IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN RE:	:	MDL NO. 13-2436
TYLENOL (ACETAMINOPHEN) MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION	:	Philadelphia, Pennsylvania December 16, 2015 10:13 a.m.

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TRANSCRIPT OF CASE MANAGEMENT CONFERENCE
BEFORE THE HONORABLE LAWRENCE F. STENGEL
UNITED STATES DISTRICT JUDGE

- - -

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(The following was heard in open court at 10:13 a.m.)

THE COURT: Good morning.

ALL: Good morning, Your Honor.

THE COURT: Welcome back to the 14th floor. Please have a seat. So, this is our monthly status conference. We have several items on the agenda. I believe Laura has already taking roll for the record. Is that right, Laura?

COURTROOM DEPUTY: Yes.

THE COURT: Okay. So, I don't need to do that. I have a list of who is here and we have two participants by telephone.

This morning we want to talk about the update on the New Jersey litigation. We have motions involving two experts, and then motion in limine number 14.

There was late breaking news involving the supplemental expert disclosure. I'm watching too much CNN these days, everything is late breaking. So, we will talk about that and I want to talk about the possible dates for a trial and see where we go with that.

Okay. In terms of the New Jersey litigation, I have your reports. Is there anything that you want

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to talk about? Is there a trial date in a new case? I think your next status conference is January, right? Is that right?

MS. JONES: I don't believe that we have one scheduled.

THE COURT: You don't have one scheduled?

MR. BERMAN: No.

THE COURT: Okay. I thought it was --

MS. JONES: And we don't have a trial date. We have assumed that the next trial would be in the Taylor case which was prepared, but we don't have any trial date or any -- we have nothing.

THE COURT: Okay.

MS. JONES: To my knowledge we have nothing scheduled before the Court at this time.

THE COURT: Okay. All right. Well, that's -- okay. That's good. There are no motions, nothing pending here?

MS. JONES: Well, there have been no motions other than -- frankly we anticipate raising the same motion that we have about, as Your Honor described, about the late breaking news --

THE COURT: Right.

MS. JONES: -- on experts --

THE COURT: Right.

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MS. JONES: -- so that will be presented to the Court --

THE COURT: Okay.

MS. JONES: -- unless we can resolve it.

THE COURT: Okay. Very good. Anything to add?

MR. BERMAN: Nothing to add, Your Honor.

THE COURT: Very good. Okay. So, no news is good news. Let's talk about the two experts. I know we had four listed, but Mr. Milling had an emergency, so we're going to just defer those until a later conference.

MR. BERMAN: And we appreciate that.

THE COURT: Sure.

MR. BERMAN: Thank you, Your Honor.

THE COURT: Sure. So, we have Daubert motions involving the expert, Cheryl Blume and I believe Marvin Goldberg is on the agenda, right?

(Pause in proceedings.)

THE COURT: Okay. Good morning.

MS. JONES: Good morning. I'm here to argue Dr. Blume, is that is your --

THE COURT: I think that works. Okay. And you can argue from counsel table, that's fine, or from the podium.

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MS. JONES: I'll get up here just to make it a little easier for the court reporter. Your Honor, obviously the briefing is fairly complete with respect to Dr. Blume, and what I would like to do is just to talk about I think three discrete issues that relate to her potential testimony.

THE COURT: Okay. Sure.

MS. JONES: Frankly, some of what is included in the motion and the brief with respect to future FDA actions or adverse experience reports, some of that is covered by other motions in limine that have been already argued or separately argued --

THE COURT: Right.

MS. JONES: -- and I am happy to answer any questions about it, but I don't know that it's necessary to go through that today.

THE COURT: Okay.

MS. JONES: Dr. Blume is presented by the plaintiffs principally as a regulatory expert.

THE COURT: Right.

MS. JONES: We have challenged her testimony on several grounds, but the ones that I wish to bring principally to Your Honor's attention are those that respect medical causation or the mechanism of potential action, acetaminophen causing acute liver failure,

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number one.

Number two, certain of her proposed testimony that relates to vulnerable populations which is related in some respects to the first, but really is more subject to exclusion under the third prong of the fifth criteria for Daubert in that it is unrelated to the issues involved in the case with respect to Ms. Hayes.

The third aspect is a motion to exclude any testimony or opinions based upon the state of mind or intent of either the FDA or McNeil. Perhaps that is the easiest place to start on the end --

THE COURT: Okay.

MS. JONES: -- is Dr. Blume has included within her report certain statements that purport to reflect what the state of mind of the intent is of certain actions on the part of McNeil.

As we have cited to Your Honor --

THE COURT: Where in her --

MS. JONES: -- in the brief, those opinions and similar opinions to that have routinely been excluded including the opinions of Dr. Blume on that subject.

The basis for excluding those opinions by other courts has been essentially that it is not the proper subject of expert testimony in that while

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documents may be referred to and used, the jury is equally competent to draw their own conclusions from the documents as to the intent of the parties as to experts and, therefore, it's not a proper subject of expert testimony and not opinion testimony that should be allowed.

THE COURT: Where in her report does she go into that? Can you --

MS. JONES: You know, Your Honor, I apologize, I did not --

THE COURT: -- orient me to the report?

MS. JONES: I don't have that with me and with Your Honor's permission I will be happy to send to you exactly those comments. It is -- you could just review the testimony and, frankly, having known Dr. Blume before, and she makes statements like it's clear that the company intended to put profits over safety.

THE COURT: Right.

MS. JONES: Or it's clear that the company was intending to hide this information. It is that type of conclusory statement that she has both in the report and elsewhere, and it's those types of remarks and opinions that we're seeking to exclude.

In all candor, it's kind of woven through her report. There are different statements throughout

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there, and we have cited to Your Honor several opinions where the court has considered exactly the same issue, whether it's In Re: Baycol, In Re: Viagra, In Re: Trasylol.

You know, all of these courts, some of whom have specifically addressed Dr. Blume, others have addressed this type of testimony and generally have excluded it on the basis that it's just not the proper subject of expert testimony.

THE COURT: Right. Okay.

MS. JONES: The second point I would like to raise with Your Honor is relating to Dr. Blume's opinions on medical causation. We make it clear that Dr. Blume has not reviewed any medical records in this case, nor talked to any doctors or reviewed anything relating to specific causation and has admitted at her deposition that she does not intend to offer any testimony with respect to specific causation of the individual claimant.

That said, she has approximately 14 pages of her opinion in her report, and I think, Your Honor, to pages 24 to 36, if I'm not mistaken, that are related to the mechanism of action and the medical causation, and whether or not there is scientific evidence that acetaminophen at or below the recommended dose can

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cause acute liver failure or hepatotoxicity.

Now, we challenge this primarily on the basis of Dr. Blume's qualifications and credentials. She is not a medical doctor. She is a pharmacologist. She's done no work whatsoever with respect to acetaminophen. She has not done any either (inaudible) research or clinical trials with respect to it. She has never published anything with respect to acetaminophen.

She has done no work with respect to hepatotoxicity or hepatic injury or hepatic failure at all, and it's clear that if you look at Dr. Blume's testimony both at her deposition in New Jersey and her expert report that she really does not distinguish, nor does she have the basis to distinguish between hepatotoxicity and acute level failure.

I will remind, Your Honor, if we go back to the science day that we had, that there is a significant difference between the two. These cases involve acute liver failure. Hepatotoxicity essentially involves laboratory findings of elevated liver enzymes. That's the Jones simplified definition of it, and Dr. Blume does not distinguish between those.

It's our view that she simply lacks the appropriate qualifications to testify on the mechanism

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of potential injury or on medical causation. That's the first thing.

THE COURT: Okay.

MS. JONES: The second aspect that relates to that is that her opinions are based at least in part upon adverse experience reports which are unreliable in and of themselves.

I don't want to go back and reargue things that have been argued elsewhere. As Your Honor knows, we have sought the exclusion of the adverse experience reports based on hearsay and unreliability.

But, what is important for the purposes here is that it is generally recognized in science, in the courts, and by the FDA that adverse experience reports by their very nature are incomplete and inadequate to establish a causal relationship.

The FDA has specifically addressed this in the context of acetaminophen. In the context of acetaminophen, the FDA has specifically addressed it and pointed it out, and we've got the quotes, Your Honor, on pages 10 and 11 of the brief where the FDA points out specifically the problems with the adverse experience reports and drawing causal conclusions based upon that when dealing with acetaminophen, and that being that dosing information is unreliable.

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The medicine is taken on as needed basis, so it's often difficult to find out how much was taken or when it was taken. You can't determine the actual dose. There is no certainty particularly in the adult cases that it was an unintentional as opposed to an intentional overdose and they point out the stigma associated with reporting an intentional overdose for a variety of different reasons.

And, so the FDA has specifically said you can't rely upon these to establish causation. And when you look at Dr. Blume's opinions, Dr. Blume's opinions on causation are in large part dependent upon reviewing those specific adverse experience reports.

The second aspect of that, as kind of an aside, is that that provides an unreliable basis for her opinion and, therefore, her opinion on medical causation ought to be excluded with respect to that.

Secondly, to the extent that she relied upon those reports, surely there should be a requirement that the reports relied upon must be consistent with the circumstances or substantially similar to the circumstances involved in Ms. Hayes case instead of just the raw gamut.

THE COURT: Is that a matter of admissibility of the opinion --

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MS. JONES: I'm sorry, Your Honor.

THE COURT: Is that a matter of admissibility of the opinion or is that a matter of the weight of the opinion? I mean, is that something that you can address on cross-examination with her?

MS. JONES: Well, I think you can address it on cross-examination to some extent, but I think truly it goes to the admissibility of the opinion because I think that it doesn't meet -- and the Court's role as a gatekeeper under Daubert, I think you have to look at and examine whether or not the opinions are based upon reliable methodology.

And where the opinions are premised upon case reports that the FDA recognizes are unreliable as a matter of law, that I think that that comes within the Court's gatekeeper function and they ought to be excluded.

Again, we're talking in this case about limiting her opinions on medical causation and as a regulatory expert, I would suggest to you that any opinions that she would offer in these circumstances are cumulative under the circumstances given the other experts that are lined up to testify, who are properly qualified to testify as to the mechanism of action, if you would.

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So, I think as to those issues they go to qualifications. I understand the question, but if you allow testimony in and say it only goes to the weight and is subject to cross-examination and it's based on adverse experience reports, then we are placed in the untenable position of having to use adverse experience reports arguably to cross-examine or to cross-examine her about at least what the FDA says with respect to them being unreliable.

THE COURT: Okay.

MS. JONES: The other aspect of that that is tangential that relates to it is that Dr. Blume has offered testimony with respect to certain vulnerable populations.

Now, in order to identify a vulnerable population, if you will, you have to draw some medical conclusions, and so I think it's an extension of this. But, in addition, she focuses primarily in her report on those populations who have abused alcohol or been subject to alcohol abuse, then vulnerable to acetaminophen.

That does not fall within the third criteria of Rule 702 in terms of the relevance or fit requirement under Daubert in the sense that we are not here in this case to address a vulnerable population.

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We are here to talk about Ms. Hayes and there is no showing or evidence of which I am aware that she was either alcohol dependent or had abused alcohol or is accused of taking alcohol during the pertinent time frame. And so that evidence and those opinions relating to that should be irrelevant and excluded under any circumstances.

Your Honor, I am prepared to address any of the other --

THE COURT: Okay.

MS. JONES: -- arguments that are set forth in there. I think that I want to specifically to address with Your Honor the issue of medical causation and that reliance and the state of mind and --

THE COURT: Okay.

MS. JONES: -- while I'm happy to answer any --

THE COURT: The state of mind would include her comments about the J&J credo?

THE COURT: Well, to some extent when she starts talking about the J&J credo, she is either offering legal opinions or she's offering a question of state of mind based upon a credo that's out there.

The reality of it is, Your Honor, she is not -- a regulatory expert talking about an inhouse

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credo is certainly irrelevant. It is related to the state of mind because, frankly, that part of what she testifies to is to say they failed to follow their credo.

I mean, her testimony is framed -- she does the same as she did in New Jersey, is basically I'm going to address pharmacovigilance, and pharmacovigilance involves a number of different things, some of which relates to monitoring and reporting of adverse event reports which she has not looked at, and can't say in a timely fashion that we responded to.

She then would take that in terms of the credo and looking at it and suggest that we didn't perform proper pharmacovigilance as a result, and as a result breached the credo and the state of mind to do that. It's just not the proper subject of expert testimony.

It's just not something that her opinion is any different from that of individual jurors or yours or mine or anybody else that can look at the circumstances and draw their own conclusions in terms of what the intent was.

THE COURT: Okay. Thank you,

MS. JONES: Thank you.

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THE COURT: Good morning, Mr. Tisi.

MR. TISI: Good morning, Your Honor. Nice to be here. Chris Tisi for the plaintiff in this case. I don't want to take anything for granted, so I just wanted to say this out front.

Trial courts and appellate courts both state and federal have concluded that Dr. Blume is both qualified to render expert opinions on both pharmacovigilance and risk reduction measures using standard methodology that she uses in both her career as a executive in a pharmaceutical company, and as a consultant even until today to the pharmaceutical companies working with the FDA for things like labeling, other risk reduction measures.

In fact, the State Court in New Jersey concluded that Dr. Blume was specifically able to speak to these very issues that are being challenged here, and in ruling Judge Johnson found her to be thoughtful, measured and focused on facts, research and science. I think those were his terms.

So, the question really is whether this Court should reach a different result that the other courts that have looked at Dr. Blume have, and this Court should not.

THE COURT: I don't feel this is a challenge

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to her qualifications.

MR. TISI: And her methodology, Your Honor.

THE COURT: Right.

MR. TISI: It was methodology and fit that they challenged and in every one of those opinions they looked at the methodology she used for both pharmacovigilance and risk reduction. And just so the record is clear, there really are two halves of the same coin, and there is this iterative process that happens during the life cycle of a drug.

You assess risk, you take risk reduction measures, you assess how well you are doing with your risk reduction, and if you have to tweak it, you take further risk reduction, and that's kind of the process that goes on and she will explain that.

Ms. Jones has chosen to focus her argument on three areas, and I am going to try weave those three areas into my argument, and those would be what Ms. Jones calls "medical causation." That's not what this is at all, and I'll just be clear.

She is assessing the science around acetaminophen, hepatotoxicity for the purposes of establishing whether or not there is a risk that would require risk reduction measures, labeling, all those kinds of things. Those are the things she does in her

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normal career.

Assessing vulnerable sub-populations, and I will demonstrate that she not only has does this, but the courts have approved that she has done this before, and the intent of the company.

And the third prong -- the third I want to talk about really briefly and get that right out front because you had a question about what is intent and what is not intent.

She is not going to testify in this case and get in the minds of executives and say that they wanted -- it's very clear from the record that they wanted to kill people. I mean, that's not going to be the testimony. So, to that extent, the state of mind, frankly, is a little bit of a red herring.

What she will say and what I think is important that she does say is part of what she does and part of what is at issue in this case is what is known and what is knowable. So, to the extent of what is known and what is knowable is state of mind. I suppose that she will testify to those things.

For example, she will say as of a certain date there was enough medical information in the medical community for somebody who does risk reduction measures, what was known was X. What McNeil understood

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from the clinical trials that they conducted was Y. Based upon that evidence, they should have taken certain actions.

So, I just want it to be clear and it's a little bit of a detour from my outline here, but when we're talking about state of mind, it can be an umbrella term that frankly can be misused.

If a ruling comes out that she can't testify to state of mind we are going to have a real dispute as to whether or not state of mind includes what is known and knowable. So, she will testify or intends to testify, subject to your ruling, about what is known and what is knowable.

So, I would like to just take a moment if I could and talk about two cases that I think are illustrative of the kinds of methodology she uses to both assess risk, which Ms. Jones calls medical causation, but is really risk in the pharmacovigilance world and apply them to vulnerable sub-groups.

The first case that I would like to talk about is one that we've talked about before, and it is the Decker versus G.E. Healthcare case, and it's a case in which Dr. Blume testified and was approved by the United States Court of Appeals for the Sixth Circuit, and that's 77 F.Supp 378, and the discussion of her

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testimony is on page 393 and 394, 395 and 396.

That case was a case involving -- it was an MDL -- it grew out of an MDL involving patients who were at risk for developing a particular disease because they were kidney patients, okay, they were a vulnerable sub-group.

The question was whether or not there was enough information known and knowable to the defendant in that case to take risk reduction measures, including changing the label and educating doctors through various mechanisms, including dear doctor letters and those kinds of things that are done in prescription drugs.

In that case, the MDL carefully considered under Daubert, it had a Daubert challenge of Dr. Blume, and Dr. Blume's generic opinions with respect to pharmacovigilance and labeling were approved.

There the court allowed Dr. Blume to testify to safety signals, and I think we talked about signals in other context in other motions, so unless the Court has any discussions about that, I will move on.

But, one of the key pieces of evidence that she relied upon were four adverse event reports in patients that the company received, and it wasn't even identified as the disease in question. It was the

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person just had a reaction.

They were kidney patients. It wasn't identified as nephrogenic systemic fibrosis, and the court determined that they can rely on those case report, four of them, and here we have thousands in the published medical literature, four cases as well as clinical trials, other kinds of evidence and put together a risk reduction. Her conclusion was there was a signal and that risk reduction measures were appropriate.

So, the Court of Appeals took a look at that issue after a verdict for the plaintiff and concluded that the court was appropriate in allowing her to testify to vulnerable sub-groups. relying on adverse event reports, risk reduction measures based upon that analysis.

The court even addressed the issue that Ms. Jones pointed out which is that she is not a medical doctor, and the court said -- the District Court concluded and I am quoting here, "That because Blume was a pharmacovigilance expert irrespective of whether she was a medical doctor, she was qualified to reliably testify to the significance of adverse event reports."

In fact in that case the court excluded a medical doctor from testifying to the same thing

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because just being qualified as a medical doctor doesn't qualify you to testify to pharmacovigilance.

The second case I would like to talk about very briefly is the cases in New Jersey. In that case, Judge Johnson heard very similar challenges to Dr. Blume based upon the very same report that's before Your Honor.

He rejected both of the challenges to her methodology on both occasions, and allowed her to testify at trial and even denied a directed verdict motion after having heard her testimony on the stand both as to her reliance on all the lines of evidence, including case reports, case series, clinical trials, et cetera. So, let me turn really -- having with those two cases, let me turn to the issues in the case.

McNeil posits that Dr. Blume may not testify to medical causation and vulnerable sub-populations based on AERs and other data, in part because she is not a doctor, and in part because that evidence is allegedly unreliable.

But, as the Court remembers and we have attached this to our brief, the guidance for pharmacovigilance specifically allows experts in pharmacovigilance to rely on case reports, rely on other kinds of evidence, and I just -- quoting of it is

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"Even a single well documented case report can be viewed as a signal." So, the FDA itself has recognize that.

THE COURT: What is it that you will have her say or ask her about medical causation.

MR. TISI: She will not testify to medical causation.

THE COURT: She won't testify as to causation with this plaintiff, right?

MR. TISI: No. She will not do that, and that's really a good question, Your Honor. Let me just take a moment and step back for a minute because there really are several questions on causation that can be put in the causation bucket, and I want to make very clear what those distinctions are.

The first would be medical causation in this particular case with respect to Ms. Hayes. She will not testify to that. She's not a medical doctor, she did not perform a clinical evaluation of the plaintiff, she is not going to testify to that.

The second question is, is there enough evidence to demonstrate what we call general causation, and that is, does the totality of the evidence establish a causal link more likely than not between acetaminophen at or near therapeutic doses and acute

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liver failure, or acute liver injury in a human being. That's a medical question and, frankly, we will have people to testify to that. Her testimony will be consistent with that, but that's not where she is going.

Her testimony will be on the question of is there enough medical evidence to establish an association between acute liver failure and acute liver injury and acetaminophen to require a company to do more.

In other words, is there enough evidence out there in the medical literature for them to take risk reduction measures that would include things like, and this is no surprise because this is what she testified to in New Jersey, there are several different methods that could be used to reduce the risk.

It could be labeling changes, it could be reducing the dose, it could be through educating consumers about the risk, and you will hear some testimony about this later, some discussion about the marketing.

This drug is truly unique in the fact that it has been so heavily marketed for 30 years, and the interplay between the label and marketing. She will testify to those.

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So, yes, her testimony will dovetail with the issues of scientific general causation, but she is not a doctor and she will testify to was there enough evidence to take action.

So, I hope that answers your question --

THE COURT: It does.

MR. TISI: -- in the best way that I could answer it.

And, you know, I think what is really important here is that even the defendant in this case and their pharmacovigilance director, Dr. Kwan, testified very clearly that even doctors are not, just by virtue of having a medical degree, are not always the best people to identify what risk reduction measures are appropriate and whether there is a signal.

He said, and we attached this to our brief as Exhibit 6, he said "Even hepatologists might necessarily be the best person to look at it because someone who practices medicine is quite different than somebody who looks at pharmacovigilance." In fact, Your Honor, that is the very same point made by Judge Polster in the Gadolinium case and affirmed by the Sixth Circuit in the Decker case. Pharmacovigilance is a very distinct discipline.

So, now the question becomes well, what kind

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of evidence can they rely on? Ms. Jones and her team have repeatedly said that the FDA does not rely on case reports and case series, but that's just simply not true, nor does the law recognize that.

In your opinions that you issued last month, I think it was last month, maybe it was the month before, you recognized the Bonetti case. The Bonetti case, as you know, talked about using adverse event reports to say that there was at least evidence of a risk associated with alcohol and acetaminophen to include it on the label.

Okay. And so the law recognizes it as well as the FDA itself. The FDA apart from the guidance document that we talked about generally, you have seen evidence and we have attached it our brief where the FDA over and over and over again in the advisory committees, in the working group document, in the presentations it made to the advisory committees, consistently in the federal rules -- the registers that you have read and quoted in your opinions, have referred to different lines of evidence including case reports and case series.

So, it is simply not true, and I can't say this enough, that the FDA does not rely on them. Are they caveats about, you know, do you have to be careful

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with case reports? Of course that is true. That is true with any evidence. It's true with epidemiology studies, it's true of clinical trials, it's true of everything.

Every line of evidence has its pluses and its minuses, including case reports, and both courts and the FDA says you have to look at them all. So, I think it's important to really focus on what people like Dr. Blume, what the FDA do in the real world, and that is what they do.

So, I think the question in this case, and I am trying to get to the end here, the question of whether she applied an appropriate methodology on the sub-group population issue and the fit issue, Ms. Hayes was fasting at the time. She had lost a lot of weight, she was fasting because she was ill. She had had gastric bypass surgery and you talked about that in your opinion, and she had numerous risk factors that stem from what you have identified as glutathione depleted states.

So, one of the things that she will testify to is that people -- there are going to be people and it's recognized in the medical literature that was out at the time and before Ms. Hayes' death, that allowed people who do what she does to identify people and

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groups that might be at increased risk, that's not to say that people don't have a risk if they don't have these risk factors, but might be an increased risk depending upon who they are and what condition they are in.

That's what she did, frankly, in the Gadolinium case, okay. If you look in the medical literature and you note that it's a pattern of people who have a particular condition like kidney failure and you see a pattern of things happening over time. You've got to take risk reduction measures to address that.

That's the same thing that she did here. She looked at the medical literature for decades. You see people who are fasting, it's identified in the textbooks on hepatotoxicity, it's identified the in medical literature.

And when you see that you should in her opinion, you should take steps in order to at least inform people, if you are not eating well, if you have the flu, for example, if you are not eating well, don't take acetaminophen in high doses, and don't take it for more than several days.

Those are the kinds of things that she does in her normal career. Those are the kinds of things

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that fit the facts of this case, and those are the kinds of things that the jury should hear. And, ultimately, I think as you had indicated, the question is whether or not the jury -- it goes to the weight. So, I think that that is the issue.

So, I tried to address the general causation issue which is really how she analyzes the data for risk reduction. I have tried to identify the vulnerable sub-population issue that Ms. Jones identified, and I believe and I hope that I identified the issue of intent and how that differs depending upon what her testimony would be.

So, unless there is some question that you have, I believe I have exhausted my --

THE COURT: I think I understand your position.

MR. TISI: -- ability to put a period on the end of the sentence.

THE COURT: All right. Thank you.

MR. TISI: Thank you very much, Your Honor.

MS. JONES: May I respond very briefly, Your Honor?

THE COURT: Sure.

MS. JONES: Thank you. I would call Your Honor's attention to section three of Dr. Blume's

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report. I do have it here, unfortunately what I have is marked up.

At pages 22 to 36 of her report, that section is entitled "Acetaminophen related hepatotoxicity event."

THE COURT: Right, I have it here.

MS. JONES: That section in and of itself is what we are talking about here. That section does not and is not restricted to saying certain reports have been made and those, therefore, give rise to a suggestion that there is a risk that should be warned about.

Instead, this section is directly related to and is written as, I called it medical causation testimony, maybe it's scientific causation testimony, but that's what is being used and that is what confuses the entire issue here.

This is not pharmacovigilance. What is in this report is Dr. Blume giving scientific and medical scientifically causation opinions, period. General causation opinions, "Acetaminophen can cause acute liver failure" --

THE COURT: Right.

MS. JONES: -- and that is the issue, number one.

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Number two, just briefly to respond in the, I think it's Heinoma, H-E-I-N-O-M-A, Colorado opinion that we've cited in the brief, the court specifically considered whether or not Dr. Blume could testify about what the company knew, and that court specifically held that that is not the proper subject of expert opinion. It does fall within the state of mind notice intent, and so forth.

So, I just wanted to call it to your attention that what is known and knowable is something that's not separate and apart from the state of mind as courts have recognized that testimony. It's not a way to get around somebody saying this is what your motive is, or this was a bad motive, or the intent here.

THE COURT: It seems to me that Dr. Blume -- she clearly is not going to testify that this particular plaintiff suffered a condition because of her ingestion of acetaminophen.

But, if her area of expertise is pharmacovigilance, I mean there has to be something that gives rise to the need to exercise pharmacovigilance, which it seems to me is what she covers in section three of the report.

I understand your position, but I mean if there is no recognition that acetaminophen at certain

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doses can cause acute liver failure, then why be vigilant at all? Why take risk reduction measurements?

I mean her area of expertise, it seems to me, is risk reduction and what was required. And so she has to assume that relationship between acetaminophen at a certain dose, and liver problems.

MS. JONES: I mean I understand what Your Honor is saying. I think what I'm saying is two different things. It's one thing for her to say there have been reports of these things and, therefore, you should consider certain risks. It's another thing for her to say acetaminophen does cause acute liver failure at four grams or less.

THE COURT: Based on those reports, I find or I conclude, right.

MS. JONES: Exactly. I mean those are two --

THE COURT: Okay. I think --

MS. JONES: I mean it's a distinct, perhaps semantics, but I think it's an important distinction.

THE COURT: All right. Okay. I think I can understand that.

MS. JONES: Thank you, Your Honor.

THE COURT: Thank you. I think the next Daubert motion would be regarding Dr. Goldberg. Who wants to address that? Good morning.

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MR. TISI: Good morning, Your Honor.

THE COURT: Are you all right?

MR. TISI: I got them, I got them, thank you.

THE COURT: You didn't trip him, he didn't -- right. I understand that.

MR. TISI: I didn't throw anything --

MR. ABERNETHY: I can really do that all on my own, Your Honor, and unfortunately I regularly do.

THE COURT: Chevy Chase made a career of it.

MR. ABERNETHY: Unfortunately I don't get paid for it either. So, this is the Daubert motion on Dr. Goldberg.

THE COURT: Yes.

MR. ABERNETHY: I have two motions this morning, this one and also defendant's motion in limine 14 on marketing, and I do want to take them one at a time, if that is satisfactory to the Court --

THE COURT: Sure.

MR. ABERNETHY: -- because I think they are analytically distinct and there are non-overlapping issues, but there is one overarching issue that's common to both which is the question of whether marketing evidence, either opinions from Dr. Goldberg or otherwise is relevant, we say it's not, and so in the course of discussing the motion on Dr. Goldberg, I

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am probably going to weave some of that stuff together.

With respect to the motion specific to Dr. Goldberg, just as a preliminary matter, the scope of the motion is an important thing here, Your Honor, because what was disclosed for Dr. Goldberg in this case was actually a 120-page, single-spaced report from a different case, one of the New Jersey cases, along with a shorter, much shorter supplemental report for this case.

That 120 pages which was presented as the disclosure of his expert opinions, included a wide-range of opinions that we challenged in this Daubert motion, and in response the plaintiff disclaimed any intention to present a lot of the opinions that they had disclosed as his opinions in this case.

So, I think from a starting point you have to exclude the multiple opinions that they now say on page one of his opposition, he's not going to talk about those things and try to drill down to what is left. Doing so, obviously mindful of not only of the gatekeeper role the Court has under Daubert, but also the fact that these are not new issues.

Dr. Goldberg is regularly engaged to attack McNeil's marketing and advertising in Tylenol cases as

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well as in Motrin cases, and while it is true that there are a number of cases in which he has been permitted to testify on some of those issues, if you look at the recent rulings and opinions you will see that he is pretty consistently excluded, even in Pennsylvania State Court with much more liberal expert rules.

He was excluded entirely in Esquivel which was essentially the same opinions and types of opinions relating to Motrin. Judge DuBois excluded him here entirely in Wolf, same opinions and, of course, Judge Johnson excluded him from the Lyles case in New Jersey.

So, if we take Mr. Tisi's question from a minute ago, should you reach a different result, it's a slightly different question because the question is should you reach a different result from Judge Johnson and Judge DuBois and Judge Bernstein in Esquivel. There is a consistent pattern of exclusion and for very good reasons.

So, we turn to what he is actually going to say, what's left after the things that have been disclaimed, and I'll take these one at a time, Your Honor, and to the extent that you find any of them not necessary to get into, I'm happy to move on. But, like Mr. Tisi, I am trying not to take anything for granted

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here.

THE COURT: Thank you.

MR. ABERNETHY: I think the central opinion or one of the central opinions in the case Dr. Goldberg wants to testify that the advertising and marketing of Tylenol negated the warnings.

So, plaintiffs' say we don't concede that the warnings on the label were adequate, but even if they were it doesn't matter because your advertising negated them and made them inadequate when they otherwise would have been adequate.

Our position is Alabama law does not permit failure to warn liability on a theory that warnings on the label that are adequate on their face were somehow negated or nullified by advertising at least not on the facts of this case.

I think it is important to take the context of this case both to understand what Dr. Goldberg is saying and what the plaintiffs' evidence is relating to Denise Hayes.

So, obviously to be relevant to a theory that advertising negated the warnings, the evidence has to go to what the advertising message was that Denise Hayes got and how, if at all, it influenced her understanding of the warnings, because if it doesn't

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relate to that, it has nothing to do with anything that caused her injury.

In fact, we have some testimony in the case about what Ms. Hayes allegedly took from advertising, mostly in testimony from her sister. It's not specific to I saw this ad and it said X, but there are some general messages that Ms. Hayes testified she and her sister got from Tylenol advertising, and those are the messages that Dr. Goldberg bases his opinion on, messages that Tylenol is safe and effective, it is the safest analgesic available, most doctor recommended, most used by hospitals.

So, I think it's important here, Your Honor, to keep in mind that Dr. Goldberg doesn't claim that any of those statements were untrue. If you look at his deposition in Lyles, and he was deposed in Lyles, his main report comes from Lyles, at pages 147 and 249 to 250, which we have cited in the papers, he says "These statements in the advertising are true or at least I don't have any basis to claim otherwise."

He talks a lot in his report about something he calls "a truth effect," the idea that constant repetition of a statement gets people to believe that it's true, which is one of the opinions that I would suggest has nothing to do with anything here because

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the statements that he says we keep repeating, are statements that he says he can't say are not true.

So, there is no issue here of you kept repeating a lie over and over again to get people to believe it, he doesn't claim they are not true. He also doesn't claim, nor can he that the advertising prevented Ms. Hayes from reading or understanding the warnings on the label.

In fact, the plaintiff's testimony at page 45 of her deposition and our Exhibit C, is that she did read the label. He also doesn't claim, nor could he, that anything in these advertising messages that he's testifying about contradicted or told the consumer to disregard the warnings.

So, no one disputes the warnings, and the instructions on the label tell you how much to take and when and for what, and they tell you that if you take more than the label says you should take, liver damage may result.

So, Dr. Goldberg's opinions among the 120 pages include a statement, this is actually in his shorter report for this case at page five, that it's reasonable for the consumer to think that if you take the recommended dose and you don't get relief, you can go ahead and take more even though presumably he would

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acknowledge the label says don't do it.

THE COURT: That's what he wants to say?

MR. ABERNETHY: Right, but he doesn't say, but you said in advertising that it was safe or okay to take more than the label says and you would still be safe. We didn't say that and he doesn't claim otherwise.

He does say or wants to say that the advertising was inadequate or deceiving in some way because even though he acknowledges that it regularly said use as directed, meaning use as directed on the label, it didn't say specifically in the advertising that if you use more than directed you might have liver damage.

But, he also testified at his deposition that that isn't required in OTC advertising, but he thought it would be, his word, "beneficial" to include that information. So, that is the context of what the plaintiff said the decedent knew and what Dr. Goldberg wants to say, so what does Alabama law say about this in relation to failure to warn?

In their opposition to the motion in limine they cite a bunch of cases and some of them are cited in the Goldberg opposition as well, and they say on page 23 of their opposition to the motion in limine,

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"Courts outside Alabama have held that an adequate warning may be eroded or even nullified by over-promotion of the drug."

Now, there are a lot of cases from other states cited in both of their memos. We are more than happy if it is helpful to the Court to brief all those individual cases if you want.

They are presented without a discussion of their factual context, so that it doesn't give you any indication as to why they would be germane here, but what I want to come back to is they are not Alabama law.

Alabama has failure to warn law, and since Alabama law controls here, you have to determine what an Alabama court would allow in terms of a failure to warn theory based on what Alabama courts say.

And the Alabama decisions, including Kelly and the Squibb versus Cox case which we have cited, say "You have to prove that the warnings were inadequate and defective. You also have to prove that the plaintiff did or would have read them, and if the plaintiff doesn't read the warning, then you can't claim the warning is inadequate."

The same principle applies with even greater force, Your Honor, if as is being suggested I think in

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connection with this theory, you read the label but you choose to use the product in a way that's contrary to what the label tells you to do. So, you can argue under Alabama law well, the label wasn't adequate because it said X and it should have said Y. That's a failure to warn claim.

What Alabama law does not support and they don't have any Alabama case that holds this, if the label says don't do X, you can read it say but I thought it was safe based on the advertising I saw, so I felt I didn't have to follow what the label says. That's just not Alabama law.

It really turns failure to warn law on its head, the notion that I've given adequate warning, I tell you specifically what not to do. I tell you that you are going to have an injury, liver damage if you do it, but because I make a general statement which no one claims is untrue, that the product is safe and effective or doctor recommended, I don't have to follow it. I don't have to read it, or if I read it, I don't have to do what it says. That's not failure to warn law, sound failure to warn law and it's certainly not Alabama law.

The Kelly case, I just want to say one thing about specifically because it's kind of an unusual

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case, and the plaintiff argues that that case supports them because the case says well, failure to read the warning might not protect the defendant in a particular set of factual circumstances, and the facts of that case were the product was an air freshener, a chemical air freshener, and the allegation was that the person who used it, used it as an inhalant, like substance abuse to get high.

The court said essentially if you are marketing or selling this product for one use but you are warning for another, your warnings may not be adequate. But, nobody claims or could claim that we gave warnings about Tylenol for one use and actually were selling it or advertising it for another use.

We advertised it and sold it as analgesic, Denise Hayes used it for that purpose, and the warnings were designed for that purpose. So, I think the principle still applies. Alabama law says the consumer has to read and heed the warnings. If they are inadequate --

THE COURT: But, isn't the issue, and I think you were about to talk about that, really whether the warnings were adequate under the circumstances?

MR. ABERNETHY: Whether the warning was adequate is a distinct claim. So, let me put it in a

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concrete situation to try to respond to Your Honor's question.

The label says don't take more than four grams a day, and if you do you could get liver damage. One of the plaintiffs' theory is, actually you can get liver injury at or below four grams. Well, obviously we don't think they are going to prove that, but that is a conventional failure to warn claim that Alabama law would recognize.

If we knew you got liver failure at three grams and we said four grams, you could argue well, you should have said three grams. That goes to the adequacy of the label.

What Alabama law doesn't accept is a theory that says well, I read four grams, I read that I could get liver damage, but I took five or six or seven grams because the ads generally said it's a safe product, so I decided that I didn't have to follow the warnings. That is a different claim and that's the claim that the Goldberg opinion goes to.

If your argument is the label should have said don't take more than three grams, advertising has nothing to do with that. That goes to what the label said or didn't say.

But, he wants to present opinions to support

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a theory well, even if you took more than we told you to take, it's still "reasonable," that's his word, because you thought it was safe based on the ads, and whether he's right about what people think, it's not consistent with Alabama law.

So, there is a couple of other problems with this opinion that I will just touch on briefly, and they are the Daubert problems, qualifications. He is qualified to talk about marketing, but the issue here is does marketing or advertising have the effect of nullifying otherwise adequate warnings, and he hasn't pointed to any qualifications relevant to that. More to the point, he doesn't have any reliable data or methodology to support this.

Now, there is a long two-page footnote in the plaintiff's opposition that says "We falsely claim that he cited no surveys or market research and he actually did." Actually that is not what we said.

What we said was that he has no data to support the proposition that the marketing nullified or negated the effect of the warnings. And if you read the stuff that is cited in that long footnote, it doesn't touch on negating the warnings.

They have a survey that suggests that some consumers take Tylenol at certain times in a manner

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inconsistent with the instructions, but none of it is tied to advertising or marketing. It's not surveys or other research that shows that because of advertising people don't follow the instructions.

We all know obviously that no matter what warnings you give on a product there will be some consumers who don't read them or don't follow them. The question is what methodology or data does he have to show that it's advertising that says truthfully and generally this is a safe and effective product causes you not to follow the warnings and it's not there.

That ties to one other problem which is a lack of fit to this case. So, there is evidence that Denise Hayes and her sister saw commercials. We can debate whether or not the testimony is competent or sufficient enough, specific enough about what they heard, but what isn't here, whatever you accept from the testimony about what advertising they heard, is any competent evidence that Denise Hayes' perception or understanding or compliance with the warnings was affected by the advertising.

The plaintiff testified that she read the warning and that she knew there was a warning that Tylenol could cause liver damage on the label, and there would be adverse effects if you took it in excess

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of the recommended dose, and that Denise Hayes, in fact, read the label and there is testimony by her sister, Rebecca, that she knew if she took more than the recommended amount it might cause her harm.

What isn't anywhere in the testimony is evidence or testimony that shows that advertising caused Denise Hayes not to understand or follow the warnings she actually read on the label.

So, just a little more briefly I hope to touch on his other opinions. He wants to testify that the advertising was misleading because it didn't refer to liver damage.

We have argued that he doesn't have adequate qualifications because he doesn't have any specific work other than as an expert witness to support the notion that we violated FTC standards and that made the advertising deceptive.

But, the more fundamental problem is that this invades the province of the Court and the jury and this was one of the reasons he was excluded in Wolf. You can't come in as an expert and say here are the FTC requirements on advertising and this advertising violated them and, therefore, it was deceptive and misleading.

Experts don't come to court and say here is

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the relevant legal standard and here is the conclusion you, the jury, are supposed to reach. You prove facts and then the jury makes that determination, and the judge tells the jury what the relevant legal standard is.

If your argument is the ads are untruthful, you prove what the ads say and you prove that the facts are contrary to them. But, you don't have an expert simply tell the jury what to decide.

Beyond that, as I mentioned, this opinion is internally inconsistent because Dr. Goldberg acknowledged in his deposition, this is actually discussed on page 26 of their opposition, that OTC drug makers aren't required to list side effects in advertising, but he opines that it would be beneficial to provide it.

Well, whether it's beneficial to add that piece of information, or whether he thinks it is, isn't relevant to anything in this case. There is no Alabama law that supports the notion that omitting a reference to specific side effects in an advertising, telling the person to use the product as directed and then including the side effects on the label where they are supposed to be, allows a jury to find that the advertising is false or misleading.

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Dr. Goldberg also proposes to say that he wants to talk about the J&J credo as well. It seems to be a popular topic. He says this credo established a standard of care for our advertising and marketing, and that we violated it.

I don't want to belabor this point because I think the case law is pretty clear in the briefing, Your Honor. Internal policies do not establish standards of care that may be used to impose liability, and regardless of where the standard of care comes from, experts aren't allowed to tell the jury what the standard of care is. That's what judges do, and juries decide whether --

THE COURT: Well, that's not true, right? I mean, if you're trying a medical malpractice case and it's, you know, say against an orthopedic surgeon, you will have an orthopedic surgeon testify as to standard of care for orthopedic procedures, right?

MR. ABERNETHY: Right, but --

THE COURT: The expert provides the jury with the standard of care, the court provides the jury with the definition of duty and breach and all those things. But the standard of care goes to the jury from the expert.

MR. ABERNETHY: The standard of medical care

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goes from the medical expert to the jury but, of course, this isn't a medical malpractice case.

THE COURT: I understand that.

MR. ABERNETHY: And whether or not advertising directed to consumers is accurate, truthful and fair is not a uniquely expert issue that you would have to bring a doctor to testify on, it's a determination that a jury is perfectly competent to make.

THE COURT: Right. There isn't a negligent marketing or false advertising claim here. I mean, if the marketing information comes in, it's to set a backdrop or a context for whether these warnings were obvious and adequate, right?

MR. ABERNETHY: Right, but I would not use the word "context" or "backdrop." I would use the word that Dr. Goldberg uses, which is did the advertising negate or nullify what's otherwise an adequate warning, and I don't want to circle back to whether that's permissible because I think --

THE COURT: I understand your position on that.

MR. ABERNETHY: I think most of the rest of the issues about Dr. Goldberg are addressed in the briefing. There is one issue that I think is a little

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bit unclear because Dr. Goldberg wanted to opine that we manipulated research studies to support our marketing efforts.

Now, page one of their opposition says that he's not going to do that, but page 34 argues that he should be allowed to do it. I don't know what to make of that, whether he's going to testify to it or not,

But, I did want to comment on the context which is the notion that our marketing to doctors was improper or misleading. I don't think Dr. Goldberg is qualified on this topic because he may be an expert on consumer marketing, but he's not an expert or certainly he hasn't shown to be one on what doctors know or understand about drug risks or how they respond to drug marketing.

But, I think the bigger issue on that topic, Your Honor, is that there is no fit to the case because there is no evidence that Denise Hayes' decision to use Tylenol was driven by a doctor.

Their argument is well, you started on Tylenol 20 years or so ago with samples, but they continued to use Tylenol. Rebecca testified based on their own experience, and more to the point here there is no evidence in this record that either the doctor who gave them samples or any doctors who more recently

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recommended Tylenol heard, read or were influenced by any of the marketing practices that Dr. Goldberg wants to criticize.

So, whether or not his criticisms are valid and we obviously think they are not, they don't have any fit to the case involving Denise Hayes.

THE COURT: Thank you. Good morning, Mr. Berman.

MR. BERMAN: Good morning, Your Honor.

THE COURT: So, is it your position that the marketing efforts conducted by McNeil negated any warnings on the pill bottle? Is that where marketing fits into this case?

MR. BERMAN: Well, I think that's a difficult question to answer because marketing is such a omnibus part of the sale of Tylenol for as many years as that product has been on the market.

THE COURT: I mean, why will you put Dr. Goldberg on? What do you want him to say?

MR. BERMAN: Well, in our reply brief, Your Honor, or opposition brief we identified I guess it's maybe four generalized broad topics where we would like to present Dr. Goldberg.

One was on the impact of the defendant's marketing and advertising on consumers, that he would

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have opinions that the marketing and advertising was misleading and it's not so much that it's misleading in terms of that what was said was not necessarily true, but what was said was incomplete cultivating of perceptions by consumers as to the safety of the product, the fact that it is an OTC product, that OTC products are viewed generally as being safer and the warnings that may appear on labels, while certainly should be heeded, are warnings that may have a margin of safety or a scope of safety associated with them.

The next point in our response brief was to discuss standard of care as you raised with Mr. Abernathy, and then to sort of wrap up the generality of what marketing is.

If I could step back a moment, you know, Dr. Goldberg is being offered here in two contexts, one as a generic expert and the one as a case-specific expert. And his lengthy report that was prepared back in 2014, which was submitted both for this Court and in New Jersey, was the generic report. It provides the large scope of what marketing is all about.

Marketing is, and I don't want to be pejorative to his degree or to the science, but it's a "soft science." It's not a mathematical science or a hard science. So it's not -- and it's a psychological

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or sociological science. So it is a science. I mean it's --

THE COURT: What's the relevance of that at all in this case?

MR. BERMAN: Well, with respect to -- if I may draw upon Your Honor's opinions that you issued with respect to the motions for summary judgment, one opinion was denying the motion with respect to punitive damages. And you spoke about under Alabama law, that one of the issues is whether or not the defendant engaged in some form of reprehensible conduct.

And you were discussing that in the context the admissibility of wealth information and whether that would be permitted as part of the trial evidence. And the question here, as I look at it, is that you have a company that was able to spend over the years billions of dollars on marketing, or a billion dollars, whatever the amount was, for marketing and advertising, and by comparison, the amount spent for R&D and pharmacovigilance was very, very small.

THE COURT: But you don't need Goldberg to say that, right?

MR. BERMAN: Well, I need Goldberg I think to help the context to how marketing by a company, and he knows -- he understands the sophistication of the

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marketing, how the use of a budget, the development of the budget, the goals and the objectives of the marketing are part of the corporate being.

And laypeople will not understand that I don't -- I don't believe. I think it does require somebody who has studied big budget marketing by big corporate America.

I know that Mr. Abernathy discussed his exclusion in some of the Motrin cases. I think he -- Tylenol is more akin to tobacco cases where he has been admitted on multiple occasions, because tobacco spent the kinds of money on marketing and advertising that was spent here for Tylenol.

I would ask Your Honor to take judicial notice as to how often you may have seen Tylenol commercials over the years in comparison to Motrin commercials. Motrin is not marketed the way Tylenol is, and I think there's a relevance to how Tylenol had been marketed over the years.

I think there's also a relevance here on the -- on the failure to warn. And, again, drawing on Your Honor's opinion on the failure to warn, on page 14, you spoke about the FTC rules and how the proposed rule recognized that the FTC regulated commercial advertising and urged cautionary language and that,

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"Pros also noted that acetaminophen advertising may indicate that it is a safer product when, in fact, it may not be under the circumstances."

In your same opinion on page 34, you quoted from Ashley McEvoy's deposition about how advertising is one way that McNeil uses to education consumers about products.

It is true that advertising is a method to educate consumers, and the question is how that education process affects consumer reactions in the face of warnings on a product that becomes ubiquitous and common for their usage, and I think there's a relevance of the advertising and the marketing that was done in terms of how it impacted Ms. Hayes.

THE COURT: Okay. So what is that relevance? I mean what -- what does the -- what does this vast marketing campaign have to do with any of the issues in this case? I mean the issue in this case is did she take -- how much did she take? Did it cause her death, and were warnings on the packaging that came with the Tylenol, was that adequate, right? I mean this is a failure to warn products case.

So it's not -- I mean I think the whole marketing discussion is interesting, but I need -- I need to know from your perspective where it fits into

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this case.

MR. BERMAN: Well, she did testify that -- well, not she, her sister had testified --

THE COURT: Right, Rebecca.

MR. BERMAN: -- about the fact that they had seen hundreds, if not more, advertising and marketing over the years, and that cultivated in their minds a belief that this was a safe product, and it's advertising as a safe product.

And while Dr. Goldberg doesn't opine that he thought there was inaccuracies in the advertising, I think the question is how did you -- how did the company get to be able to make the advertisements that it did, and in terms of number one, doctor recommended, his opinion goes into how doctors were cultivated to recommend Tylenol.

How did it become hospital number one recommended, the same thing. His opinion speaks about the direct marketing to healthcare providers in order for the company to then be able to say, at least insofar as FTC rules might be concerned, that we are the number one recommended.

But the question is how did they get to become the number one recommended? And if they got that through marketing and advertising that may not

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have revealed to the healthcare providers all of the risks associated with Tylenol, particularly at the recommended four gram level, whether that bears on their responsibility to reprehensibility under the Alabama law.

THE COURT: Isn't your case really that this product, among maybe all over-the-counter products in recent history, has been marketed as the safest pain reliever you can take, right?

MR. BERMAN: Yes.

THE COURT: I mean that's the impression that this long-term, persistent marketing campaign has created in our population?

MR. BERMAN: Yes.

THE COURT: Right?

MR. BERMAN: Yes.

THE COURT: Okay. So against that backdrop, you have this woman who had pain, was taking Tylenol for that pain, and then against that backdrop, the warnings that were provided to her were somehow inadequate, right?

MR. BERMAN: Yes.

THE COURT: I mean that --

MR. BERMAN: That --

THE COURT: You're not talking about the

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marketing after the fact somehow truncating those warnings? You're saying that against this whole backdrop, those warnings were less than adequate, right?

MR. BERMAN: Yes.

THE COURT: Okay. So where does Goldberg fit in to that?

MR. BERMAN: Well, again, I'm trying to explain that the marketing is part and parcel of the understanding by consumers of warnings. Now, on the one hand, we have Dr. Blume and other experts who are criticizing the warnings themselves --

THE COURT: Yes.

MR. BERMAN: -- their adequacy, the degree to which they warn about the severity of the dangers, the risk of liver failure or liver damage, the nuances of the damage that occurs to the liver.

Nowhere in the advertising, however, is there any mention of liver damage or liver risks or risks if you exceed the recommended dose. So he brings into the analysis how consumers respond psychologically to advertising that repeatedly talks about safety, trustworthy, number one recommended, without any disclosure of risks.

THE COURT: So he'll talk about the

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pervasive, effective, advertising campaign?

MR. BERMAN: Yes.

THE COURT: Right?

MR. BERMAN: Yes.

THE COURT: And then you'll have other experts to talk about the adequacy of the warnings?

MR. BERMAN: Well, again, Dr. Blume, Dr. Plunkett, there are other experts --

THE COURT: Right.

MR. BERMAN: -- who will be discussing more specifically the science aspect of why recommended doses of four grams were or were not adequately warned and the issues of dose titration, one -- take one, if it does not work, take two, things like that.

Well, he reviewed information about that. I mean he reviewed hundreds of thousands of pages. He's not a pure warnings expert. He's an expert on how marketing impacts warning, impacts psychological -- psychologically consumers.

THE COURT: Right.

MR. BERMAN: Again, as I was saying, it's sort of a soft science. It's not -- it's not that you go and take a blood test and the result is you have a high ALT level and it's very objective and that means you're in liver failure.

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It's a science of psychology and sociology that, unless you have the degree in it, you're not going to be able to appreciate as I think as a layperson what impacts market-driven -- marketing driven budgets generate on a population.

In the context of this case, Ms. Hayes test -- the Hayes family testified they saw these commercials. I think they relaxed their vigilance a bit as a result of seeing it in terms of the belief that taking the medication at the recommended dose or even an addition -- one additional pill --

THE COURT: You have no evidence that the Hayes's relaxed their vigilance because of all the advertising they saw, right?

MR. BERMAN: Well --

THE COURT: There's no evidence in this case of that. There's evidence that they were -- that they were label readers --

MR. BERMAN: Yes.

THE COURT: -- that they were careful people.

MR. BERMAN: Yes.

THE COURT: That they weren't popping handfuls of pills every time they had a headache --

MR. BERMAN: Yes.

THE COURT: -- you know, that they were

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careful --

MR. BERMAN: That's true.

THE COURT: -- people.

MR. BERMAN: Yes.

THE COURT: So that's the extent of that.

MR. BERMAN: But they had a comfort level reinforced by the advertisements that they saw that it was a safe product to take. I don't know whether that's a relaxing of --

THE COURT: Well, you're not getting that from them. You're getting -- you're laying that interpretation over what you know about their habits and their behaviors.

MR. BERMAN: Yes.

THE COURT: Right.

MR. BERMAN: Yes, Your Honor.

THE COURT: Okay. I think I understand your position.

MR. BERMAN: Mr. Tisi wanted to make a couple comments if he may. You know, I did want to show you a few PowerPoints that were produced in the McEvoy deposition. It was to emphasize the point --

(Pause in proceedings.)

MR. BERMAN: -- how the budgeting worked and how much was spent.

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(Pause in proceedings.)

THE COURT: This looks dramatic. What is it?

MR. BERMAN: Well, you know, this -- I provided you with two PowerPoints, Your Honor. This came from McEvoy and it may have been buried in some of the papers that you have seen.

And if we can look at McEvoy 21 first, which is the liver ad there in 2008 and 2009, liver ad relates to ads that McNeil did run where they were discussing liver issues publicly on their TV ads, and the red bars are all other ads.

And the point that we were trying to make through this is to show and demonstrate, again, how pervasive the ads were that did not discuss the liver issue.

And getting back to the reprehensibility standard under the Alabama law, when a company has the ability to run ads and they run 37,000 ads in 2009 and 98.6 of those ads don't mention the word "liver" at all, but 1.4 percent do and those are buried in a very short window of time, which Dr. Goldberg does explain, that has an impact. That's the psychological impact on consumers in cultivating their beliefs and how they then respond to warnings, particularly with an OTC product.

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Exhibit 20 is a similar depiction. It's for different years, 2004, '5, and '6, and the graphing is almost as dramatic, not quite. The blue here, Pavelski and Bass, those were liver-specific ads as well that were aired.

But, again, we're looking 2004, 2005, 2006, I don't have a graphic for '7, but 2008 and 2009, consistently extreme amounts of the numbers of ads and, therefore, the budget, all went towards non-liver associated issues.

THE COURT: And that relevant to your punitive claim, right?

MR. BERMAN: Well, it's relevant to the punitive claim I think under the Alabama law, under the standard that you did articulate, the reprehensibility of the company and what they did do and what they could have done with budgeting for 37,000 ads, those ads -- and an ability to talk about liver issues reflected by the fact that 500 times they did do that.

They certainly could have had a different balance. And I understand we're not talking about prescription drugs and fair balance and the issue of disclosing all the warnings. I mean I understand all that.

But the ability, the opportunity, the budget

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to be able to talk about liver was available to them, and, you know, I think these graphics help to show that.

(Pause in proceedings.)

THE COURT: Okay, thank you, Mr. Berman.

MR. BERMAN: All right, I think --

(Pause in proceedings.)

MR. TISI: Do you mind, Your Honor? I think I can answer one of your questions --

THE COURT: Go ahead.

MR. TISI: -- with reference to -- and I appreciate you giving me the opportunity. I don't like to play whack-a-mole here where people are jumping up and down.

But, you asked a very important question, where does marketing fit in this case and how does it fit in? We talked with respect to Dr. Blume before about the role of risk reduction, okay, and one of the things I said is what you do is you see if you determine there's a risk. Then you take risk reduction measures, and then you seek how you're doing, okay.

Mr. Abernathy spent a lot of time talking about the fact well, we amended the label to add a liver -- a liver warning or a liver statement, okay. The next question is how are you doing, okay? And when

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you have this ubiquitous advertising, okay, and you don't tell people you've changed the label, okay, you need to take a look at the new label, okay, and your label -- and your warn -- your advertising is the same as it's always been, okay, people don't know.

And what Ms. -- what is the testimony in this case and what the jury will hear is that had they -- that they saw this ubiquitous advertising, and had they known, had there been information in the advertising that there was something different, that the information had evolved over time, you know, there's a new warning, and we've all seen advertises -- advertisements on this, that they are -- that they are to really focus on something new about the drug, that they would never have purchased it.

I mean there's testimony -- Ms. Terry testified that she purchased this in part because of the advertising, and had she known there was any risk of liver, she never would have done it in the first place.

So when we talk about -- what I find interesting about Mr. Abernathy's argument is he focuses solely on the label. With the FDA advisory committee, with the working group, and what everybody -- and our experts will say is that because this is A,

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an over-the-counter drug, B, it was so heavily promoted and advertised for so long, that you need to do more because the goal isn't just to slap a label and so oh, I'm done with it, I just slapped a label on. The goal is to make sure that the warning works and it gets through to the consumer.

What you're going to see and when the testimony comes out of this case is changing the word -- adding the word "severe" didn't change behavior at all. It was just a palliative measure to just say okay, we're doing something, when the fact of the matter is year after year after year, acute liver failure, acute liver failure remained and was the number one cause -- acetaminophen was the number one cause of it.

So, advertising totally fits into the risk mitigation aspect of this case. And I wanted to address that because I think your question was where does marketing fit into this case, and it fits in as part of the risk reduction measure.

When you realize your label isn't doing enough you got to do more, you got to educate consumers, you got to make sure that people know that there's -- that there's a risk. I wanted to make sure that you -- that that question was actually answered

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directly. And I appreciate you --

THE COURT: Thank you.

MR. TISI: -- letting me -- letting me jump up.

THE COURT: Thank you.

(Pause in proceedings.)

THE COURT: Mr. Abernathy?

MR. ABERNETHY: Your Honor, before I address motion in limine number 14, could I briefly respond to a couple of points --

THE COURT: Sure.

MR. ABERNETHY: -- these gentlemen made? I would suggest to Your Honor that the advertising has nothing to do with the punitive damage claim because conduct justifies punitive damages if it's wrongful and reprehensible.

Truthful advertising is not wrongful or reprehensible. We have a right to advertise our product truthfully, and they have not pointed to any Alabama law that would suggest that truthful advertising to sell a product is reprehensible conduct that would allow punitive damages.

Mr. Berman made some reference to Tylenol, tobacco, and motrin. I think clearly, Your Honor cannot take judicial notice of the relative frequency

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of Motrin and Tylenol advertising, but --

THE COURT: I have no idea.

MR. ABERNETHY: -- I don't --

THE COURT: I have no idea.

MR. ABERNETHY: -- I don't think it makes any difference actually. And in terms of Tylenol versus Motrin, I would urge Your Honor to read what was briefed and decided in Wolf because if you read what Judge DuBois said, I think you'll see that the parallel in what Dr. Goldberg wanted to say but was excluded from saying there and what he wants to say here are really kind of striking.

I can't comment much on these two PowerPoints. I couldn't find them as I was looking through the exhibits to the opposition, and I'm not actually familiar with them, although I'm familiar with the general topic of the Pavelski and Bass ads because they are discussed in Dr. Goldberg's report, although I didn't see these tables. I'm told these were prepared by plaintiff's counsel in some case to illustrate a point I guess they wanted to make.

What the Pavelski and Bass chart shows, Your Honor, is that in addition to running ads that were positive about Tylenol and tried to sell Tylenol and advertised its merits, which a seller has a right to

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do, it also shows a substantial amount of ads, the Pavelski and Bass ads, which are discussed in the Goldberg report, which actually are kind of unusual I would suggest in one's general experience. They were ads that specifically were designed to tell consumers -- make a point of telling consumers don't use Tylenol contrary to the instructions. So, in fact, we didn't just say in the ads use as directed and then the directions tell you what to do. We had ads that drove home that point.

Just to briefly touch on the last point Mr. Tisi made, I did focus on the label because the focus of the failure to warn claim under Alabama law is the label. Plaintiffs have conceded there's no cause of action for negligent marketing, and there's no Alabama law that they've cited or that I know of that imposes a legal duty under state law to institute a generalized risk reduction program that includes advertising.

The requirement of Alabama law is that you give an adequate warning, not the best warning, but an adequate warning of the risks associated with a product on the label, and that's what we did.

If Your Honor please, I would briefly talk about motion in limine --

THE COURT: Yes, I --

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MR. ABERNETHY: -- number 14.

THE COURT: Yes, I --

MR. ABERNETHY: But more brief --

THE COURT: I think I understand your position.

MR. ABERNETHY: Much more briefly, because obviously we've talked about the relevance issue of marketing, and that's an overarching issue for both motions.

The only other thing I want to drive home here is this point. We don't think the marketing evidence is relevant, but if Your Honor decides to admit marketing evidence, I would suggest that it should be, must be focused on evidence relating to the message or information or statements that the decedent got from advertising or marketing.

This global idea that we have to present context by presenting testimony equivalent to 120 pages about the whole history of Tylenol marketing just doesn't have any fit or relevance to this case.

If marketing is relevant at all, the question is did marketing or advertising affect Denise Hayes and cause her to use the product when she otherwise wouldn't because she was given information that wasn't accurate?

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There is for -- and I'll just pull one example out. It's one of many. There's a whole lot of discussion in Dr. Goldberg's report about McNeil allegedly improperly influencing third party organizations to recommend Tylenol. Obviously we don't agree with its premise, but what does that have to do with this case? There's no evidence that Denise Hayes took Tylenol because some third party organization said it was good or safe.

There was a whole big discussion in Dr. Goldberg's supplemental report about how we marketing Tylenol cool verse caplets. Nobody has ever suggested that Denise Hayes used Tylenol cool verse caplets or saw the advertising for it, so what does that have to do with this case?

Dr. Goldberg's purpose here, and a lot of the other evidence on marketing, is a generalized attack to say McNeil is a bad company that sells its products in a bad way and spends too much money doing it. That doesn't have anything to do with these claims. And I just want to touch on two issues in that respect.

There is an argument that the marketing is relevant to the design defect claim because it goes to consumer expectations, but if you read the briefing, there is no explanation here. There is no explanation

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about what it is about the marketing, how they affected consumer expectations, in a way that would make the product unreasonably dangerous. Certainly, the product was advertised as the safest analgesic.

By the way, I actually went and looked at the testimony. It's on page 249 of Dr. Goldberg's deposition. He was asked "Is that true, that statement, it's the safest pain reliever, analgesic?" He said "I don't know whether it is or isn't." Well, the point is there's no evidence here that the statements are untrue, but there's no explanation as to how consumer expectations were altered in some legally relevant way that would make marketing relevant to the design defect claim.

The last thing that I want to talk about, and I do want to talk about this because I think it's important. I think it's important to plaintiffs for obvious reasons and important to us I guess for, in a sense, the same reason.

They have this colorful graphic in their opposition to the motion in limine that shows that at a certain point in time, they say we spent $200 million on marketing and advertising and $2 million on scientific research, and they want to present that to the jury obviously. It's irrelevant. It's also

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unfairly prejudicial because it really goes directly to the purpose that I mentioned a minute ago. It's designed to tell the jury this is a bad company. They spend -- all they care about is selling. They spend all this money on selling. They don't spend near as much money on science.

Go back to the question of why those numbers are relevant. They aren't. So there's nothing inherently improper about spending $200 million marketing a product if you're marketing it with truthful information, and there's nothing inherently improper or inadequate about spending $2 million on scientific research.

These numbers could, in theory, be relevant, Your Honor, if there was some claim being made you didn't find out what you should have found out about the liver risk associated with Tylenol because you didn't spend enough money on research, and if you had done this study and spent five million of $10 million dollars on it, you would have found out fact X and you should have done that.

I don't think that's the theory of this case. The theory of the case is you knew there was a bigger liver risk than you were saying and you should have said that, but that really has nothing to do with how

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much money is spent on scientific research.

And, in fact, the amount of money we spent on research or marketing wouldn't be relevant even to that unless they were presenting some specific evidence to say you should have done this research and spent this money, and we said well, we couldn't, we didn't have the money or we didn't have the resources.

None of that is in this case and that's not what this evidence is for. Whatever patina of relevance the briefing attempts to put on it, I think anybody who looks at that graphic with common sense knows that it's simply designed to try to imply to the jury that we're a bad company that only cares about sales because we spent money trying to market our product. That's not a relevant or proper purpose of the evidence, and it shouldn't be permitted.

THE COURT: Thank you. Anything else you want to argue on marketing, Mr. Berman?

(Pause in proceedings.)

MR. BERMAN: Well, I do think that one comment I would like to make, Your Honor, is that there's marketing evidence to be submitted factually as well as through an expert.

And I don't know if plaintiffs understand precisely what the motion in limine number 14 seeks to

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exclude. Is it seeking to exclude all marketing evidence or is it seeking to exclude Dr. Goldberg, which sounded to me to be what was re-argued as part of MIL14, or is it some hybrid of that?

I do think that as we develop the exhibit list and the deposition designations, we can narrow down exactly what will be available to use in the marketing case.

But there clearly is a marketing case and it's been I think recognized by Your Honor on multiple times in permitting the marketing discovery to go forward.

So, I certainly don't think that the -- the request that's being made is that there should be no marketing evidence at all in the case. There has to be marketing evidence is my opinion.

I had a few more slides I did want to just show you and, again, it relates to the cultivation of the consumers. And these slides actually come from defendant's PowerPoints used at the Jackson trial.

And the reason I want to present them, Your Honor, is that these are slides showing how they're going to try the case. They are going to emphasize number one recommended, all the societies that support the use of Tylenol, how important it is a product in

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healthcare, how ubiquitous it is in consumer locations, and how long it's been on the market, that it is a 60-year product.

(Pause in proceedings.)

MR. BERMAN: I think I have it bent over and, again, as I said, these are slides that were produced by defendants as PowerPoints during the Jackson case and this is, again, to demonstrate how they're going to try the case.

And we cannot have our hands tied behind our back not being able to anticipate the marketing case that will be tried -- marketing case defense that they may raise. We need to be able to have our evidence to support the marketing.

So we've got all of the societies that they claim support the use of APAP, acetaminophen, in clinical use, how 28 billion doses are sold each year, and how Tylenol products have been on the market for 60 years, since 1955.

This is all part of the impressions that consumers are going to have as to the safety of the use of Tylenol, and we need to have an ability not only scientifically, but also to show how they came to be able to make these representations.

Just to touch on a couple other points. In

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denying the motion for preemption of the fraud claims, you said that in your opinion that fraud and fraudulent concealment, causes of action survive under Alabama law.

So, plaintiffs are not simply relying on a punitive damages component to the admissibility of this evidence, but there is a fraud or fraudulent concealment or a misrepresentation component that this -- that the marketing evidence will support and establish.

It will establish that because, again, it's what was not conveyed to the consumer by the -- by the company, yet what was known by the company in terms of the margin of safety and the risks.

(Pause in proceedings.)

MR. BERMAN: There was also testimony by the Hayes family that they would not have purchased Tylenol if the ad had included risk information. The ads didn't include that, so I think that's a relevant part of the marketing case, Your Honor.

THE COURT: So you're not contending that this is fraudulent, right? It just doesn't -- it doesn't go into --

MR. BERMAN: It doesn't go into --

THE COURT: -- potential risk?

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MR. BERMAN: It's misleading. It's not a complete picture. It's not the four corners of the circumstances or the situation. It may be that APAP is important and it has been endorsed by multiple different medical societies, but being able to say that and that it's number one recommended doesn't provide information to the consumer about the risks associated with taking it at the recommended dose or even above the recommended dose. So it's just -- it's not a full picture, Your Honor. It's sort of like weaving through and navigating the rules I guess.

You've got OTC, FTC regulations that are different than the FDA rules government prescription drugs, but consumers don't understand that. They don't -- they don't know that there are different rules and that's why they're not being -- the risks and the -- are not being disclosed in the advertising that they receive.

THE COURT: I think I understand your point. Okay.

(Pause in proceedings.)

THE COURT: All right. The defendant submitted last week a motion to supplement expert disclosures, and the plaintiff has responded to that as of yesterday. Would you like to address that?

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MS. JONES: Yes, I would, Your Honor.

THE COURT: Okay.

MS. JONES: Your Honor, I'll try and do this briefly, but I think it's clear that rather than just filing supplemental expert reports, we filed this because we thought it was so very important and because it, in fact, I recognize certainly, is somewhat extraordinary in that this issue has come up after the close of discovery and while motions are pending, and I certainly need to acknowledge that, and at the same time, think that it's important for the Court to understand how extraordinarily important this issue is.

In fact, I would suggest to Your Honor that it is so important that it is necessary to avoid ultimately a potential miscarriage of justice and deprivation of due process.

Certainly, without relief, it would be clear that this Court would try the first bellwether case in this MDL without all of the information and, in fact, with information that might not only be missing, but be erroneous and somewhat misrepresent -- represent a misrepresentation to both the Court and the jury.

THE COURT: This goes to some of the foundation for Dr. Lee's findings, right?

MR. BERMAN: Well, it does, but it goes to

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more than that.

THE COURT: Okay.

MR. BERMAN: If I could just brief that. I mean it goes to what we refer to as the ALFSG, the Acute Liver Failure Study Group.

THE COURT: Yes.

MR. BERMAN: That group was formed back in the late 1990s to discuss -- to study acute liver failure. The plaintiffs have pointed out it actually involves over 20 different groups and their NHI grants that were granted to study this in the registry.

But, what's particularly important, and it relates to the narrow issue before the Court, is that in 2005, that group published a paper that we have referred to as the Larson paper. The Larson paper includes 19 reports of alleged acute liver failure at or about the therapeutic dose, four grams or less.

Now, as this Court will remember, that those, in fact, are the claims before this Court here that at or about a therapeutic dose it caused acute liver failure.

And to put it into perspective, Your Honor, it has been known since the 1970s that an acute overdose -- a significant overdose of acetaminophen could lead to acute liver failure, and that's the

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importance of these alleged low dose cases then to both this litigation and the difference from what has been known as a science is crucial.

When the paper was published in 2005, the Larson paper, at that time -- well, let me back up. The reason that that's so important is that it relates -- Dr. Lee is one of the authors on the paper, but so is Dr. Davern, who is one of the plaintiff's experts in this case. Dr. Kaplowitz (ph) another one of the plaintiff's experts in this case relies upon it.

The FDA, in its working group paper and some of the other papers that we've talked about, specifically cites and relies upon it. However, when that article was published in 2005, McNeil began seeking and trying to seek the underlying data so it could understand the basis for the suggestion that there were acute liver failures occurring at or about the therapeutic does. The ALFSG --

THE COURT: Yes.

MR. BERMAN: I have a hard time getting those letters together, refused to produce those, that underlying data, and have never --

THE COURT: And you went --

MR. BERMAN: -- produced that letter.

THE COURT: You went to court in Texas and

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got them.

MR. BERMAN: I beg your pardon?

THE COURT: You went to court in Texas and got the documents?

MR. BERMAN: We went to court and got them, and just to put it into perspective, we ultimately went to court and we got them this year, and the documents that I want to talk about and that are crucial here we got in September of this year just as the Jackson case was beginning.

I have here -- there's a little bit of a suggestion in the plaintiffs' papers that would suggest that we're sandbagging them and we've had secret negotiations and we've done all this stuff.

I, in fact, have here the correspondence that I would be happy to give to the Court where all of these documents have been furnished to plaintiffs' counsel in this litigation as it was received.

So, you could read through the correspondence. The only reason that I furnish it is simply to show that or demonstrate that this data has not been withheld at all from plaintiffs' counsel.

And exact -- and although the plaintiff suggests that well, all of this was related to the New Jersey litigation, I simply point out to Your Honor I

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think it's unnecessary, but Your Honor clearly recognizes those have been parallel proceedings with exactly the same counsel there. And, in fact, it was because the plaintiffs initially noticed the deposition of Dr. Lee and Dr. Higby (ph) and we said we're entitled to the documents before he testifies, and Judge Higby said go get them, which started the process there.

I would suggest, Your Honor, under the ways that this litigation has proceeded, it was unnecessary to both burden this Court and have two separate proceedings to get exactly the same document which have the same impact.

In short, Your Honor, once we got this information, we have looked at it, and for purposes of our discussion today, and for purposes of this motion and what we intend to do, we are limiting this discussion to those 19 reported cases of acute liver failure that occurred at or about a therapeutic dose.

We've analyzed those cases in the last basically 60 days and, frankly, Your Honor, the results were shocking.

THE COURT: Yes.

MR. BERMAN: So that Your Honor understands the breadth of what we're talking about, although we

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have now gotten thousands of pages of documents, including 275 case report forms and so forth, in order that we don't delay anything in this litigation, our plan is, and what we have given to our experts are those 19 case report forms that we have identified or received from the University of Texas Southwest, along with the protocols, I think they call operations manuals for the studies.

My understanding is that the totality of those documents that we are concerned with for this very case that relates only to the issue of whether or not those reports demonstrate acute liver failure at or about the therapeutic dose, is to limit our discussion and our disclosures to those issues only and not to get into the far broader picture, which if the Court wanted us to do certainly would delay things because it's a much broader issue. We're not trying to get to that point. We're trying to be very reasonable and efficient in how this is produced.

THE COURT: So which expert's -- I take it you'll be supplementing expert reports if given leave?

MR. BERMAN: We have three expert reports.

THE COURT: All right.

MR. BERMAN: That would leave two hepatologists, Dr. Flamm and Dr. Brown, and a

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toxicologist, Dr. Brent, who approached things from a different standpoint.

THE COURT: And --

MR. BERMAN: And we would like to --

THE COURT: And -- go ahead.

MR. BERMAN: What we intend to do, Your Honor, is to supplement those. We will produce those witnesses for supplemental deposition on that subject matter on a timely basis.

We understand -- we do not know -- we have obtained permission from the University of Texas Southwest under a confidentiality agreement to furnish that information to the experts. I do not know whether the plaintiffs have obtained a similar agreement to furnish that with theirs or not. We do know that they have been in contact with the University of Texas Southwest over time.

I don't know what they have done. I'm assuming that they have not, but we have no objection to them or even to us assisting them with UTSW getting the same permission to show those confidential documents.

There are only, Your Honor, a limited number of confidential documents. The vast majority of what was produced is not confidential, to their experts for

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them to supplement those reports to the extent that they think necessary and to take an additional deposition if need be.

We are prepared to do that to move forward. We are not asking this Court -- Your Honor said at the beginning you anticipated a trial date in late April or May, as we discussed beforehand. We have no intention of trying to delay that. We're ready to move forward with that and we'll do so with -- we'll move forward with alacrity on this.

And what I would suggest to Your Honor is that it may very well be that the subject matter requires some additional Daubert briefing on just that or, alternatively, a 104 hearing on the admissibil -- under any circumstances, I think we're looking at a 104 hearing on the admissibility of any testimony related to the Larson paper and the ALSFG or any documents that rely upon it.

I think that is, frankly, a little bit premature at this stage until we get -- what we propose to do is to supplement those expert reports.

THE COURT: How long do you anticipate that would take?

MR. BERMAN: We said in the papers we'll do it within 30 days. I mean I would think by mid-January

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we could easily have it done. And if we can do it before then, we will. And it's unfortunate as the holidays as -- we lose about ten days in here, but other than that, we are -- the experts currently have that date and we are prepared to move forward quickly.

THE COURT: Okay. All right, thank you. Mr. Tisi?

MR. TISI: Judge, I really struggled. I'm going to be honest with you. I've done a lot of MDLs over the course of the past 15 years, 20 years, a lot of pharmaceutical litigation, and I can assure you that I am choosing my words really carefully on this and thought long and hard about it.

Ms. Jones talks about due process and she mentioned due process. What they propose to do, and make no mistake about it, what they propose to do, frankly, is to -- will result in the destruction of this MDL.

And let me be really clear. We had anticipated Daubert arguments mid-next Jan -- mid-month. The Court tried to move them up to this month, and as I understand it from speaking -- from speaking to my colleagues, part of the reasons why you did that was so that you can give us guidance long before the trial so that we know what the parameters of the trial

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are going to be.

Instead, we're now in a position where we our first bellwether trial that has already been pushed back twice because of the massive briefing that has gone on in this case. And McNeil now wants to -- wants to go behind published peer reviewed literature that has been out there for the entire time.

This isn't some new article that came out last month. This was -- this has been out in peer review since 2005, and at no point did they come to this Court and say we need a subpoena and get it quickly. At no point -- we have monthly status conferences, and at no point, at any time, did they say you know something, Your Honor, we are arguing motions every single month for the past six months, we're scheduled for Daubert, and you know something, we have this issue looming on the horizon. We want to let you know about it and we want to let the plaintiffs know about it.

Instead, because your court clerk sent an email the other day saying that they were moving up Daubert hearings, we get an immediate response back from Butler Snow say oh, by the way, there are new developments we're going to brief and we got this brief. I would suggest to you that because that email

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was sent, that's the only reason we even got this motion at this early time.

Let me just state some facts so that you understand exactly why I am as bothered by this proposal as I am. Number one, McNeil never issued a subpoena out of this court where they could have gotten the documents resolved a lot sooner.

Number two, the documents, by the terms reached by the attorney general of Texas and Butler Snow, approved only for usable in the Boca matters, which are the New Jersey State Court and specifically not this MDL. That's what we thought the whole time.

Number three, throughout 2015, McNeil, and behind our back, negotiated a unilateral one-sided agreement of unequal access for this data. Let me be really clear.

We attached two agreements, Exhibit 1 and Exhibit 2 to our motion that we filed yesterday. Exhibit 1, which was -- which was entered on May 28th, 2015, allows McNeil and its consultants access to this data, signed by a Butler Snow attorney, David Cohen, not the expert, David Cohen.

Several days later, they reached a separate agreement for plaintiffs. That separate agreement says that neither our consultants nor our experts can have

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access to this data, and you know who signed that agreement, the same Butler-Snow attorney. We were never given copies of that, to my knowledge.

The next thing that happens is I get -- we are in middle of trial and we wouldn't have known this for -- but for fortuitous questions by Judge Johnson.

We are in the middle of trial and Dr. Temple, one of their witnesses, get up and said exactly what Ms. Jones said in his videotaped deposition. We were trying to get some of this data at the time and Dr. Lee didn't turn it over, and Judge Johnson said wait a second, counsel. This data they requested and you didn't turn over, and Mr. Hughes stood up and said, the quote was the, "We have massive and massive amounts of data, Judge. We did get it, and we have our epidemiologist going through the data." Okay, that was in the middle of trial. We couldn't do anything about that.

We then come back to this Court in October and November, and each time the attorneys for McNeil file status conference reports with this Court telling this Court what's purportedly going on in New Jersey. At no time during any of those hearings prior to any of those reports did they ever say you know something, we got these documents.

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On November 23rd, they renegotiated their unilateral agreement to allow their experts to now look at the data, not just their consultants, but now their experts.

And while Ms. Jones gets up here and says oh, we're willing to facilitate this, they left in place the very agreement that Mr. Cohen negotiated back in May that doesn't allow us or our experts to take a look at it. We weren't concerned about it, because those applied in New Jersey that didn't apply in this case, and we were actually preparing for this case.

If you read those agreements, they specifically exclude the only -- the only cases in which they could be used were New Jersey State Courts, not the MDL.

So then we get the email from Allison Jones the other day bearing the -- bearing the news of well, we got this new information on these published peer reviewed articles and we looked into it. You know, Judge, they try to minimize this and say well, you know, there are only 19 cases that they're concerned about. Well, I don't want to be presumptuous here, but when we looked at the documents there are 130,000 pages of documents in the -- in the production of doc -- of production, almost 20,000.

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Now, the fact that they have had these documents for six months and chose to actually look at 19 and decide how they wanted to focus their inquiry, well, you know, I think that's great of them, but we may want to look at them.

If we are going to be fair about this, we may want to go and look at the entire 130, and we may look at it and say you know, it's not so shocking at all what your experts say.

So now we're in a position here where we were supposed to be arguing and, in fact, did argue Daubert today. We still don't have access to all of the documents. We still don't have an agreement --

THE COURT: Do those documents affect the motions that we've argued today?

MR. TISI: In part. They argued -- they argued that Dr. Blume cannot rely on case reports to support her opinions. One of the articles that Dr. Blume testified to was the Larson article, the efforts of the Acute Liver Failure Study Group.

I mean I've got to tell you, Judge, you know, there is only one other time that I can recall in my MDL experience where a company went behind the data of a published peer reviewed article and they did so in the very early part of the case.

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This is not what they're doing here, okay? This is a case in which the Acute Liver Failure Study Group has -- is -- and I don't want to diminish this at all. They've been around for 20 years.

They are the source of information of acute liver failure in this country that doctors, the FDA, the NIH, the DEA, and agencies of the government rely on for this disease, not only for acetaminophen. I mean that's been the focus of this. Illicit drugs, over-the-counter drugs, viral causes of hepatitis.

That's why the NIH, the FDA support this and have supported this for close to 20 years. That's why over 20 medical centers actually participate in this process.

What they are proposing to do, frankly, is to create a -- they don't want to rely on the published, peer reviewed literature of this organization. They want to now start having a trial within a trial, you know, about whether or not this case is truly I assume acute liver failure, this one isn't. This case has this problem, this one doesn't.

This kind of sideshow will create, in our view an I will predict this as the day is long, if they are permitted to do this at this point in this litigation, this trial and the ability to conduct this

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trial in an orderly fashion, which is, after all, why you continued this case several times, will be put on hold a third time, and this bellwether process will be off the rails.

I want to show you just to give you a sense of it, yesterday, they sent a letter to my colleague, David Towell (ph) at Seiger-Wise (ph), if I can approach, Your Honor, here -- in New Jersey, proposing a schedule for the analysis of this data.

Now, mind you, plaintiffs don't even have an agreement with UT Southwestern that our consultants or experts can even look at this stuff, and their experts have been looking at this stuff, epidemiologists.

I mean if you look at the -- look at the quote that I put in the brief, when the Court specifically asked Mr. Hughes whether he had the data on September 25th -- this is what, three, four months ago now -- Mr. Hughes said, "So the data has started coming in, Your Honor, but it doesn't come in with one page line listing the data. It's a massive, massive amount of data we are trying to pull apart and trying to process."

THE COURT: That was the colloquy that the New Jersey judge had?

MR. TISI: Correct. Okay. So to come in

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here and say well, you know, we have these 19 case report forms and maybe a protocol when their lawyer got up in New Jersey three months ago and said we're pulling apart the data and it's a massive, massive amount of stuff, that's exactly what we would have to be doing and we don't even have access to the data yet and we can't give it to our consultants, we can't give it to our experts and, frankly, as a cost matter, we don't have epidemiologists and toxicologists and we can't go back to McNeil and go into their labs and say here's a document dump of data. Help us figure this out before we give it to our experts.

So, now we're in a position a week and a half before Christmas holidays and we get this motion. We don't have anything in place. Now, I just gave you a copy of the letter that they sent to my colleague in the New Jersey litigation where this is -- where this is properly, and they propose a schedule.

Let's look at what they say. If you go to the proposed schedule, they say, "Defendant shall be permitted to serve supplemental expert reports on or before January 30. Plaintiff, you get 30 days," okay. That's not 30 days to look at 19 case report forms. That's 30 days to look at -- to look at 130,000 pages of documents.

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Then, they propose that the experts get -- they get 60 days beyond that to conduct follow up depositions. That takes us, Judge, until April 30th, May 1st.

But, now if you look at the end paragraph -- of paragraph four, it says, "The parties may engage in third party discovery related to the above reference materials, including, but not limited to, depositions and written discovery to establish authenticity and admissibility."

So, they anticipate not only expert depositions, but now follow up depositions, maybe Dr. Lee, maybe other people, in connection with this. This takes us -- this takes us up until the eve of trial.

Now, again, I'm just trying to put this on a calendar to try to be practical here. You, the Court wanted to have Daubert hearings this month so that you could give us guidance on what we're doing for a trial in May. The schedule that they propose brings us to May 1st, and we haven't even filed motions yet.

So, when Ms. Jones stands up here and says well, you know, there may be -- there may be additional motions, of course there are going to be additional motions. They're going to come marching in here saying no, Judge, this proves our point. This peer reviewed

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public literature can't be relied on.

And then we're going to have a big sideshow and a big debate about whether or not you can look at the peer reviewed literature or you can look at their experts, paid experts who looked at the original data and perhaps come to a different conclusion than the people who actually looked at this in the process.

Judge, I have to tell you, we have to rely on the process of this Court and we have to rely on the process of science. We have a process of peer review for a reason, okay.

This organization, this is not some fly-by-the-night scientist who just happened to pick up the issue and say let me -- let me conduct a -- let me see if I look at a couple of cases. This is the Acute Liver Failure Study Group, FDA/NIH-funded.

You would have to think that 20 -- the 20 different medical centers, including Yale, University of Chicago, UCLA, different groups that have been part of this, I think University of Pennsylvania was part of it at one point, somehow collaborated to create cases that perhaps weren't acute liver failure or didn't have acetaminophen or had the wrong dose or whatever theory the defendant is going to come in and try to undermine these published, peer reviewed studies, and we're going

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to be here for the next year on this issue.

This is not a small matter. And it's not a small matter involving 19 cases because to be fair to us, if you want to talk about due process, to be fair to us, we're going to want to say, you know, maybe the issue isn't as narrow as those 19 cases. Maybe we want to do a little bit more. And, you know, maybe we want to get behind some of your peer reviewed published literature, Dr. Temple, who published for McNeil. Maybe we'll start looking at that cases that you -- that were here, and maybe we'll -- we'll be here forever.

I can be a passionate guy and I can be a very -- you know, and I know I sometimes can say something is really important, and to me everything is important, but we're going to be -- we need to get this MDL moving.

If this was as important as Ms. Jones suggested, they could have come in here a long time ago when we were setting bellwether trials and said, you know, there is this one outstanding issue. It's taking too long in New Jersey. Can you intervene, Judge?

THE COURT: All right.

MR. TISI: Can you assist us?

THE COURT: So they didn't, all right, and

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we have no trial date yet for the bellwether case. It had been my hope that we would set a trial date. We have an issue that's come up. I mean what is the prejudice?

MR. TISI: Enormous prejudice, Your Honor. I mean I've already -- we have argued -- we have briefed and argued multiple motions dealing with issues related to science, medicine, admissibility of issues.

THE COURT: I'm aware. I've been here.

MR. TISI: Yeah. I mean you've issued almost 200 pages of orders, a lot dealing with these -- a lot of these issues.

THE COURT: Right.

MR. TISI: And now we're going to unravel the yarn? Why? Because they -- because they can't rely -- they cannot rely on the published peer reviewed literature.

And if they don't like the Larson article and somehow we don't do that, then they're going to pick another article and we're going to do this all over again.

Sometimes, Judge, you know -- I had a judge say to me at one point said, you know, sometimes enough is enough. You know, Mr. Tisi, I was asking to do one more thing, kind of like what they're doing now. The

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judge said -- it was in context of asking depositions and he said, judge -- you know, Mr. Tisi, no. He said depositions are to lawyers what peanuts are to elephants. I'm going to suggest to you that you give out some peanuts here, this elephant is going to be eating for the next couple years.

This is -- this is -- there's enormous prejudice. I want, frankly, this case to go to trial. I want to get the bellwether process done. We have 200 plus cases in this MDL. I want to figure out a way to get to the end of this process, and we can't do it and you can't have an orderly administration of justice if we have this kind -- this kind of sandbagging, and make no mistake, we don't even have access to these materials. We can't start.

THE COURT: What about these letters that go back to December 18th of last year --

MR. TISI: The letters?

THE COURT: -- where Mr. Buchanan of Seiger Wise was provided documents from the University of Texas Southwest Medical --

MR. TISI: Yes.

THE COURT: -- Center?

MR. TISI: Let me address that. You will notice that in none of those -- none of those are what

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would be agreements that Mr. Cohen entered into that does not allow our experts to even look at this. Okay. Yes, we have been receiving materials, but, frankly, they are not part of --

THE COURT: So you've been getting the documents that we're talking about, right?

MR. TISI: But we haven't -- honestly, Judge, we haven't looked at them. The reason why we haven't looked at them is A, they're produced in New Jersey, they have not been the subject of any experts up until now; B, we've been proceeding in this MDL on the basis of what we have.

THE COURT: Well, my understanding is these cases are roughly similar to each other, right?

MR. TISI: What cases?

THE COURT: The New Jersey cases and our MDL cases.

MR. TISI: Some of them are, some of them aren't, Judge. Some of them are pediatric cases, some of them are -- some of them aren't. But the point is that the documents --

THE COURT: All right.

MR. TISI: I'm going to read -- the disclosure says --

THE COURT: I see it.

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MR. TISI: I can't even use them. So the fact that we're getting them, big deal, so we're getting them. I can't use them.

THE COURT: Well, have you looked into using them?

MR. TISI: We called -- we -- Mr. Gainer, he can certainly -- he can certainly provide -- he called during -- you know recently he called down there and he said yeah, he said the assistant state's attorney or whatever, however they use it down there, yeah, he says, you know, the agreements don't allow you to use it. And they are -- they're -- apparently, they're negotiating -- McNeil is now negotiating to have that evidence imported into this MDL. But none of this was done. I mean look, if any --

THE COURT: Right. It's -- so I get it. I get it, okay.

MR. TISI: Yes.

THE COURT: It's a little late in the game. It may result in some delay, right? And, you know, you can roll your eyes and exhale all you want --

MR. TISI: I'm sorry.

THE COURT: -- and I appreciate your advice on how I should manage the case, frankly, but, you know, we have an issue that's come up. The defendants

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have represented that it's important information.

If it comes up time and again, then we'll have to at some point cut it off. But I mean it looks to me like it's come up in the New Jersey case within the last couple of months. I would have preferred, I suppose, that it had been flagged in October or November. It wasn't.

You know, we have a trial date that's -- we were hoping to try the case in the late spring. We may be able to do that, we may not be able to do that. I simply don't know how long all this is going to take.

MR. TISI: I would ask --

THE COURT: But --

MR. TISI: I would ask this. We have an issue, we have a couple of issues, Judge. Even if we were to get the final documents, which we don't have, apparently, there was some documents that were delivered to McNeil this past week. We don't have them. I have called our -- I have called our experts, and they are simply not available. I mean this is -- this is the --

THE COURT: I --

MR. TISI: -- holiday season.

THE COURT: I get it.

MR. TISI: Even if everything, the stars, the

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moon, and the sun, were aligned, I can't even get the stuff to them realistically until some time in mid-January.

THE COURT: Right.

MR. TISI: And it's -- it's not just -- it's 130,000 pages. I mean I may have to name a new expert because it may not be enough for me, frankly. These experts may not have the time or the inclination to sift through 130,000 pages.

THE COURT: Okay. Thank you.

MR. TISI: No, I'm sorry. Mr. Gainer, who has been negotiating with the state's attorney, has a comment, if you don't mind, Your Honor.

MR. GAINER: Your Honor, I appreciate it and I will be brief.

THE COURT: Sure.

MR. GAINER: And let me start out by saying this, Your Honor. I'm not an MDL lawyer. I am a lawyer of 35 years, and you have been very conscientious and you have gone out of your way time and time again to see that the motions of the defense are accommodated, that they are fully briefed, that they are heard, oral arguments. You have gone above and beyond.

This article is a decade old, a decade old.

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If it was a searing, burning issue, they have had ten years to pursue through Texas a subpoena to get these records and to analyze them all that they wish. But in this case, Your Honor, and we have worked so diligently and so hard, discovery is closed. Discovery has to close at some point.

This is one article, hardly the entirety of what Dr. Kaplowitz and Dr. Davern rely on. They have testified and Dr. Kaplowitz, frankly, is not even a member of the Acute Liver Failure Study Group, neither is his center.

But he's 30 years and he runs a liver research center at University of Southern California that is funded by the NIH, and his opinions are informed by his own work for 30-plus years. He is published on drug-induced liver failure. It's in its third edition.

He has seen patients who have had acute liver failure at four grams or less. He's read the literature where hospitals have administered patients four grams or less and have had acute liver failure.

This is not the whole sum and substance. In fact, it's a very small part of Dr. Kaplowitz. If the defense is allowed to take any tangential point that Dr. Kaplowitz or Dr. Davern may have relied upon,

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discovery will never end. If they want to pursue this, then fine. But should it derail our bellwether process that you have worked so hard to get us to, I think not.

I think that in fairness, they can pursue this through New Jersey as they have initiated it. The proposal that they have made that Mr. Tisi went over with you was not even discussed with any of us. It was just sent by a letter. It will be discussed further and I suspect will have to be modified and expanded.

They will be able to get to the bottom of this particular issue if they are so inclined to do so. But I do not think, Your Honor, and I would respectfully ask that this supplementation of expert reports in this case, the Hayes case, that has been thoroughly litigated be denied. Thank you.

THE COURT: All right, thank you, Mr. Gainer. Ms. Jones?

MS. JONES: I don't want to belabor the issue, Your Honor. I have acknowledged that this is a rare circumstance and I understand that, and we wouldn't be here if it were not so crucial.

I apologize, I handed the Court our correspondence. There's one piece I neglected to handle. But I think what I want the Court to know are two things.

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To our knowledge, and I represent to the Court to my knowledge, the plaintiffs have been produced every document that we have. The 19 documents that we are talking about case reports are all found in this specific notebook.

This doesn't include the protocols, but this is what we're talking about. We specifically narrowed this not to be unfair, but because we were trying to move this case along.

Secondly, we've shown Your Honor the correspondence so that Your Honor can appreciate we weren't operating in secrecy. Plaintiffs were given notice and invited to attend every hearing that was held in Texas.

I don't know whether there's been any correspondence or whether there has been any discussion beyond what Mr. Gainer said, but I'm confident that if our experts are given permission under the circumstances of a confidentiality argument by UTSW, theirs will be as well.

This is not -- this is not a usual situation, Your Honor, where somebody is simply trying to go behind the documents. This is a crucial article, crucial to the litigation and virtually the only one published that purports to be a study.

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The documents underlying this study have never been reviewed or seen by the FDA, the NIH, or anybody else as best we can tell, ever. And if we're not able to challenge these and not able to introduce this evidence, it does, in fact or will, in fact, result in a miscarriage of justice to say that the Court has not even considered it.

So we will do our very best to accommodate the Court, to move it along as quickly as we possibly can. But we think that justice in this case is more important than simply rushing through something. Thank you, Your Honor.

THE COURT: Thank you. I appreciate the suggestion that this proceed in New Jersey and that we keep the bellwether on track. You know, and just thinking through this perhaps, one of the reasons to have the bellwether case is so that you have one case that's fully litigated, presented to a jury, and then you have the benefit of the result of that case to inform the disposition of the remaining cases, sometimes through settlement, sometimes through further trial.

I'm concerned that if we move to trial on this case with what appears to be a significant discovery issue proceeding in New Jersey but not here,

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that any result that we would have in this bellwether case could be less convincing and less important to the parties if there's a feeling that there was an important component, at least from a defense perspective, that was left out.

So, while I appreciate the suggestion that we let this proceed in New Jersey and cut it off here, I I think I don't want to go that route. Do we have a proposed order from you in terms of a schedule, or is the only schedule this one that was proposed --

MS. JONES: I don't think --

THE COURT: -- to the --

MS. JONES: -- we do, Your Honor. We can certainly submit one later today or in the morning, but I don't think we submitted one setting a particular schedule.

My recollection is that we said in the motion that we would file the supplemental expert reports within 30 days of an order, which would take us to mid-January. But we'll do whatever Your Honor asks, or if Your Honor wants to give us some dates, we'll supply an order promptly.

THE COURT: All right. Let me take a look at this. Can I hang on to these copies --

MS. JONES: Yes, Your Honor.

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THE COURT: -- of these e-mails and these letters? And, Mr. Tisi, you handed up a consent order. Can I hang on to this?

MR. TISI: Absolutely, Your Honor.

THE COURT: Okay. All right. Let me give this some thought. And I can say I'm inclined to grant the motion, but I want to look at the papers a little more carefully. I looked at them in preparation for today but really only went through them once. And then we'll get a decision out to you probably by sometime tomorrow.

If I allow the defendant to supplement the expert reports, you know, obviously the plaintiff would have the opportunity to, if you need to, obtain a confidentiality order from the university and then share those documents with your experts. So we'll need -- we'll need to talk further about the time frame for that, but okay.

Let's end it there. I had hoped to talk about a trial date, but I think I want to see what's involved with --

MR. TISI: Judge, may I ask the Court for clarification?

THE COURT: Yes.

MR. TISI: I'm obviously reacting on my feet

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a little bit on this, but I do anticipate some difficulty with either Dr. Davern or Dr. Kaplowitz. It may be that they're capable of looking at this data.

It may be that the time constraints do not permit that to be the case. And I suspect for one or both of them, that may be the case. I may have to be in a position where I have to go out and find somebody different, and I don't want there to be a -- just because it was framed in terms of supplementing expert reports, I don't want there to be a suggestion that either of our two experts --

THE COURT: Right.

MR. TISI: -- or any others are -- you know, that were confined --

THE COURT: Well, it's the defendant's request to supplement their own expert reports --

MR. TISI: Yeah, and it may be --

THE COURT: -- and your response is your response. I mean if your experts can fold this in to their analysis, fine. If you have to get somebody else, then we'll have to talk about that.

MR. TISI: And, you know, there may be some other -- we're trying to dig out some information to try to address this and provide the Court with written papers before today, but technically it's before they

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are due, so we may need to supplement and provide you with additional information we get from UT Southwestern.

I mean it may be, frankly, that we take somebody's deposition at UT Southwestern depending upon -- one of the things I would like to see is if McNeil can make a representation even at this point as to what they think their experts will testify about, it will give us something we can focus on.

Right now, this is such a nebulous, out-of-the-blue suggestion, I don't really know the issues. I mean I think I can guess if I'm, you know, being a lawyer for 30 years, but I would like to have some sense so I can focus my experts as to what they think they're doing. It sounds like they've had people looking at this stuff for three months. Can we have a proffer?

THE COURT: Wait, you're asking for that today?

MR. TISI: Yes, today, so I can -- so I can call them and say can you do this? Can you address these questions?

THE COURT: You know, I want to look at the motions.

(Pause in proceedings.)

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MS. MAZUR: Did you -- did you get everything from Texas? Is that complete production --

MS. A. JONES: Yes.

MS. MAZUR: Okay. And they have it all?

MS. C. JONES: And they have it all.

MS. A. JONES: And they have it all. Okay.

MR. TISI: I do not have it all. I did not get the most recent production. We did not get it.

MS. C. JONES: Well, it's been sent to you.

MR. TISI: To my knowledge --

THE COURT: When was -- when was it sent?

MS. MAZUR: Do you know the date?

MS. C. JONES: It was sent in December.

MR. BERMAN: Two days ago.

MR. TISI: Oh, two days ago.

THE COURT: Okay.

MR. TISI: So it may be sitting --

THE COURT: All right. So --

MR. TISI: -- on my desk.

THE COURT: Right, it may be there.

MR. BERMAN: It's not part of this issue.

THE COURT: And I guess -- I guess the issue is your getting the consent from University of Texas Southwest --

MR. TISI: I guess we got to go --

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THE COURT: -- to share the information with your experts?

MR. TISI: Yes, because what I understand -- maybe Mr. Gainer could -- I understand that going back to the -- to the Texas judge in some fashion to finalize an agreement. I haven't been part of that process.

I had to do in the past week a lot of digging to figure out what the issues were and where they stood, but I don't know whether we're going to get consent. We may or may not. I mean I don't -- what I don't really understand, frankly, Your Honor, is how we came to the point where we had two different agreements that -- I don't understand why -- it may be that they had a particular problem with us looking at the data. I don't know.

THE COURT: I have no idea.

MR. TISI: I don't either.

THE COURT: Let me look at this motion. As I said, we'll get a decision on this to you shortly, and then maybe you want to meet and confer and --

MR. TISI: Sure.

THE COURT: -- figure out what --

MR. WEINKOWITZ: Your Honor, can I just --

THE COURT: -- you have to do.

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MR. WEINKOWITZ: -- point out that the protective order that you do have in place in this litigation has a provision that extends to third parties. I don't know if that would in any way facilitate our ability to get the materials to our experts, but --

THE COURT: Well, it certainly might help with the discussions with the University of Texas Southwest --

MR. WEINKOWITZ: I just wanted to point --

THE COURT: -- I would think.

MR. WEINKOWITZ: -- that out.

THE COURT: Thank you. Okay. We'll take a look at this, as I said. We'll get a decision to you and then I'll ask you to get together and work on some schedule. I will probably want you to supplement your expert reports in fairly short order, okay. I would think by the end of January we should be able to do that.

MR. BERMAN: We will do so, Your Honor.

THE COURT: Okay. Okay. All right, good. Thank you very much.

(Proceedings adjourned, 12:58 p.m.)

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CERTIFICATION

I, Donna Anders, do hereby certify that the foregoing is a true and correct transcript from the electronic sound recordings of the proceedings in the above-captioned matter.

12/15/15
Date

Donna Anders
Donna Anders

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