typically done or
4 collected. But it is the best, it is the most accurate way of
5 measuring it, because, as our experts would testify, a lot of
6 these samplings that they are relying on, there's always the
7 potential for air contamination sampling, there's always the
8 potential for error on some of these blood draws. So, the fact
9 that you have this kind of data, whether this is conclusive or
10 not, I'm not arguing. What I'm arguing is this is very strong
11 for consideration, and when you don't consider this kind of
12 evidence, that becomes problematic.

13 So, if we could turn to the next page, Page 6, this is
14 just the manner in which it was laid out and collected. So,
15 it's collected, it's collected through their Euclid, which is
16 just their European clinical database, and this is the manner.
17 There were patients. The patients are identified by number,
18 there is certain data that's collected across. And this is
19 just a sampling of the kind of data that was collected on all
20 186 patients, and we had access to the spreadsheet for the
21 entire group of patients, so we got all of this data. So, the
22 same data that you see here replicated 186 times in the
23 spreadsheet, that was there. So, our experts were able to go
24 through and look at that particular data.

25 So, one of the things I want to do is sort of cut to

1 the highlight, and if we could go to Dr. Colton's report, and
2 that is his Supplemental Report, I should say. That's
3 GFPL4685, and if we could just bring up Page 37. And the only
4 reason I didn't produce an entire copy is it's a giant stack of
5 paper, and I only want to show one page, and it basically
6 replicates the data that's already in the PowerPoint that I
7 have given you in terms of the conclusions.

8 Okay. Now, your Honors, this is the 16
9 hemodialysis-only patients. And I did a slide. I'm not going
10 to show you the slide about the summary, but this is
11 Dr. Colton's compilation directly from the data, and here are
12 the results: 4 of the 16 patients exceeded the dialysate
13 bicarbonate prescription. That's 25 percent of them. So, when
14 you heard Ms. Brooks stand up and tell you about how there's no
15 other data, and we don't know, and no one else can show what
16 the effect of acetate is, dialysate bicarbonate controls alone,
17 well, if dialysate bicarbonate controls alone, here we have got
18 an example of hard data for 16 patients and their study on
19 acetate transport, which they parade out there for Dr. Maddux,
20 that had 6 patients. So, the number is not the limiting factor
21 here.

22 Then, 15 of the 16 patients had potassium less than
23 3.5. Well, why is that important, the lowest end of normal?
24 That is what the plaintiffs allege is the causation chain:
25 bicarbonate goes up too high, potassium and calcium drop, you

1 have more arrhythmias. You are certainly at risk to have
2 arrhythmias. That is really not in dispute, that when your
3 potassium goes low you can have a CPA.

4 And then the last thing is they say, "Well, no, wait a
5 minute, where is your data on pH levels? How do we know
6 whether all these patients have alkalemia?" 14 of the 16 HD
7 patients there had pHs 7.45 or above. So, in determining
8 what's the effect of an acetate -- and the acetate, by the way,
9 used here is -- I'm sure I'm saying this wrong, now that I've
10 heard Ms. Brooks say it -- I'm going to say "Granudial," but
11 that has 6 milliequivalents of acetate, 2 more than NaturaLyte,
12 2 less than GranuFlo, but it's the same product, does the same
13 thing, and it's only -- I believe it's only available in
14 Europe. I don't know if it's used here in the United States.
15 But its effect is the same. It's acetate. It's bicarbonate.
16 It's the effect of what is it doing to the patients?

17 And this is the evidence that Drs. Colton and Zydney
18 have been asking for in terms of the expansive data. Look at
19 all those patient parameters in that spreadsheet. I mean, look
20 at all of the things. That's what they needed to do in order
21 to run the modeling. And so, one of the things they raised in
22 their brief was, they said, "Hey, you guys didn't run it
23 against actual patient data." They got the actual patient
24 data, they ran it, and guess what? It verified, not to an
25 exact extent, but it validated a lot of the results of the

1 modeling, that what they said was basically going to happen,
2 happened. Now, did that happen with the ABC (ph) study? No.
3 The model wasn't perfectly correlative, and there were
4 criticisms from Dr. Sargent. Sure, readily admit that. But
5 the idea of when you finally give the patient data that we've
6 asked for and certainly wasn't -- I don't know if it was
7 affirmative or not, because it took until the end of July of
8 this year to get it, even though they had it all this time,
9 that, when we finally get it we can conclusively prove here is
10 what acetate comes across, the modeling is correct, we can
11 predict roughly what an individual patient will receive from
12 acetate when they have it.

13 This idea of the delimiter? Here is data. Would I
14 stand here and say, Judge, this is conclusive proof?
15 Absolutely not. But it is certainly more than just some
16 evidence. And if you're going to stand and say it's
17 impossible, and the only thing which controls is dialysate
18 bicarbonate, and that's a scientific fact, that's not true.

19 And there were other data points before this. There
20 weren't a lot of them. There were things that Dr. Hakim had
21 which he relied on in some of his Indian Kalamazoo studies
22 which show that there was -- he was asked about this, by the
23 way at his deposition -- "When you saw data points like this,
24 what did that make you think?" "Well, it made me think that
25 acetate was having an effect on dialysate bicarbonate." Hence,

1 that's all the way back in 2004 and 2005 he was seeing that
2 data. This is just confirming what he said.

3 JUDGE WOODLOCK: All right. I want to be sure that we
4 are within the time period.

5 MR. KETTERER: Sure.

6 JUDGE WOODLOCK: I think I understand the point.

7 MR. KETTERER: Got it.

8 MR. DENNING: Thank you, your Honor.

9 JUDGE WOODLOCK: So, isn't the fat in the fire with
10 this?

11 MR. DENNING: Is the fat in the fire? Help me out.

12 JUDGE WOODLOCK: Now this is a real fight. So, you
13 have got Sargent and you have got Colton and Zydney, if I
14 pronounce it correctly, but, in any event, you have got people
15 who are going to take the materials data, and they are going to
16 treat it in different ways and draw different conclusions, and
17 why should we be interfering with the potential for people who
18 have actually studied the data to do precisely that?

19 MR. DENNING: No problems with that whatsoever.
20 People who have studied the data, talking about what the data
21 shows, no problem whatsoever. We are not moving to exclude
22 this study at all. It's coming in. People can talk about it,
23 people can look at the numbers that were just displayed. And
24 if you look at those numbers just displayed, counsel kind of
25 waves their hand and says, "Oh, sometimes it shows that the

1 post-dialysis serum bicarbonate levels are higher than the
2 dialysate bicarbonate levels." That proves their theory. Look
3 at how much they exceed the dialysate levels.

4 JUDGE WOODLOCK: But aren't you looking in the wrong
5 direction, then? That is an argument made to people over there
6 (indicating). The question here is whether or not we exclude
7 the expertise of these two individuals.

8 MR. DENNING: Fair point. And I don't think we should
9 exclude the study that we were just talking about, and we are
10 happy to argue to the jury about that.

11 JUDGE WOODLOCK: The opinions that are expressed by
12 these two individuals.

13 MR. DENNING: Well, the opinions about the studies are
14 one thing. The model that they employed to try to predict what
15 post-dialysis serum bicarbonate levels are, the mathematical
16 model that they've come up with, that's a whole other ball of
17 wax, and that's something we very strenuously object to and
18 think needs to be excluded. I'm happy to do that, your Honor.

19 JUDGE WOODLOCK: Why don't you focus on it.

20 MR. DENNING: Okay. If I could hand up some slides?

21 JUDGE WOODLOCK: Sure.

22 MR. DENNING: Okay. So, let's talk about Drs. Colton
23 and Zydney. Both of these are chemical engineers, one from
24 MIT, very esteemed, very smart people. The question is does
25 the model that they have created pass muster for Daubert? It's

1 particularly important here. You heard counsel for the
2 plaintiffs say the real issue in this case is how much of the
3 acetate gets metabolized into bicarbonate and, in effect, what
4 happens in the body. You've also heard them say there are no
5 studies that actually look at experimental data and make that
6 determination.

7 Dr. Zydney in his report on Page 4 says, "There have
8 been no direct quantitative studies of the effects of added
9 acetate in bicarbonate-based dialysate solutions." What they
10 are attempting to do is substitute for real data, for real
11 study, for real scientific analysis, a model, a simulation, an
12 equation that they've put together and have the jury rely on
13 that. This is the type of scientific evidence that requires
14 the Court to act as a gatekeeper. The equations that they are
15 going to put up, that these MIT-educated people are going to
16 put up on the board, are going to be beyond the ken of the
17 average juror. The juror is going to be dazzled by the
18 differential equations that they see on the board and will
19 assume, "Oh, this must be impressive."

20 The Court needs to take a hard look at whether this
21 model, whether these equations, past muster by Daubert. They
22 haven't been tested, they haven't been peer-reviewed, they
23 haven't been accepted in the communities. The hallmark for
24 Daubert and Lanigan acceptance, they're all missing here, and
25 that's why we need to exclude them.

1 On Page 3 -- if we could go to Page 3 of my slides.

2 Could we switch the slides over to our side, please?

3 JUDGE WOODLOCK: Let me just ask in that connection --

4 MR. DENNING: Yes, sir.

5 JUDGE WOODLOCK: -- it rises with Daubert generally.

6 So someone constructs a model to deal with something new, and
7 it undermines the model to say, "You are the first kid on the
8 block to do this," but that does not end it. There has to be
9 some showing, I think, that this modeling is simply
10 inappropriate, substantively inappropriate; that, if it were
11 peer-reviewed, "Now we are going to try it, we are your peers,
12 and now we are going to show you that," then that is something
13 different. But it is not so clear about this modeling, is it?

14 MR. DENNING: Well, I will get to that, your Honor. I
15 will get to that directly, because it sounds like that's what
16 you're interested in. You're right, this has not been
17 peer-reviewed, this has not been tested, this has not been used
18 outside of Drs. Colton and Zydney. They are the only two who
19 have ever used this model. They say that pharmacokinetic
20 modeling has been used. They're right, but you really have to
21 look at how they're using it, what equation they're using, what
22 model they're using. They're the only ones ever to use it in
23 this way. We need to look and see if they are doing it right.
24 It doesn't meet any of the other benchmarks of Daubert.

25 So, let's look. If we can go to Slide 6, please.

1 What did Drs. Colton and Zydney do? And this was the evidence
2 that we had at the time we filed the motion, and then I'm going
3 to move on to the ABChD and Portugal after that. But initially
4 when they prepared their reports in this case, they wanted to
5 validate their model, they said. So, they plugged in some data
6 from some kidney dialysis from hemodialysis to see how it would
7 fit their model. The problem is the data that they used was
8 old, and it was sparse, and it was irrelevant to what we're
9 dealing with in modern dialysis.

10 First, they picked only three patients, and they
11 analyzed the data from only three patients to see if their
12 model was validated by that.

13 JUDGE WOODLOCK: Can I ask --

14 MR. DENNING: Yes, sir. Of course, your Honor.

15 JUDGE WOODLOCK: -- because I am intensely concerned
16 about time. I do not mean to cut off the argument, but I want
17 to get to the focus of it, and if we spill over to tomorrow, we
18 spill over to tomorrow.

19 MR. DENNING: Understood.

20 JUDGE WOODLOCK: But that was then. Now we have
21 Portugal and we have ABCDH (ph), or whatever it's called.

22 MR. DENNING: ABChD? Yes, sir.

23 JUDGE WOODLOCK: Right.

24 MR. DENNING: Well, let's go to that, then. I'm happy
25 to jump straight to that. If you're looking at the crux of my

1 argument, it will be in the next five minutes. On Slide 8, we
2 see at the top --

3 JUDGE WOODLOCK: So, I do not listen after five
4 minutes?

5 MR. DENNING: Well, diminishing returns after five
6 minutes. How about that?

7 On Slide 8 we see part of their model, and this is a
8 very significant part of the model that Drs. Colton and Zydney
9 have put together to estimate various parameters. They have to
10 estimate all of these variables, DB, CBD, CB, R, MH. Those are
11 very patient-specific variables about biological functions in
12 the body that they are not able to take from a spreadsheet, not
13 able to take from a chart. They had to make estimates. They
14 had to make guesses that they are plugging into their model,
15 and then they are going to spit out at the end VB, which is the
16 volume of bicarbonate. And this is how they determine how much
17 bicarbonate goes into the patient. It's based on estimates.
18 Those estimates are tricky things to do.

19 One of the things that we will look at is the DB, for
20 example. DB is the dialysance of bicarbonate. "Dialysance,"
21 in essence, means how much, how quickly is the bicarbonate
22 going from the dialysate through the dialyzer into the
23 patient's blood, right? You multiply that by the concentration
24 gradient to see how much bicarbonate is getting into the body.

25 Drs. Colton and Zydney said, "Well, let's see if our

1 model matches up with the ABChD Study. This will be a good way
2 to test our model, see if it matches. So, they needed to pull
3 what is the dialysance, what is kind of the way the bicarbonate
4 flows from the dialysate into the blood, in the ABChD Study.
5 They said, "Well, the flow rates aren't provided," and
6 Ms. Brooks showed you earlier this dialyzer (indicating). The
7 dialysis fluid goes in one end -- I'm sorry, on the bottom,
8 actually -- comes up, comes out the other end, blood goes in
9 the top, blood comes out the bottom (indicating). They both
10 have flow rates. The faster the flow rates are, the more
11 diffusion you're going to get, and you have separate blood flow
12 rates and dialysis flow rates.

13 They said, "Well we don't know what the flow rates are
14 for ABChD, so we can't calculate the dialysance."

15 JUDGE WOODLOCK: Is there somebody who can say what
16 those flow rates are?

17 MR. DENNING: It actually was available to them. They
18 missed it. They didn't see that the flow rates were available.

19 If we can go forward to Slide 10, please, Mr. Barnes.
20 There we are.

21 On the left-hand side of this slide, on Slide 10, you
22 can see an actual patient chart, a patient sheet, the red block
23 highlighted. "BFR" is "Blood Flow Rate," DFR is "Dialysis Flow
24 Rate." This is from one patient. This is from Patient S020,
25 but there was one of these for every patient, and on the right

1 side of that sheet we have compiled the blood flow rates and
2 the dialysis flow rates for each of the patients.

3 JUDGE WOODLOCK: So, how do these relate to the
4 calculated DB flow rate? I see that they are much, much
5 higher, but is that true throughout, or is there data that
6 falls within the estimate that was supposed to provide a
7 reasonable fit?

8 MR. DENNING: Widely different, actually. It turns
9 out that the estimate that they made -- and this is important
10 to know how they decided to make the estimate that they came up
11 with. They used their model, they used the data from ABChD,
12 and tried to back out of that, "Well, using the end results of
13 this study and using our model, what would the right flow rates
14 be?" They came up with those flow rates, and then they said,
15 "Okay, we'll plug the flow rates back in the model and see if
16 the results fit at the end." Well, of course they do. That's
17 how you made them.

18 JUDGE WOODLOCK: You use the average flow rate from
19 the ABChD and you say it is 290?

20 MR. DENNING: That's right.

21 JUDGE WOODLOCK: Were there ones in the range of the
22 estimates?

23 MR. DENNING: None. So, their estimates, and you are
24 looking --

25 JUDGE WOODLOCK: Slide 11.

1 MR. DENNING: Slide 11. The actual flow rate,
2 calculated not by me but by Dr. Sargent in the report that he
3 filed yesterday, the average flow rate for the blood was 472,
4 which leads to, you can calculate from that the DB, which is
5 290. Their range went from 40 at the bottom to 140 at the top.
6 They're 2 to 7 times off on their DB, yet their model fit the
7 results from ABChD. If they use wrong data and their model
8 produces the right results, what does that tell you? It tells
9 you their model is wrong. If they had put in the right data --

10 JUDGE WOODLOCK: I admit to not having read the
11 Sargent Supplemental Affidavit closely enough. Obviously, I
12 will at some point. Whenever anybody says "average," I say why
13 don't you have median? What does the median do for this?

14 MR. DENNING: It would be very simple to know that,
15 your Honor. It's a knowable thing. The blood flow rates went
16 from 400 at the bottom to 600 at the top. Dr. Sargent said
17 that averaged to 472. 400 to 600, average 472. So, the DB,
18 the low DB, just doing some quick math in my head, would be no
19 lower than 240. The high DB would be what, 330, maybe? So, a
20 tight range that doesn't overlap whatsoever is still a multiple
21 of at least 2 from the range that Drs. Colton and Zydney apply.
22 That's telling. What it tells us is their model is wrong.
23 They can't plug in the wrong data and get the right result and
24 say the model is right.

25 JUDGE WOODLOCK: What does that do with the Portugal

1 Study?

2 MR. DENNING: So, the Portuguese Study is interesting
3 in that, first of all, counsel said they're going to ignore all
4 of the hemodiafiltration patients; they're going to focus only
5 on the HD patients. That's not what Dr. Colton did.
6 Dr. Colton tried to draw a connection between the
7 hemodiafiltration patients and hemodialysis patients and say --
8 he said, the word he used is "indistinguishable," and it's on
9 Slide 14. They are not indistinguishable, and I will take a
10 second to make sure your Honors understand the difference.

11 The fundamental difference between hemodiafiltration
12 and hemodialysis is that, in hemodiafiltration the bicarbonate
13 and acetate are infused into your blood. It's not a diffusion
14 process through a dialyzer (indicating). It's more like an
15 injection of the bicarbonate straight into the bloodstream.

16 Why is that relevant? Well, this concentration
17 gradient that we've been talking about is overwhelmed. It
18 doesn't apply.

19 JUDGE WOODLOCK: Let's assume we exclude the HDF and
20 Colton. Zydney does not do that.

21 MR. DENNING: Dr. Zydney does not say that the HDF is
22 the same as HD.

23 JUDGE WOODLOCK: Right. So, we just carve that out a
24 little bit. What does it end up doing?

25 MR. DENNING: And Dr. Colton and Dr. Zydney are both

1 free to look at the HD data in here (indicating) and say,
2 "Okay, this is informative, this tells us something." What
3 they can't do is say, "Well, that lines up with our model."

4 JUDGE WOODLOCK: Let's assume that someone does that.
5 What I want is a comparison with your ABChD Study and some
6 comparison between that study and the Portugal Study. You tell
7 us that you end up, when you actually use the actual data from
8 the ABChD, you get to 290.

9 MR. DENNING: Yes.

10 JUDGE WOODLOCK: What happens if you use the Portugal
11 Study?

12 MR. DENNING: So, there are other things they didn't
13 do the same estimation with the Portugal Study to arrive at the
14 results that they came up with. Predictably, their model was
15 not as accurate for the Portugal Study as it was for the ABChD,
16 because they didn't know the answer before they did the
17 question, like they did in the ABChD. So, fundamentally --

18 JUDGE WOODLOCK: You know the factual answer. Based
19 on the data within the Portugal Study, how would it work out if
20 you were to do the same thing you did to ABChD?

21 MR. DENNING: So, they made several mistakes, and
22 that's in Dr. Sargent's Report that was filed just yesterday.

23 JUDGE WOODLOCK: So, I can see that?

24 MR. DENNING: You can see that in Dr. Sargent's Report
25 in his critique of Drs. Colton and Zydney. The fundamental

1 fact is, this is not true, but let's say, even for the benefit
2 of the doubt, that their model was okay at lining up with the
3 Portugal Study, it was demonstrably wrong in lining up with the
4 ABChD Study. We can't let a model that's right half the time
5 and wrong half the time get put in front of a jury and say,
6 "This is the one thing," because there are no experimental
7 data, "This is the one thing that you can look at and determine
8 what happens in the human body with regard to the metabolism of
9 acetate into bicarbonate." We have to throw the model out.

10 They can come in and testify about the ABChD results,
11 not their model. They can look at the results, "they" meaning
12 plaintiffs and their experts who have opined appropriately on
13 the ABChD results, and they can say that there were 4 people
14 out of the 16 people in Portugal who had final serum
15 bicarbonate levels that were greater than the dialysate, and
16 they can say one of the patients in the ABChD Study also had a
17 final serum bicarbonate that was higher than the dialysate
18 bicarbonate. All of those were very -- just a tiny bit higher.
19 But they can say that. That's fine.

20 What they can't do is come in and try to use this
21 faulty model to overwhelm, wow the jury, and come in and start
22 trying to use that to back up theories that they have no proof
23 for.

24 JUDGE WOODLOCK: Do you have a model of your own?

25 MR. DENNING: I don't think we're presenting --

1 Dr. Sargent's model. Dr. Lipps is not going to testify about
2 it. Dr. Sargent is. There is, I understand, no motion against
3 Dr. Sargent's model. He hasn't been challenged in the way that
4 Drs. Colton and Zydney's model has been challenged, and
5 rightfully so.

6 In deference for time, there are a few opinions that I
7 think Drs. Colton and Zydney are unqualified to make, because
8 they are not physicians and they made some opinions about
9 whether -- Dr. Zydney had some opinions in his rebuttal report
10 last week about whether the patient census for the studies was
11 appropriate, whether there are too many African Americans in
12 the study, and that influenced the results. As a chemical
13 engineer, he's not an expert in that field. He's not
14 qualified.

15 JUDGE WOODLOCK: Even one from MIT?

16 MR. DENNING: Even from MIT, your Honor. An
17 epidemiologist, maybe, a statistician, maybe. A chemical
18 engineer is not qualified to make that sort of opinion. I
19 wanted to mention it.

20 There are a few others that are in the briefing. I
21 will rest on the briefing, because I know we're worried about
22 time. But that was the crux.

23 MR. KETTERER: Very quickly, your Honor. First of
24 all, that opinion, just backing up on it, is based on a report
25 from a nephrologist, Derek Fine, who worked with Dr. Zidney, so

1 it's not just Dr. Zydney making it up out of thin air, because
2 he's not a physician. He's basing it partially on --

3 JUDGE WOODLOCK: Let's focus really on the model.

4 MR. KETTERER: The modeling itself, your Honor. Look,
5 the modeling itself, they're sort of glazing over this how
6 accurate were they with the VFX data. This is the kind of
7 modeling that rarely shows the accuracy, after looking at all
8 the patient data, that their model did, in fact, when they were
9 given all the patient data. That's why Dr. Sargent doesn't
10 really comment on it. If there were some giant comment out
11 there about critiquing the actual model -- and, by the way, the
12 methodology of the modeling, if that wasn't such an issue --
13 there's a reason we didn't file a motion against Dr. Sargent.
14 It's because the modeling is accepted as a methodology.

15 JUDGE WOODLOCK: If the modeling is so far out, just
16 using the ABC materials, and your estimate for DB is --

17 MR. KETTERER: Blood flow rates.

18 JUDGE WOODLOCK: -- so disparate from what the actual
19 experience is, and your estimate is based on an effort to find
20 a fit, nothing unusual about that, but if it is so disparate,
21 then one begins to question the model itself.

22 MR. KETTERER: So, I agree with that if it doesn't
23 have any context, right? And the context is they had asked for
24 the flow rates. Now, did they see those specific flow rates?
25 They did not. And the reason they estimated the way they did

1 wasn't because of some flaw in the logical thinking. What's
2 actually in the protocol is that that's the lowest end at which
3 they can set it out, which was 200. So, the estimate came from
4 a specific point at what they thought they could assume without
5 actually seeing what they did.

6 Now, look, one of the things I don't like to do is, I
7 don't like to say, like, we should forgive the mistake and the
8 mistake is a mistake. If there's a mistake in the computation
9 that they didn't see that data and it had been provided to
10 them, that is what it is. It doesn't make the model
11 inaccurate, and I'll tell you why.

12 JUDGE WOODLOCK: Why wouldn't it be appropriate for
13 us, and particularly given the moving-train quality of the
14 disclosure of this information, for us to say, "So, now you
15 have got more material. We will give you a chance to refine
16 your model and come forward." But right now the model is out
17 of whack with what has most recently been disclosed.

18 MR. KETTERER: I don't think that it's so out of
19 whack. First of all, you have far more patients in Portugal,
20 and the model was much more accurate. In fact, it hit the line
21 of the model 4 times out of 16, and it was clustered right
22 around -- now, we have this in the report, your Honor -- it's
23 clustered right around what's called the "line of identity." I
24 mean, they were very accurate --

25 JUDGE WOODLOCK: So you are happy enough with the

1 model as it stands right now?

2 MR. KETTERER: What I would say, your Honors, is that,
3 in theory, the model isn't the problem. The problem is
4 parameters in the modeling, which is what they are really
5 alluding to. What they are saying is they are critiquing
6 parameters and calling it a problem with the actual model.

7 But if you look through what Dr. Sargent critiques in
8 either report, what he is correcting is the parameter values
9 that are being chosen in order to go against the results. The
10 methodology of the model itself is flawed, because he says,
11 "Well, you can't input this parameter," "Well, you made this
12 assumption on this." That's not the written calculation.
13 That's something separate and apart. So, you have to
14 distinguish those two things.

15 JUDGE WOODLOCK: But this much we know, or think I
16 know, based on the ABChD Study, and that is the model does not
17 fit the data.

18 MR. KETTERER: It didn't fit the data -- first of all,
19 I wouldn't concede that, your Honor. I would say it didn't
20 fit --

21 JUDGE WOODLOCK: But I always thought that your
22 position was that more is greater than less.

23 MR. KETTERER: That's true.

24 JUDGE WOODLOCK: And so, what we have here is a great
25 deal more, 240, 270, depending on how you deal with it, for

1 average flow, and you have got it calculated 40 to 140. Now,
2 not to do too much with simple arithmetic, more being more than
3 less, but that is more than 250 percent.

4 MR. KETTERER: I think you're blending over some
5 concepts here, your Honor, in terms of what the model actually
6 computes, and the problem with the model being the parameters
7 that are being used, which can lead to --

8 JUDGE WOODLOCK: Let's just take the DB estimate.

9 MR. KETTERER: That's a parameter. That's not --

10 JUDGE WOODLOCK: A rose by any other name. The point
11 is that it is out of whack with the data that exists.

12 MR. KETTERER: That's true, your Honor, but that
13 doesn't make it a flaw in the actual model. That's what I'm
14 trying to say, is, if you put in a different value there,
15 right, that doesn't make the calculation or the algorithm
16 inaccurate. What it makes is the numerical value that's used
17 as a parameter within the model an error. Because if I change
18 the parameters does that automatically invalidate the model?
19 The answer is no.

20 JUDGE WOODLOCK: It may not. But this much I know,
21 is, it is out of whack with the data right now, and so it is
22 not the best parameter I have ever encountered.

23 (Counsel conferred off the record)

24 MR. KETTERER: So, what I would say, your Honor, is,
25 if they went back and fixed the parameters -- let's say we went

1 back and they had the correct parameters and they reran the
2 data. What I would say is that the model has already been
3 validated on the VFX Study, so they should be allowed to have
4 their model, present it with respect to that data. And it is a
5 cross question if they rerun the data and they have their
6 model, and they rerun it with the correct parameters and it's
7 put in there in, let's say, another supplemental report, and
8 the data shows whatever it shows, the model shows whatever it
9 shows, following the change in the parameter, then I would
10 argue that both should be able to be presented. Any time
11 they've run it against real patient data, what the model, what
12 they predicted, and I think it's just as valid to say, "We
13 predicted this, and it said this, and the model predicted this
14 and it said this."

15 JUDGE WOODLOCK: I guess what I ask is, is this your
16 best and final model?

17 MR. KETTERER: Would I like to rerun the number with
18 the correct parameter? Absolutely, your Honor.

19 JUDGE WOODLOCK: So, what is the problem with that,
20 frankly, given the late disclosure of this information? My
21 general view is, and I am sure it is the same as
22 Judge Kirpalani's, get to the merits of it. There has been an
23 ongoing dispute about how quickly this material has been turned
24 over. It has been one of the kind of last-minute glitches in
25 the case. It raises some issues about the modeling. If you do

1 not want to do it, that's fine.

2 MR. KETTERER: No, I want to do it.

3 MR. DENNING: So, I would argue, your Honor, they have
4 had plenty of time to do that. We turned over the data months
5 ago.

6 JUDGE WOODLOCK: What is your next argument?

7 (Laughter)

8 MR. DENNING: My next argument -- that's my primary
9 argument, they should have done this all along. But their
10 model is so broken, it's off by a factor of 2 to 4. Now they
11 are going to go back and try to fix the model and make it fit.
12 What they're doing, and it's pretty evident by what they did in
13 the ABChD, they're just trying to make a model that supports
14 the plaintiffs' theory.

15 JUDGE WOODLOCK: I understand that.

16 MR. DENNING: And we are giving them another shot to
17 make another model that supports the plaintiffs' theory.

18 JUDGE WOODLOCK: The problem is that I have been
19 hearing about, but I have never been able to master the
20 acronym, ABChD for the last couple of months, and it has been
21 disclosed slowly here, and I have happily not had to deal with
22 real discovery motions about it, except, "Come on, get going."
23 And now we have got it, and they made a model. They didn't
24 have the material at the time they made the model. It wasn't
25 because they didn't think it was going to fit. It was simply

1 that they did not have the material at that time. So, give
2 them a chance to do that. That is the only question I have.

3 MR. DENNING: They had a chance. They had this data.
4 They said, "We've looked through this stuff. We don't see flow
5 rates anywhere." There was a deposition of Dr. Smith, who
6 presided over the study, not a Fresenius employee, but an
7 external expert. They asked him at the deposition, "How are we
8 supposed to figure out the flow rates?" Dr. Smith said,
9 "They're in the patient charts. Here's a CD. I've given them
10 to you already."

11 JUDGE WOODLOCK: When did that happen?

12 MR. DENNING: That was September 23rd, was the
13 deposition of Dr. Smith. The documents had been given to them
14 well before the deposition.

15 JUDGE WOODLOCK: September 23rd of what year?

16 MR. DENNING: Of 2015. That's right. But they've had
17 the data. They've had all of this.

18 JUDGE WOODLOCK: So, I think I understand it, and
19 maybe the argument of timeliness will become more timely if the
20 new model shows something that they should have seen or could
21 have seen before. Judge Kirpalani has got a different schedule
22 to deal with. I am prepared to let them develop it, but that
23 would, it strikes me, be available by next Monday.

24 MR. DENNING: Thank you, your Honor.

25 JUDGE KIRPALANI: And I would say that they have the

1 same leave, but we are on a much tighter time track on the
2 Ogburn-Sisneros case.

3 MR. KETTERER: Your Honor, given the guidance, I will
4 make sure that it's conveyed, and we will produce whatever we
5 need to produce in a timely fashion. I am happy to address it
6 tomorrow, if you tell me we have got "X" time.

7 JUDGE KIRPALANI: We can talk about it tomorrow.

8 MR. DENNING: I assume Dr. Sargent is going to want to
9 look at the new model and be able to provide an opinion
10 regarding that as well.

11 JUDGE WOODLOCK: Sure. I will be very surprised if he
12 does not.

13 MR. DENNING: Thank you, your Honor.

14 JUDGE WOODLOCK: So, is this a point to break?

15 JUDGE KIRPALANI: Yes. I think that, in the interest
16 of time, we need to break right now.

17 THE CLERK: All rise.

18 (WHEREUPON, the proceedings adjourned at 4:55 p.m.)
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Dated this 21st day of October, 2015.

/s/ Brenda Hancock

Brenda Hancock, RMR, CRR
Official Court Reporter

/s/ Kelly Mortellite

Kelly Mortellite, RMR, CRR
Official Court Reporter