UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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IN RE: PROPULSID PRODUCT LIABILITY LITIGATION

MDL 1355
Section "L"
New Orleans, Louisiana
Friday, March 7, 2003
9:00 a.m.

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TRANSCRIPT OF MOTION PROCEEDINGS
HEARD BEFORE THE HONORABLE ELDON E. FALLON
UNITED STATES DISTRICT JUDGE

APPEARANCES:

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entitled to them. Look at what we had to go to them, and we have no remedy other than sanctions. And we were denied by the court and we ask that you reconsider the fact of giving sanctions for producing these materials in such a late date.

THE COURT: My experience with the litigants in this case has actually been a good experience. The parties, while they have represented their clients effectively and strongly, have also understood their responsibility to the bar and to the court. They have given some seven or eight million documents. It hasn't been easy. A lot of material takes a long time to first figure out what you need; secondly, to articulate with specificity the material and then to find it. It hasn't been my experience throughout the litigation that the people have been stonewalling unduly and it has been improper conduct to justify sanctions. I didn't see it in this instance. I considered it again, but I will not grant sanctions in this case. I appreciate your bringing it to my attention.

MR. AMEDEE: I reurge to the court that since the relevance of the alternative design is a first impression situation, that the court is inclined to grant the defendant's motion that you do make final judgment so we can --

THE COURT: I will get with you all regardless of what I deal with. I will get with you, and we will talk about it and see what we do with whatever it is. I don't know exactly how I am coming down.

Stuppy. So they now want to eliminate Stuppy. Same thing was said of Shell and Eckberg. They shouldn't do it because you need a gastroenterologist and now you have got a gastroenterologist. Now they want to eliminate him. So I think if, in fact, if the design claim goes then obviously Dr. Stuppy's testimony would be certain to go.

THE COURT: Okay. Anything else you want to say?

PLAINTIFF STEERING COMMITTEE MEMBER: The motion to reconsider or on behalf of the plaintiffs in these cases for the minute entry of January 2nd.

THE COURT: Right.

PLAINTIFF STEERING COMMITTEE MEMBER: And I just wanted to ask the court for reconsideration of the fact that the sanctions such as we were talking about in chambers. There was quite some delay in getting these documents. If we would have had them prior to our European depositions, I believe they could have been a lot more fruitful. And I believe as Mr. Davis pointed out earlier and it was pointed out by a memorandum that you have that there was a contemplated area of discoverable electronic data that was focused that I presume was to have been turned over to plaintiffs early on. It was never give to us for any defendant, any of the deponents. We have now since received about a thousand pages of documents about a week and a half, two weeks ago that at one point we didn't execute. Now we are told that, well, you are not

So I asked him, I said, well, do you realize a normal QT might be 50 -- you are talking about anywhere from 5 to 50 something per 50 millisecond increase. We have got a drug out there that's taken off the market because of a five to six millisecond and Janssen was aware of this.

THE COURT: What's the other drug?

MR. AMEDEE: Seldane. And the others are obviously have to do with plaintiff's design defect.

THE COURT: Right. I will reserve ruling on that.

MR. CAMPION: Our last motion, Judge, it is now clear in view of the arguments that we have had today we will soon have decided in the context basis that this motion is not appropriate for resolution at this time. And I think the resolution of this motion will be tied in with the way in which you rule on the design defect issue. Thank you, Judge.

THE COURT: Okay. Dr. Stuppy.

MR. AMEDEE: I don't know if I can let it go at that, because I want to make it clear to the court that Dr. Stuppy is a board-certified gastroenterologist and certainly with 20 years of clinical experience is qualified to address the efficacy of Propulsid and various other things, especially about this drug's risks and benefits.

In their opposition to my response about Dr. Schwartz as an additional pharmacologist it was a5rgued that well, we don't, plaintiffs don't need Schwartz because they have got

litigate Seldane or Posicor or any other number of drugs. And I think there may be as many as 100 drugs that have known impact on the QT. And of course I realize that the argument is that this is something we knew about and should have known about it and might have known about it and is out there in the literature; that, in fact, some of our drugs, for example, kisplanole I believe was one of our drugs also was associated with a QT. And certainly in certain circumstances and our view is that this is clearly an easily definable action 403 if nothing else -- we don't think this is relevant number one. And number two there is a Cisapride case and we are not litigating all of these others.

THE COURT: They say it is all relevant because they say that other drugs is an alternative design and therefore should be admitted.

MR. AMEDEE: That's one of the arguments. And obviously that's depending upon your Honors' re-decision with regard to Seldane, it is a question of notice. Seldane was a drug that was taken off the market because it changed that five to six millisecond increase in the QTC was significant enough for this drug to be removed from the market. So it shows notice to the defendant, and it also shows what, how many milliseconds is significant. The defense expert was questioned about that, and as I understand it, and said, well, he never would give me an answer. So he finally said 10 to 15 percent.

documents which I think relate specifically it would be hard for the court to make a decision on today. But the purpose of this motion was to bring it to your attention.

THE COURT: Check with Mr. Amedee over these things, because if you are going to adverse reports, that's admitted. But you have to be a little bit more specific. It has to be incidents that are similar, incidents that are the same, incidents that are close enough to get past that and then get past the 403 confusion and misleading and all the rest of the things.

MR. AMEDEE: I have to tell you about five documents that he just mentioned. I don't even intend to use any of them.

THE COURT: That's what I'm saying. I think you can cut them down more.

MR. AMEDEE: Are they on the list I gave you today?

MR. IRWIN: Yes, they are. The last motion -- I feel like Karnak -- I have the last motion, next-to-last motion, next-to-last. This one pertains to other drugs, Judge.

THE COURT: Which is that?

MR. IRWIN: We are going to litigate Cisapride.

THE COURT: Number eight. I've got it.

MR. IRWIN: The issue here is whether we are going to litigate Cisapride and the association between Cisapride and prolong QT and cardiac interval. Or if we are going to

Doctor letter. The FDA has seen some increase in adverse event reporting and some other things.

The next document -- I only have two more -- is dated February 17, 1998. It was Janssen, it looks like a transmittal letter from the FDA, and it is a one-page document and all it does is merely transmit a manufacturer's control number. And the report of a death. It only has a report code number. It gives no information to determine whether it is substantially similar or not.

And then there is an e-mail and this is the last one that I have chosen for example purposes. There is an e-mail dated March 24, 2000, which would be a serious 407 question. Apparently it is from people within Janssen, and apparently it deals with some questions from J.P. Morgan, and it talks about questions from the analyst. And we describe the sudden adverse event, further breakout of adverse events. What exactly happened? Everybody has -- and patient has stopped taking the drug. And there is a discussion about according to our standard procedures we follow up on every case. And that sort of thing. I don't know how that's adverse event report or how that's notice.

So those -- and I did have one more, Judge. There is another exhibit which is a risk question and answer module. It was a number of pates of questions and answers. There is marginalia all over the page. So to me these were examples of

can recite them to you as follows: The ones that are now subject to this motion are number 21 -- this is in our reply brief. Number 50, number 58, number 62, number 70, 71, 77, 108, 146 and 144.

THE COURT: That's plaintiffs' exhibits?

MR. IRWIN: Yes, sir. Now, I have just sampled a few of these exhibits. We know that the standard here is substantially similar and liability and notice and all that. But an example of these documents is one, and I don't have the number here. I should have written it down, but one of them is a letter from Dr. Alexander Walker dated October 2, 1994 to Dr. Yee at Janssen. And it is unquestionably hearsay from Dr. Walker, and I guess the issue is whether it is substantially similar. And so I would draw the court's attention to that. I know it is going to be hard for the court to rule on each one of these.

I will use by way of another example another document is the FDA record of contact dated February 21, 1996. This is the Janssen internal document, and it records Janssen's meeting, phone call I think, with the FDA. And I didn't understand what it had to do with anything in our case. And I will just read one sentence: This is why the court has to look at these things. It says: Melody McNeil called with the question from Dr. Fred. Dr. Fred from the FDA wants to know why physicians are not following the directives from the Dear

like the jury to see.

MR. IRWIN: We will cross that bridge when we get there. The motion addresses these pediatric use in these two.

THE COURT: So as I understand it, they are agreeing to at least on those issues withdraw it.

MR. AMEDEE: Withdraw any reference to pediatric.

THE COURT: Withdraw any and all reference to pediatric. Am I correct that motion is subject to another motion, those minutes?

MR. IRWIN: Yes, those minutes are subject to another motion, yes, they are.

MR. AMEDEE: And we would be happy if the court allows the FDA document in to redact any portion or any document that we have no pediatric mentioned nor any evidence will be presented by testimony.

MR. IRWIN: Your Honor, the next is the motion regarding adverse events, reports and other lawsuits. On that motion may I proceed, your Honor?

THE COURT: Yes.

MR. IRWIN: We have agreed that there will be no reference to other lawsuits. Is that correct, Mr. Amedee?

MR. AMEDEE: That's correct.

MR. IRWIN: So the debate we have is with respect to the admissibility of other adverse event reports, and I think that the number of documents at issue has been reduced, and I

MR. AMEDEE: To that motion, but if the court would look at these two particular documents, we want only to use portions that deal with relevant portions of theses claims Diez brought, not with pediatric. And I thought we tried to do that.

THE COURT: Take a look at it and let e know.

MR. IRWIN: I have got, I think I have two documents here, one is Exhibit 49, which is a list of Propulsid facilities reports, and there is one table here that talks about pediatric. There is a whole table that describes pediatric cases. Now, I don't know if this table is otherwise admissible on other grounds or excludable on the other hand, but here this is just a list of pediatric cases.

And then the other document, and Mr. Amedee may have marked these along, but this other one is a Janssen record on FDA contact days: April 1, 1998. It shows meeting, mentions a March 27, 1998, meeting. It is a favorite document of my friend on the other side because it talks about the FDA opinion since plaintiffs have deferred defecation issues, and we have see that before. But on the back page it makes a reference to there was a brief discussion on pediatric use.

THE COURT: People were discussing Dr Ward's survey on pediatric use.

MR. AMEDEE: Your Honor, we will be amenable to take that out. There is a paragraph here that we certainly would

in a particular case. And that's really the issue here. Generally when you withdraw something from the market, that's the same concept that society profits from having things off the market until the case is finished, it may stay out on the market too long. And the question really for limited access is in this category. I will still look it over. I understand it. I will reserve ruling on it. Do we have any others?

MR. IRWIN: Three more, Judge, three briefly, I think.

THE COURT: Okay.

MR. IRWIN: Pediatrics.

THE COURT: How is that in this particular case? It seems to me that pediatrics may or may not be for another case. But in this case how does it fit?

MR. AMEDEE: It is not. I have two documents that I have offered to redact any or all partial that have to do with pediatrics. But there are certain letters regarding Janssen's warnings.

THE COURT: But they may have been issued in the pediatric area?

MR. IRWIN: No, they cover all areas, Judge. In that regard I ask the court on previous motion to CPMP, to please look at the documents, because you had mentioned that you thought it was a pediatric document. It really isn't but that's on another matter. If you would do so.

THE COURT: That's Exhibit 8?

reference by somebody that this product is no longer on the market. And it's still available from a doctor. If a doctor wanted to go and put a patient on this, he could apply to Janssen. In other words, it hasn't been recalled. It hasn't ben withdrawn. It is a limited access program.

THE COURT: Their question is whether or not a limited access is similar to withdrawal from the market.

MR. IRWIN: We think the question is whether it is remedial, and we think it clearly is remedial.

THE COURT: Right, right. Well --

MR. IRWIN: Withdrawal is generally remedial. And I also think, Judge, the law is very, very clear here. Stall v. Navarsuch. And the reason this has been the subject matter of a number of depositions is because the witnesses were asked about it and that's why they answered the questions.

THE COURT: Also, with the deposition, the fact that something is not admissible generally doesn't stop it from at least being inquired about or talked about at the deposition, because it may lead to admissible information. That's the whole purpose of the discovery. So that is not significant.

The issue really to some extent is subsequent remedial measures is really a policy question. And the basis is that you want to encourage people to change matters if they are unsafe, if they have a shilling effect. To prevent them from changing anything would hurt society more than by allowing it

label. I don't know on the other one. It seems to me also to be a subsequent remedial measure on 406. But is there any dispute that here is nobody selling Propulsid anymore on this market or in this market other than in the limited?

MR. IRWIN: It is access.

THE COURT: Restricted?

MR. IRWIN: Yes, your Honor. Its access is restricted under the limited access program.

THE COURT: Is that going to be admitted, is that part of the case?

MR. AMEDEE: We do not intend on admitting it. We do not intend on admitting evidence after the relevant time period. So we clearly believe that limited access program is a remedial measure because it limited the way in which the product could be distributed by the doctors and controlling their distribution of it. So we clearly look at it as a product, it is in the nature of a product change. Your Honor, this particular has permeated throughout every deposition, throughout the four or five times if not more in every deposition. It is prevalent throughout all of the testimony, the evidence that has been presented in this case. It will be almost impossible without somebody making reference to it. Now, we are not going to make a big issue of it and go into what the program is entailed, but I think that it is going to be impossible to conduct this trial without there being a

was right prior to the drug being taken off the market. It is also, I guess, evidence of the fact that he didn't want to got to an advisory board meeting with the FDA because they knew that certain things were going to happen, that they did not want to happen. So subsequently they took the product off the market.

So quite simply put I think that your Honor has in the courtroom on previous occasions alluded to the fact that the product is no longer available in the open market. When questioned about this by virtually eery witness that we have questioned, if you look at the back of our brief we show numerous quotes from various Janssen employees that they steadfastly said that it is not off the market -- you can still get it -- we have never recalled it. We have never determined, never been a recall or story that we withdrew it form the market. And the cases that the defendants cite all deal with recalls, not al of which were not allowed -- there were several that did allow evidence of recall. There is not a recall as to the liability itself. I have actually warning labels in this case is an integral part, and their label once again came just a month after Mr. Diez, tow or three months after he died. And I think it goes to help establish measures that could have ben taken. But through their efforts they fought these labels.

THE COURT: I don't see the label -- I see the label as clearly subsequent remedial measure. I would exclude the

that is so extenuating to what we are doing litigation in -- if a party was scheduled and then cancelled -- to what we are going to be litigating.

THE COURT: Let me look at 90 through 93 and just can other ones, and I will be more specific on that. Let me look at 90 through 93. I will reserve ruling on it.

Mr. IRWIN: Your Honor, subsequent remedial measures.

THE COURT: Yes. Let me hear from the plaintiffs on that. How does subsequent remedial measures get into evidence in this situation?

MR. AMEDEE: We are only talking about tow things here. We are talking about a label that came out in January of 2000 and the overall inaccessible program in general, limited accessible program. And first off, in my view this is not a remedial measure, just a decision to market this product in a different manner. Limited accessible program is obviously important in this case because it is an acknowledgement by the company that this product was unreasonably dangerous and shouldn't be on the market. Knowledge by the company that an adequate warning just couldn't be given about this product.

There is a question in one of the depositions, and I can't think of it right now; I think it might be Mr. Prudent's where he is actually questioned about whether or not statements were made to him by the FDA as to whether or not you could really give an adequate warning about this product, and this

jurisdiction that permitted punitive damages, and if one were to look at that question about profit and so forth, it might have some relevance. But I don't understand what the relevance of it is in the context of a failure-to-warn case.

THE COURT: Let me see what the plaintiffs say. Why do you want 91 through 93 in? What does that have to do with it?

MR. AMEDEE: It shows motive obviously. One of the issues that we are going to raise is that this product stayed on the market much longer than it should have. These are in the promotional materials. These are documents internally showing celebrations of $2 billion of sales. Number 92 says stay positive, make Propulsid money. They all lead up to 93 which says spend more time selling, less time on safety. And they show that safety and recognition of risk associated with this product were ignored and put aside in favor of profits. I think that's relevant evidence in this particular litigation especially given the fact that had the drug ben taken off the market four months sooner Mr. Diez might not be dead today.

THE COURT: Do you want to respond to that?

MR. IRWIN: Yes, Judge. I do remember one of the documents. One of them talked about a party that Janssen was going to hold to celebrate $2 billion in sales. That $2 billion in sales was for all of the Janssen products, not just -- and other documents show that the party was cancelled and never held. And to me maybe this is a 403 question, but

appropriate to take up right now is the one that relates to marketing materials. This is the motion to exclude evidence consisting of marketing materials.

THE COURT: I have it. These are as a result of the --

MR. IRWIN: Refined exhibit list there are four exhibits at issue as I appreciate it. They are Plaintiffs' Exhibits 90, 91, 92 and 93. These exhibits are business plans, sales strategies. They also have some numbers and sales numbers in them. I think I can be a little more specific about them. I have got the right ones.

THE COURT: 225, 231 and 232, 332, 52, 91 through 97, 161, 172.

MR. IRWIN: That is correct, Judge. However, when Mr. Amedee streamlined his exhibit list, it reduced those exhibits at issue to 91, pardon me, Judge, 90, 91, 92 and 93. I'm sure he will correct me if I'm misstating that. But I think that those are the exhibits in question.

THE COURT: Okay.

MR. IRWIN: These exhibits are, and it is hard for me to understand really why these have been selected and why the suggestion is for relevance, but these exhibits again are marketing materials. And there is not connection between Dr. Prejean and these various selected materials about bid plans, what the number of dollars were that were expected to be earned form the sales of Propulsid. I guess that we were in a

trying to stay out of the rain under says that we can't penetrate that. We have a company that was in contact, interaction with the FDA. We have meetings that were properly recorded that were even though "that they have a low-level FDA employee who recorded the minutes who is not an MD" but the fact of the matter is the investigators that were at those meetings prior to any final version looked them over, approved them, and they actually came out as a report, as a record of those meetings.

And I don't think that Dr. Lumpkin said something at meetings that he didn't mean to say, that was taken out of context, that he would have allowed it in the final version of those meetings. They are obviously subject to the exception because they are public record. They are trustworthy. I mean, if they are not trustworthy, then what is? The government record of its own meeting, its own minutes is not trustworthy, then I don't know what could be.

And they are obviously relevant in proving the plaintiffs' case under the LPLA. They address efficacy. They address writs. They address whether or not this product is unreasonable dangerous. And they only have two of them, and they do address adequacy of warnings.

The COURT: I will look at it again. I will rule on it either before or during trial.

MR. IRWIN: Your Honor, a motion that's probably

in that case the court admitted minutes of meetings with the FDA and as a government record, and I wanted to make sure that we pointed out at least two things about. In the E.I. Lilly case it was in an injunction proceeding, and Judge noted his opinion that the rules of evidence were relaxed. And so I think that clearly that that would demonstrate something here in front of a jury.

Then number two, those minutes in that E.I. Lilly case were minutes that were actually reviewed by Lilly. So Lilly was given the chance to review the minutes that were prepared by the FDA and say yeah or nay over those minutes. And so again, that addressed itself to the hearsay question, and we do not think that this passes the hearsay test. And we will await your Honor's ruling. We will address the notice question at the appropriate time.

THE COURT: In the Lilly case, unless I'm confusing it with another case, I think that those minutes had something to do with what the defendant said or what the parties said as opposed to what was said to them.

MR. IRWIN: I think that's right.

MR. AMEDEE: That's another case and another argument. The problem here is that I have a hard time reconciling the defendants having things both ways. Our argument about the alternative product design and the Buckman we know what we are prohibited from doing. And we know that this umbrella they are

to make a controversial statement to provoke dialogue. It was intended to provoke discussion in meeting. So let's say something that is one extreme, and then we will say something that's on the other extreme, which is often the way to conduct the meetings. And we will see where the discussion leads us. And so is that notice? I don't think that's notice. Is it prejudicial? I think we get to the 403 question. I'm mindful of what your Honor said.

THE COURT: That's where it is at in 403. I don't know where it is hearsay, because they are not offering it necessarily for the truth, but it is a question of whether it is misleading to the jury or confusing to the jury. When people sit around a meeting brain busting all of the areas, that's where it is at. I think, anyway.

MR. IRWIN: Well, your Honor, and I think the word brain busting is a good work, and I think that is a part of our concern about it. It certainly is a 403 concern, and it certainly goes to what Judge Duplantier said in Smith v. Isuzu.

THE COURT: It could well.

MR. IRWIN: Preliminary issues. So we will be guided by your comments in that regard. Let me just mention one other thing that I saw in my notes, and this goes not to the notice question, Judge, but it goes to the hearsay question. And that is one of the cases that the plaintiff cited was the Lilly case. And in the Lilly case, the case was Zenca v. E.I. Lilly,

an authority granted by law.

So you look to whether they had authority to make factual findings pursuant to an investigation. And these meeting minutes certainly are not factual findings pursuant to an investigation.

THE COURT: But aren't the plaintiffs arguing that the reason they are admissible is notice, not necessarily finding. They are taking the position that this is significant, this is relevant because Propulsid -- people sat around talking about it; the government asked these questions, and they say that Propulsid, people should have done something after they asked the question, or at least they were on notice, and they should have done some action or done something. Isn't that their whole thrust of this?

MR. IRWIN: I think that's part of the argument, Judge. So then it would, then they would suggest if it does not come in under an exception to the hearsay rule, it is not being offered as a government record, it is not being offered for the truth of the assertion; therefore, it is not hearsay. And if that is their position, then our view would be that it is not trustworthy. Because the statements that are attributed to Dr. Lumpkin, for example, cannot be cross-examined by us. It will promote and it will require that we call in witnesses to explain that as we described in our brief, our witnesses who were at the meeting would explain, well, Dr. Lumpkin was trying

representative of Janssen. It involves a discussion among other things about the decision to withdraw Propulsid and to cease commercial distribution of Propulsid is what we described it in the brief and also to implement the limited access program. These are two things they are talking to in the 403 motion.

But I think the issues here are whether these minutes, routine minutes of meetings are government records. That's really the question here. And we have referred to your 803(A), which is obviously the rule that would control here. And clearly these are not minutes of the activities of the office or the Adeoshun case that delineates that. Cases that are examples of things that document the activities of the office are cases that show whether the agency holds meetings, whether the agency receives official reports, whether the agency issues things. Activities of the office are not things such as interoffice meeting, and the course of conversations between people is more of an official function. That is 803(A) and 803(B).

803(D) are those matters observed pursuant to the entity and imposed by law, whether it was duty to report. And clearly that provision does not apply to this circumstance. The only one that would arguable apply is, of course, (C), and that is the circumstance where in civil actions factual findings resulting from an investigation are made pursuant to

consider the FDA meeting minutes. Would it be proper for me to address that one?

THE COURT: Yes.

MR. IRWIN: There are two documents in issue. Again, since we filed these motions in limine and Mr. Amedee and I have reviewed depositions and exhibits, he has trimmed down his exhibit list. So we now have two exhibits at issue. They are 6 and 12, Plaintiff's Exhibits 6 and 12. And Plaintiff's Exhibit 6, your Honor, we refer to on page three of our brief. Those are meeting minutes from the FDA dated March 27, 1998. The purport to commemorate a meeting between the FDA and representatives of Janssen. Of the things that is referenced in these FDA minutes is a statement by Dr. Murphy Lumpkin, one of the FDA deputy directors. And the statement that is attributed to Dr. Lumpkin in these minutes is "Cisapride. Basic question: Is it acceptable for your nighttime heartburn medicine, i.e., something for which you can take Tums to have the potential to kill you?" I know you have heard about that.

THE COURT: That's what the plaintiffs have been asking.

MR. IRWIN: Yes, sir. They have referenced that before. And the other document is, I believe, the minutes from March 9, 2000. These minutes refer to -- should I have that right -- these minutes refer to a meeting between Dr. Houn, if I am pronouncing that correctly, Dr. Janet Woodcock and some

THE COURT: In that regard let's see if that's the situation so a 901 stipulation can be made. I'm not saying that gets you past the hearsay because it may not. But if it is just a question of a perfunctory $10 that there ought to be a way of at least shortcoming some of that with the parties.

MR. IRWIN: We would agree on that as far as authenticity 901 of the DD Mack letters 168 and 170. We have great reservations and do not agree at all that that applies to 803(6).

THE COURT: All right. That's the way I see working out the 901 situation, because really the stamp of the government just goes to 901. It doesn't go to admissibility, it just goes to authenticity. So that I don't need to get somebody down to say, yes, that a government-issued letter. But that's one way of doing it.

In this particular case I just don't see that these documents have any part in this particular fact pattern or that the testimony I have reviewed indicates that. I don't even know whether the doctor really knew that there was and DD Mack correspondence much less that correspondence. In fact, I had the feeling I didn't even know whether he knew with the DD Mack correspondence was until this cropped up. So I don't see this playing a part. I would exclude those.

MR. IRWIN: Your Honor, the similar motion that addressed some of the same subject probably would be able to

agency's attention by a competitor or by consumers or by anyone who finds them offensive. And that's how things often come to the agency's attention and to their concern.

So the fact that these documents were sent to FDA at one point does not necessarily mean that the FDA was giving a preliminary, prior stamp of approval to these materials before they were actually disseminated. Now, I don't know whether Dr. Prejean in this case since I was not involved in the particular case saw any of these promotional materials or whether he saw simply identical materials, whether he saw the letters or whether or not he should have seen those letters. Those are other matters. But just the fact that the letter were issued does not mean that the materials were never disseminated.

The only thing I wanted to address is the government records issue under 21 CFR 20.3, the DD Mack letters, minutes of meetings that are written by FDA. FDA letters can all be certified as authentic government records. It is a $10 fee and you submit it to the agency. They will put a red ribbon on it and it becomes an official government record. Now, that's something that the plaintiffs' steering committee or Mr. Amedee could do, and we are hoping that it is unnecessary that we have to send $10 for every document to the agency to have those authenticated as official government records. But obviously if we need to do so, we would appreciate some advice about that as well.

make it as a government record, 803(6) is not a safety valve that you resort to, then get the document in as a business record. And that's United States v. Kanan.

And then finally, of course, it can't come in as a so-called business record for a regularly conducted activity until there is a custodian that can identify it as such. So I find your remarks earlier today about 401 and 403, but I think that no matter where you come down on the analysis under 803 and 803(6) this fails the most basic test because there is no connection to Dr. Prejean. Thank you.

THE COURT: You had another remark?

MR. PARR: I'm Edward Parr. I'm with the Mathis firm of Washington, D.C. I had a chance to speak to you before. There are just some things I wanted to clarify for the record. First of all, with respect to the submission of promotional materials to the Food and Drug Administration, it would, in fact, be a prior restraint and rescission of the constitutional, in fact, if the FDA were required to preapprove all promotional materials. It does not. So the regulations require that the promotional materials, thousands and thousands of them no doubt get submitted to the agency every year. And whether or not a particular item gets reviewed prior to its actually being disseminated is entirely a matter of chance. Many promotional materials are sent out and used in the ordinary course of business, and they are brought to the

Highway Department finding those letters were preliminary viewpoints of government officials and they were constituted an exchange between Isuzu and that government agency about safety issues. Now, none of those documents rise to the level of 803 that is clear. So one of the hearsay questions that the court has to address whether this is admissible as an exception to the hearsay rule under 803(A), and clearly it is not.

A brother judge of yours has found and it was affirmed by the Fifth Circuit. And there are lots of other cases we cited.

If I might just look at my notes, I think that concluded my remarks. I will make one remark about business records and this remark will apply to some other motions we have made. I will not reiterate it, but it didn't pass the government record test, which it clearly does not. We should not then resort to 803(A), this sort of catch-all to get it in as business records.

I could go through the hearsay rule, trustworthiness rule, and when I use the word trustworthiness in the context of the government records I am not suggesting that the government or the government per se is untrustworthy. I just mean that these documents were not compiled with the sense of regularity that one would expect a demand to satisfy the trustworthiness requirement. We have cited to your Honor at least one case which I am trying to call up here that says that if you can't

fairly disclosed to him. He had no problems with the information that was given to him.

Instead, what we have here are some letters which are expressed to be informal opinions. They are untitled letters. We gave you regulations on that. And they reflect an exchange of the viewpoint between the FDA and the company on certain promotional materials totally unrelated and totally unconnected to Dr. Prejean and Mr. Diez? And I will digress for a moment if I might, please. As Mr. Amedee said earlier, we were talking about the ultimate design motion, he made the reference to the fact that promotional materials are not relevant in Louisiana cases.

And that is true. We don't have a negligent promotional claim here in Louisiana. Some states do. But that makes it drive the point home all the more clearly that whatever promotional material we are talking about here number one you have got to connect them to Dr. Prejean, and there is not connection.

Then we go back to this request from these letters, informal expressions of what preliminary views by the FDA on promotional materials. And they clearly are. And they are untitled letters, and we waste that throughout and provided that information to your Honor about it and relied on the case of Judge Duplantier, Smith v. Isuzu case where he excluded letters and communications from the National Transportation and

defendants are relying upon the FDA. It is a blanket umbrella and I think what the DD Mack letters illustrate is what should be in their particular labels. And there will be obviously probative for us to prove whether or not they did, in fact, comply adequately.

THE COURT: Let counsel respond. I will let you confer with counsel, and if you have anything to add I will let you do that.

MR. ARSENAULT: Just so the PSC would have a chance.

THE COURT: I will give you an opportunity.

MR. IRWIN: These promotional materials, whatever they may be, they are the very core of this issue here is that whether they were relied upon by Dr. Prejean.

THE COURT: Nobody sees them but the office and you?

MR. IRWIN: Dr. Prejean has never sen these documents number one. And number two any of the promotional materials are the subject of this exchange between the FDA and the company about these promotional materials. He never saw nor did he ever rely on those promotional materials. We specifically asked him at his deposition what materials have you reviewed from the company, what materials have you reviewed from the company, what materials have you relied on? Were any of these materials ambiguous? Did any of these materials fail to disclose to you the risks? I know you have seen all of that testimony. And he said that he thought it was all fully and

had lack or fair balance. And there is going to be an issue in this case regarding whether or not adequate warnings were given for all concomitants. It listed a group of drugs that were not to be taken with Propulsid. There were also other drugs in that category, numerous other drugs that they didn't warn about. So these two letter will show that prior to Mr. Diez's death the company was put on notice about that particular aspect of this case. And for that reason and that reason only --

THE COURT: The problem with the DD Mack letters though is that before any advertisement goes out from the drug manufacturer to float it past the division of drug marketing act or advertising communication department, they send them the material. They get some writing from them preliminarily. They haven't even sent it out yet, haven't been advertised it. Yes, they want to know whether or not they can advertise it so they say this is what we propose to do. And they give input from the office, and whether or not the input is valid or they agree or disagree, they change their advertisement and did something to it. It is really a preliminary operation is the way I understand it. Unless I'm missing something. That fact that they have given that information, they simply are saying this is what we propose to do. Help us out, give us some information. Isn't that what we are dealing with here?

MR. AMEDEE: That's what we are dealing with, but the

THE COURT: Okay.

MR. IRWIN: Does your Honor have any particular order?

THE COURT: No. I will listen. You bring them to me the way you want them.

MR. IRWIN: Can we take up the DD Mack motion first?

THE COURT: Yes, okay, I have it.

MR. IRWIN: Judge, our motion addressed originally four DD Mack letters.

THE COURT: Let me interrupt you. Let me get a response from the plaintiff on that. Why are these admissible?

MR. ARSENAULT: Let me on behalf of the PSC, I want to reiterate so that the record will be clear and rather than stand up for every one of these motions, the PSC would offer the same argument that Mr. Levin made previously.

THE COURT: All right.

MR. AMEDEE: This will be very brief. The DD Mack letters and this is speaking only for these two cases that I am interested in, are DD Mack letters. I think they are listed numbers 168 and 170-71. And I think 170 and 171 are both the same document. And these are three public records that address a specific a cause of action of the plaintiff, namely, the warnings and whether the warnings were adequate. And those show notice. These letters were written to Janssen recording that warnings they point out that certain brochures and other materials contained in their warnings did not contain a -- they

not have died of a heart attack. And we are asking the jury to make an arbitrary choice between which they like the best. That's not good science and it is not proper science.

And so we are asking them to roll the dice, and they are the lest expert people to do that. That's where your gatekeeper function comes in.

THE COURT: I understand your argument. I understand where you are coming from and I understand the plaintiffs'.

MR. MURPHY: Thank you.

THE COURT: I appreciate your views. You make a strong point, and you have got an interesting case and a good theory. I understand the issue. I have had it before me. I have read it. I have looked at all of the documents, and I am familiar with this issue. As I said, in this case I see that there is some evidence to indicate that he had no cardiac incident before, had no ischemia before, was taking Propulsid for a period of time, had at least one documented instance -- whether or not his is valid, it is one document instance that he had QTC interval prolongation. He dies while he is taking this drug. The death is relatively rapid. He is DOA, was dead in the ambulance even. It is a question of fact for the jury. I don't see it as a question of law. So I will deny the motion.

Okay. Let's deal with the other matters before us. Any argument on any of them?

MR. IRWIN: Briefly, your Honor.

risk factor. We can ignore that one. But now let's look at what happened after he stopped going to Dr. Prejean. He has these three to four incidents of gasping for breath inconsistent with torsades. Because he doesn't get torsades that way. That didn't present as torsades. You would be on the floor if that were torsades.

And then he gets chest pains a week before he dies. So now we are up to 18 risk factors if you have ben keeping count with me, Judge. Chest pains within a week of his death, spontaneously reported by his wife in the medical record and told to the people who were caring for him at the time when he was critical to be accurate.

And so, Judge, you have got all these risk factors. You have got arm pain. That's the last one. So you have got 19 risk factors that point to the fact that this man had heart attack. So taking this to a differential diagnosis, in order for a doctor, any doctor, to say to a reasonable degree of medical certainty that it was something other than a heart attack you have got to rule it out. It is important for any reasonable doctor who is not an advocate for a position, I'm talking about a dispassionate scientific exercise over which you are the gatekeeper to be unable to rule out the fact that that man died of a heart attack. And so we are in the anomalous position of sending a case to a jury where the man cannot be said by any doctor, ever their doctors, that he could

left are simultaneously. And she is going to testify that it was about a minute or two minutes between left arm pain and his complaint about it and his collapse right there. And all the experts agree that when you die of a heart attack, fibrillation takes place after the heart attack. That's why they have had fibrillation machines where you strap on your chest and say clear and try to get your heart pumping back again. I just wanted to clear that up.

But he had a base factor for the heart attack. They are not disputed risk factors. These bad habits he had for a long time. Age is a factor. Gender: Males have a higher risk of heart attack than females. Family history: Uncle died of a heart attack. Smoking: Thirty, 40 years two packs a day. Chest pains for approximately one year. That's five. H.pylori bacteria in his stomach. That's six. High bad cholesterol, that's seven. Low good cholesterol, that eight. High or bad high fat diet of long duration, that's nine. No regular exercise, that's 10. Shortness of breath on exertion of dyspnea as it is called, that's 11.

EKG in 1994 showed t-wave abnormalities which Dr. Prejean testified as suggestive of ischemia. 1998 EKG showed t-wave; 1999 EKG during the stress test showed abnormalities suggestive of ischemia. So we are up to 14. You have been keeping count with me, Judge?

Now, he wouldn't go to the doctor. That's a very high

in that an autopsy would not have revealed blockages. It is not going to come from your experts. They are going to testify unequivocally that autopsy would have revealed blockages.

Number two, they are going to testify that the autopsy could have revealed arteriosclerosis. And Dr. St. Martin in particular is going to testify that the likely cause of death was what they call a plaque that had ruptured.

THE COURT: The only thing it would not show is the fibrillation?

MR. MURPHY: That's right.

THE COURT: Fibrillation is pretty much caused by the block?

MR. MURPHY: That's exactly right. Let me back up a second to the night he died. And this is significant. He is at a friend's bar. He had just finished going into an apartment with a friend and took a tray into the apartment. And there as soon as he finished taking the tray, he had that sharp pain in his left arm. That' not torsades. Torsades doesn't present as pain. You are not going to hear expert testimony say that torsades causes pain. Doesn't cause chest pain. Doesn't cause left arm pain. That's a heart attack.

And the evidence will show that his friend, a lady, teased him because he was suddenly complaining of this left arm. And he said, "I don't know what's wrong." And then after complaining of left, his left arm, he grabs his right arm and

As far as litigation, she didn't have the money to do it.

An interesting fact, though, is that the testimony will show that since Mr. Diez died within an hour of his having his attack more likely than not it would not have shown up on that autopsy. Thank you.

THE COURT: Where was he when he died?

MR. AMEDEE: At a friend's bar and lounge. He was not a drinker. He had stopped by there with his son earlier in the night, dropped his son in front of the house. He was on his way home and he stopped at Terry's Lounge and the caterer -- he was in the back -- there is a catering operation of the bar and restaurant talking to a young lady who was fixing sandwiches for a wedding the next day. That's when he just fell down into unconsciousness.

There are 14 -- I listed contested and disputed material issues of fact in this case. And unlike -- they are not 14 risk factors -- he had some but he didn't have 14 of them.

THE COURT: Do you know if he was DOA on arrival?

MR. AMEDEE: Yes, he was. I think that Mr. Irwin will agree that the ambulance driver's testimony was that he was dead in the ambulance. Thank you, your Honor.

THE COURT: Okay, thanks.

MR. MURPHY: I will start with the last point first. Number one, I don't know where the testimony is going to come

limits. Dr. Neotime testified that pre-stress test blood pressure readings will ordinarily be high especially for a person who hasn't taken one before.

THE COURT: Do you know if Mr. Diez was on Propulsid at the time that he died?

MR. AMEDEE: No, he had this prescription filled in on October 13th, which was just 11 days before he died. And the history, he had a pretty steady history of having it renewed. He was, we call it a mathematical computation of the number of pills that he was prescribed over a six-and-a-half month period, number of pills, number of days, that's 41 or so. So there was left in the bottle and came down to like five to six pills a day.

His wife said he too, his medication for symptomatic relief of his symptoms. So, therefore, sometimes he might take more than five a day. I would guess there are days when he took more, days when he took less.

I want to talk one second about the autopsy. No autopsy was performed, and the testimony is going to establish that Mrs. Diez was told at the hospital that she didn't need an autopsy and that this is a cyclical thing. I'm sure the doctors at the emergency room said that guy died of a heart attack. They didn't know he was on Propulsid at that time. It was not known that Propulsid could cause the problems that he had. They didn't know in the emergency room at West Jefferson.

Propulsid. Our burden of proof at the point is not to show that he did one or the other, but it is more likely so. And at this point that is a question of fact that he did so.

Had the normal QT. He had normal stress test. He also had a normal echocardiogram. His treating physician prescribed his Biaxin and Propulsid for a 10-day period. But he was off Biaxin for six months. So obviously that had nothing to do with the combination of those two drugs -- long out of the system.

We have had the argument of half lives. We know that there is no drug that could have stayed in his system that long. He was, however, on a drug, Provosay, which was a 450 inhibitor that was not warned about. That will be an issue in this case.

Both of these experts did a differential diagnosis by evaluating Mr. Diez's risk factors. He did smoke for 20 to 30 years one to two packs a day. The fact of the matter is he quit, not months but a year before. Dr. Eckberg says that is relevant. Many of the ill effects associated with smoking had ceased.

Didn't have high blood pressure. You look at the brief. He had high blood pressure on that one occasion before the stress test, and he had three readings of normal blood pressure over the course of his treatment with Dr. Prejean April 1st, April 14th and April 23rd. All were within normal

one of these experts had access to the actual monitors, the stress tests when they rendered their reports. But what they relied upon is the results of that test, namely, no arrhythmia, no chest pain, 11 minutes on the actual treadmill, two minutes into the Bruce protocol.

Now, granted there was six months before Mr. Diez died. And that's relevant, but it is also relevant in that his QTC was not elevated then. We don't know if his QTC was elevated six months later, the day he died. But if that's the case, there remains the argument with regard to the design defect. If the only way that a person can prove that they died from or that their relative died from taking Propulsid is to have a QTC measurement at the time of the death, there would never be a case proved in this state or any other because nobody is going to be on a monitor at the time they die.

So you have to look at other factors. The Propulsid relationship certainly is something you have to take into consideration. The man was taking the drug at the time. He was taking an average of five to six pills a day. Reason to believe it was a Friday night. Didn't have to go to work the next day. Had he had to work, he might have taken his more prescribed does, the seven or eight of them that day. But the fact of the matter is he either died of one or the other.

And I agree with counsel there that he either died of a heart attack or he died of an arrhythmia event associated with

state of medical knowledge. It is not simply Dr. Shell's discretion to ignore the body of science and come up with something new and say I'm going to experiment on this jury at Janssen's expense. You have got to be the gatekeeper, Judge. You have got to be the gatekeeper to decide whether or not he could ignore the sandwich of the normal QT coming in, normal QT coming out. You have got to be gatekeeper to determine whether or not he could soundly ignore the confounding factor of the Biaxin if there were a prolonged QT. He has got to rule out it was a combination of Biaxin, because he said Propulsid alone killed this man. So that's apples and oranges.

So he has got a QT. There is no controversy that the QT is measured with Biaxin and Propulsid. So can you rule it out and then by his own admission find it? Can you rule it out that it was nothing but a normal variation given the necessity of doing that? Because he presented with a normal EKG on the 14th and he leaves with a normal EKG on the 14th. And by normal I mean the QTC interval.

THE COURT: Okay. Let me hear your opponent. I will give you an opportunity to respond.

MR. AMEDEE: The stress test of April 14th is the ultimate red herring in this case. And I don't mean it by saying that it is not important to Mr. Diez's case because it certainly is. Both experts, Dr. Shell and Dr. Eckberg, relied upon this stress test but not the QTC measurements. Neither

the way he did if he were not on Propulsid. But that's the end of the case because the cases inform that there has to be a reasonably conducted with proper methodology following differential diagnosis by the physicians that the plaintiffs call. And if the differential diagnosis is flawed and as a result of the flawed diagnosis you can't rule it out, they don't go to the jury, because then we are letting science go to the jury. And the whole point of Daubert now that I am down here in Mississippi, I mean Louisiana --

THE COURT: Close enough.

MR. MURPHY: Now that we are down here in Louisiana that's the essence of Daubert. That is we can't let bad science go to the jury no matter how well intended. How in the world is that a scientific basis for saying that although this man came in with a normal QT on the 14th, walked out with a normal QT on the 14th that by some cause that they cannot explain, some non-speculative cause for which they have no evidence that he had a prolonged QT on the day he died? That being the only cause of the disease they diagnosed torsades. And so there isn't a question of permissible inference that gets them over the top. It is a question of an absence of enough evidence to infer that, that this QT was obtained by methodologically incorrect means.

And you are the gatekeeper. You have got to decide whether or not the bizalan formula was applicable given the

they need these bypass operations. Lo and behold they have a heart attack. And so we can't let this case go to the jury on guesswork or speculation.

In order for it to go to the jury, there has to be medical testimony from their doctors which rules out a heart attack by appropriate methodology. So that's why it is Daubert question. That's why it is insufficient.

Now, let's look at their methodology. They say contrary to all medical authority that the stress test rules out that he had cardiovascular disease, the kind that causes garden variety heart attack. Couldn't possibly be true. And so we have two methodological issues here and science issues, whereas in your role of the gatekeeper you have got to determine whether or not it was sound science to measure that QT, whether the QT was capable of being measured, whether it was sound to ignore the rest of the QTs on the 14th and the recovery on the 14th. Was that sound science? Or did the doctor have to rule out what he saw? Was it sound science to say on the basis of the entire medical record that you can ignore, you can ignore that rewrite and rewrite that and be able to rule out the obvious cause of the man's death?

Now, let me get back to the autopsy. Bot Dr. Shell and Dr. Eckberg, and Eckberg is the only one that comes to mind specifically who said that he couldn't rule out the fact that the man would have died of good ole garden variety heart attack

deposition that was it and by everybody else.

Now, let's go back to the stress test as I promised a few minutes ago I would. The stress test itself does not rule out a heart attack. There is a document we filed -- it is the disclaimer/inform consent document. And if you look at the bottom it says three things. It says number one don't get false hopes about the fact that this stress test didn't show any cardiovascular disease because it is only 60 to 70 percent accurate. And there is another test that can actually factor accuracy factor up to 85 percent, but the only test that's completely accurate for the presence or absence for arteriosclerotic heart disease is the angiogram. And Dr. Neotime so testified. In fact, Dr. Neotime, and it is not a contested fact because he is a disinterested doctor, he is not on either side's pay, he said that he has had cases where people pass the stress test with flying colors and died of a heart attack and he had blockages. And who passed the stress test?

I think this is a more accurate statement, passed the stress test. And it was determined later by one of the more accurate tests that he had actual blockages in their heart. Now, I think there is enough known about this to know many people who have been in that situation. We have got close friends who have been in a situation where they have been walking around after passing the stress test, and lo and behold

little of the good. He has a diet that has persisted for his 50-some years of life, bad diet. He has no regular exercise program. And I know the plaintiff is going to try to say that has something to do with the nature of his work, but the point is he had the classic risk factors of a heart attack. You have got to rule that out before you can rule in something else. You have got to rule out the simplest cause, and if you can't do that you can't get anywhere.

There is another factor, the stress test itself. On the stress test he had abnormal t-waves both in 1994 and the stress test in 1999. There were other modalities consistent with ischemic heart problem meaning a lack of oxygenation. And no matter how they slice it, it is uncontested within two to three minutes before his death he was awakened in the middle of the night. His wife has testified that this was a new thing and he was gasping for breath. Gasping for breath is a form of ischemia, which is a lack of oxygen. So he is gasping for breath. There is no controversy that this could be torsades.

They try to manufacture one. Because if it would have been torsades, he couldn't possibly last for one minute or two -- he would be out, because the heart would have stopped beating. He would have collapsed. That didn't happen.

And so these three to four incidents of gasping for breath and in the answer they said that in terms of the chest pain reported by witnesses who had testified in their

caused by a prolonged QT. Torsades is only caused by prolonged QT. So it is one or the other, it cannot be both. And so they have the burden of ruling out that it was a heart attack. And there is traditional methodology that has to be done correctly.

Bear in mind there was no autopsy, none at all. How did they then rule out that he didn't die of a garden variety heart attack? And how is it anything other than speculation or theory, however inspired that speculation or theory may be, that gets them to the jury? They have no facts. They cannot have a scintilla of evidence under these circumstances other than scientific speculation that at the time he died he had a prolonged QT and that that QT alone, prolongation alone caused torsades which caused his death. Now that is not a question of disputed fact. That is a question of scientific methodology and insufficiency.

Because just think about it from a common sense point of view. You have got a guy that has presented with all the risks of a heart attack. He smokes two or three, I'm sorry, one to two packs a day for 30 to 40 years. He has only stopped in the last six months.

Fact number one: He has got high blood pressure, though they try to explain it, he had it, and nobody knows why.

Factor number two: He has bad amounts of bad cholesterol, and he has a low amount of good cholesterol. And so he has gotten it both ways, he has too much bad and too

Now, that raises the second big issue. How did you get from a guy who walks out of the stress test with no prolonged QT and minutes later a prolonged QT at the time of death? There is no explanation in the record or in the motion response for how that's anything but an intuition, a speculation or a theory.

This isn't a case where a person has a persistence QT where it is reasonable to infer that at a certain date in the future he is likely to have the same thing. And so the only prolonged QT he has is during this period where Dr. Shell chose the controversial measurement because the other non-controversial measurements were not available and where the QTs according to Dr. Neotime and Subselento and from Dr. Shell himself are normal. So there is a big problem, and that isn't an obvious thing because it wasn't obvious to us until we looked deeply at it, and we took Dr. Neotime's deposition.

And there is a third problem and there is an obvious problem. The third problem is how do you rule out as a matter of differential diagnosis that he died of the leading cause of death in America from those who don't take Propulsid? Now, there is a very subtle thing here. It is not subtle once you understand it, but it is subtle unless it is pointed out. And that is that you can't have a heart attack and torsades at the same time. They are two different animals.

A heart attack is caused by cardiovascular disease, not

unanimous that it is improper to measure QT interval on a stress EKG.

And he can't rule out, let's assume, let's give the devil his due, so to speak. He can't rule out that the prolonged QT is the combination of Biaxin and Propulsid and not Propulsid alone. Nobody in the world can do that, and he can't rule out his admission that there is a 95 millisecond variation in the normal heart in QT. So he can't rule out that it is a normal variation, not a Propulsid variation. He can't rule out that it is a Biaxin variation prescribed improperly with Propulsid.

And so right there it is a differential diagnosis is that QT interval meaning that it is a Propulsid-induced interval and that's not something else gone down the drain and his measurement of QT because it is not scientifically accepted. I mean, there are a whole host of studies, and Dr. Eckberg admitted that by the way, Dr. Eckberg said very clearly that he has no scientific support for the measurement that Dr. Shell made.

So you have a Daubert problem right there. Now, it is compounded by the following things: Daubert problem number one is that if it is a Propulsid-caused prolongation, why isn't it in the first EKG on the 14th? And why isn't it in the last EKG on the 14th? So literally you have got a man who walks out of the stress test with no prolonged QT.

Now, the first thing that was not in the summary is, and I suggest if you have ever taken a stress test you already know this, first thing they do before they stress your heart is they give you an at-rest EKG. No prolongation of the QT at EKG, number one. We are talking about April the 14th, no other date. They give him an EKG while he was exercising. And that's where you have the variation in the heart rate. And it is scientifically unsound and there is no medical literature to the contrary: To attempt to measure the QTC interval when the heart rate is varied. The only formula is bization formula. And the bization formula is inapplicable when the heart rat is varied. Now, that's not a disputed fact. That's a Daubert question. Because right there you have got to ask two things.

And then there is a third factor. I'm going to fill you in on the third factor, which is that immediately after he was given an exercise EKG -- he is on a treadmill -- the next thing, the next EKG he gives the heart rate is now stable again. So you have got EKG number one on the 14th, stable heart rate. EKG number two on the 14th exercising, unstable heart rate. EKG number three on the 14th, stable heart rate. Guess what, Judge? Dr. Shell doesn't say QT is present in one or three. Now, unless he is a fool, he did the measurements for all three. He didn't like the first dimensions and he didn't like the last one. So he is stuck now with the only one he can measure, and that's the one where the medical opinion is

Let's back up for a moment, because I am going to fill you in on something that Dr. Neotime testified about that he only suspected shortly before. Dr. Neotime's deposition is very significant. You will recall in 1994 Mr. Diez had a normal EKG and normal QTC interval. On April 1st he goes for a normal QT interval and he presents as a heart patient to Dr. Prejean and Dr. Prejean believed that he had at least 14 risk factors for a heart attack. And there is not dispute about that, 14 risk factors, and I can name them in a moment.

Now, that's before Dr. Prejean put him on Propulsid. Well, what Dr. Prejean did next was wrong, and there is no dispute that the warning on the Propulsid label says you cannot coprescribe Biaxin with Propulsid. He did it. And at the time that the man presented for the EKG was asked what medications are you on. He was on, among other medications, Propulsid and Biaxin.

Now, Dr. Shell has said in his report that what happens when you are on Biaxin and Propulsid at the same time is that Biaxin because it inhibits the metabolism of Propulsid effectively increases the dosage three times normal. So when the man presents at the stress test, and Dr. Shell cited the study that's in there, and the man presents at the stress test, he is on a prohibited combination of Biaxin and Propulsid. And his effective dose is at least three times normal does of Propulsid.

THE COURT: But it is a malfunction of the ventricular aspect.

MR. MURPHY: No. This is an important distinction. Torsades is the resting heard goes de-dum, de-dum, de-dum. But torsades causes the, and it is only caused by the QT and nothing else. Torsades causes the heart instead of that regular sinus rhythm to go da-da-da-da. And it is literally stopping the pumping of blood immediately upon the onset of torsades. And because it stops pumping blood, a clinical setting can be seen and measured. But pitch is showing the heart looking like a bag of worms instead of actually pumping blood. So torsades is a unique type of fibrillation that's caused by a timing problem, which the timing problem being a prolonged QT.

Now, the second thing that's interesting about torsades is when you get it, because the heart has stopped pumping, you remain conscious only as long as 15 seconds. And the third thing about torsades is something that resolves by itself. The heart just starts re-pumping, and sometimes it causes death. Now, these people have staked their claim that that man died of torsades, nothing else at the time he died. So the review you have got to show a prolonged QT at the time he died. You have got to show that it was torsades that killed him caused by the prolonged QT. You have got to show that prolonged QT was caused by Propulsid. There is no dispute about that.

says that the indications are that he had some ventricular fibrillation which precipitated or caused the decedent's qualms. And therefore he says that it is caused by Propulsid.

You have got evidence the other way. But it seems to me that the question is more of a factual question than a non-factual question. There was no EKG ever. If he had stopped taking Propulsid for a long period of time, all of these things would be then Daubert questions. There would be some preliminary questions. But the way that the fact unfold it seem to me that it is a fact question more than a legal one.

MR. MURPHY: Your Honor, if you will permit me, I have some strong differences with the court's summary and I will tell you what they are. In order for the plaintiff to prove their case, they have got to show first that the QTC interval at the time of Mr. Diez's death was prolonged and that that prolongation was caused by Propulsid, not by something else and that that prolongation caused torsades.

Because the only thing that causes torsades, both sides agree, is prolonged QT interval. It isn't caused by fibrillation. It is a fibrillation, and it is unique because it can only be diagnosed by the unique signature it give on the EKG. That's where it gets its name. That signature is an oscillation, and it has a, it appears to be a twisting of the point of the sign waves. And that's why they call it a torsade.

THE COURT: Let's hear it.

MR. MURPHY: Judge, I realize that I'm swimming upstream on things, and I intend to be a salmon today.

THE COURT: All right. Let me tell you just my view of it, and you can hit the highlights and see where I need education on. The individual had some EKGs done. The EKGs did not indicate an ischemia, didn't indicate any infarctions or anything of this sort. He was put on Propulsid. He as been into Propulsid for 10 days or so. He is doing a stress test. During the stress test he is being tested, and he has a prolonged acute interval. He goes on for a while with Propulsid, develops chest pain at night. Thereafter, he drops dead.

The expert testified that he had no cardiac accident before. He had no cardiac problems before. No cardiac complaints before. He had acute prolongation by getting a stress test, which some people will say that's what happens in a stress test. It is not unusual; he has it documented.

We know that Propulsid can through the channels or through the autonomic nervous system can cause, precipitate some prolongation, acute QT. He is on Propulsid. He has a demonstrated QT interval, prolongation.

We also know that Propulsid has been related for those who have taken Propulsid through instant death to some point which is precipitated by ventricular problems. This doctor

things are admissible because it shows what he has done to advocate certain things. It goes to his credibility and advocacy.

With regard to the Madigan Report, I am going to have to reserve ruling on that.

MR. IRWIN: Can I be heard on that? What the Madigan Report was was a report that was done by counsel for a company for which Dr. Shell was employed. And it was submitted to the FTC after finding that Shell was guilty of widespread research fraud. He faked data; he faked conclusions.

THE COURT: How do you get it in?

MR. MURPHY: Well, that depends on whether or not we can lay certain foundations during the trial. And assuming that we can, we believe we can get it in.

THE COURT: You are looking at it for cross-examination of a witness?

MR. MURPHY: Absolutely, under 608(B).

THE COURT: I'm going to reserve ruling on it and take it when it comes. The think that I don't think I will let in is the divorce and the taxes.

MR. MURPHY: I don't intend to offer the divorce. I do intend to offer the money. Thank you, Judge. And I am ready to be heard as to the other matter.

THE COURT: Any problem with his motion going on?

MR. WRIGHT: No, your Honor.

MR. MURPHY: The other thing is that the taxes, same thing, Judge. It tends to show that he is in great need of money. I can get through this smartly, because liens are not in controversy. See, when you cannibal the federal government, they are the first to come after you. It tends to show a financial desperation. And so I can just get right to that without -- we are not offering that to show lack of credibility, just a lack of money.

THE COURT: I don't know how you get into the owing the money through taxes. My feeling on taxes is that it is one thing if a person has that violation and is guilty of tax fraud in a sense that they didn't file income taxes. But when you go into taking the position that you made certain deductions or you did this or you did that, it gets into the tax law. And it is confusing to the parties and to the jury because you appear, tax lawyers will give four opinions on what to do and what could be done and what should be done.

The issue of whether he owes money is relevant obviously and that can be done without specific taxes. I would listen to that. My view is that accusations, suspensions of medical licenses are admissible. It is certainly 401, and I don't think that it is excludable under 403. The investigations by the FTC and the SEC are admissible. What the doctor received from various plaintiff litigation groups is admissible. Marketing effort of Fat Magnet and the other

certainly Dr. Shell. Dr. Shell has always objected to that being circulated to any third party. But, nevertheless, everybody, they are arguing that because it was sent that the privilege is waived. Dr. Shell at no time ever waived it, nor have I ever waived it. So we believe for the reasons of hearsay and the reason of attorney/client privilege that that should not be paraded in front of the jury.

By the way, that Madigan report was not connected to any science. It has no scientific value whatsoever. It was prepared by an attorney, not a doctor, not a scientist, and it has no substantive value. It should be excluded from the jury because it is critical of Dr. Shell and his work that was performed while at Nutra Corp. Science. That's all I have.

THE COURT: Okay. Mr. Murphy? Just talk to me about the fact issues and the --

MR. MURPHY: Divorce?

THE COURT: Divorce.

MR. MURPHY: I'm not interested in getting into why he owes $4 million. And so we are not interested in bringing to the steps of the jury that he owes it to his wife. The fact is that he owes $4 million. I can get that out of him on direct examination, and, of course, it goes to his bias as a witness because it tends to show that he is in great need of money and that he is --

THE COURT: I agree with that.

science that he is offering here in the Brock matter or the Diez matter and that that would be overly prejudicial for the jury to hear that as well.

THE COURT: What's the Madigan?

PLAINTIFF'S COUNSEL: The Madigan Report in a nutshell, Dr. Shell was an employee of Nutra Corp. That's important because he was an employee of Nutra Corp. Nutra Corp. asked for a study to be done regarding the, I guess, the efficacy of and correctness of reports by an attorney. And the attorney was hired by Nutra Corp., which was Dr. Shell's employer. Dr. Shell's employer at the time prepared a report. It was an attorney-client document. It was a document prepared by a client, by an attorney at the request of a client. And that's clearly attorney/client privileged communication. And that should be excluded from the jury for that reason.

Moreover, I don't know that there is any witness going to be called to testify regarding the contents of the Madigan Report. But the defendant simply wants to introduce the Madigan Report, and we believe it is hearsay. And for those reasons we ask that that be excluded.

Incidentally, the defendants attempted to get the Madigan Report by subpoena, and the attorney filed a motion to quash the Madigan Report, but it was released by a disgruntled employee. That's attached as an affidavit to one of our motions -- against the knowledge of the company and against

his license over a Friday. The check unfortunately did not reach, I suppose, the board of California until at a time when it is too late. So his license was in limbo as a result of that. He admitted a patient over the weekend at Cedars-Sinai; he was suspended by Cedars-Sinai. And Dr. Shell simply has not chosen to try to renew that license or his privileges at Cedars-Sinai. We believe that that also for substantive, for reason of why it was suspended should be excluded from the jury.

The next is community property and the divorce of Dr. Shell. We believe that those are totally irrelevant. That's his personal affairs, his own personal affairs. We believe the personal laundry should not be paraded in front of the jury.

Also, the prenuptial agreement that he has between himself and his current wife, that should not be placed before the jury.

And a couple of final things: The products that Dr. Shell has manufactured and/or marketed -- Fat Magnet and other things such as Arousal, we don't believe those things should be placed in front of the jury. We understand that here had been some FTC charges against Dr. Shell, none of which Dr. Shell has admitted any wrongdoing in. But simply for the sake of saving a large amount of attorneys' fees and a lengthy battle, he has agreed to consent to many of those things.

And we believe that that has nothing to do with the

liens, of tax liens with Dr. Shell.

We believe that that should be excluded from the jury. I appreciate the defense counsel's argument regarding the case that's cited. However, those cases deal with someone committing tax fraud, someone, for example, that did not file income tax reports or fraudulently filing income tax. In most cases it dealt with criminal matters. And we believe that and Dr. Shell has been up front with tax issues. He has never denied that he has had tax problems, simply outstanding liens and/or debts that he owes. We see no probative value for that to go in front of the jury, but prejudicial. We would ask the court to exclude those issues.

Secondly, is that of his probation on his medical license. It is true and Dr. Shell admits that he was on probation as a result and has said in the deposition that basically he was duped by a patient to prescribe Dilaudid. He was give a probation. He was never stopped or suspended from practicing medicine and plead as a result of that. But, nevertheless, he was put on probation for a very brief time for that. And we believe that that certainly would be more prejudicial in light of the license. Probation came as a result of it.

With regard to hospital privileges, at Cedars-Sinai, he was suspended from practicing at Cedars-Sinai, and the facts were again as stated in the deposition. He sent his check for

stand in recess.

MR. LEVIN: I will be leaving now. I have a partner whose son is being barmitzvahed, and I just want to let the court know. If the court has any questions?

THE COURT: No, I don't. I appreciate the comments that all of you made in treating stuff. I think that particularly the question of designs are a fascinating issue.

MR. LEVIN: We are glad it is your issue now.

THE COURT: Okay, thank you. I have a conference at 1:30. It will take me 10 minutes, though. So be back here at 1:45. Court will stand in recess until 1:45.

(COURT RECESSED AT 12:08 P.M.)

P R O C E E D I N G S

(AFTERNOON SESSION

(Friday, March 7, 2003)

(COURT RECONVENED AT 1:45 P.M._

THE COURT: Which motion are we taking first?

MR. WRIGHT: We would like to take the motion that I filed, the motion in limine regarding Dr. Shell's issues before the court. I know that your Honor has read the briefs, and your Honor has informed us before the recess regarding what he feels about the issues of relevancy and admissibility. So I will be very brief. I will go briefly through the issue of

percent of the information comes from American patients, focuses on issues that were talked about, thought about in 1999 prior to the instance here. So there may well be some relevance under cross-examination or under even an expert taking that into consideration. But even if the expert does it under 703 basis of his opinion remember under the Knee Amendment that fact or data that are otherwise inadmissible shall not be exposed to the jury. Experts can take notice of them; experts can base his opinion on them but the fact of disclosing them to the jury may not be done under 703 unless, of course, the court determines that the probative value is greater than and can be of greater assistance to the jury than the other. That's the more recent amendment than when this case started. It has just come down, and it does do something to the 703 part. I'm going to take this issue under advisement.

I make these comments to the attorneys just so they know what my thinking is on those particular documents.

MR. AMEDEE: In that regard, your Honor, the court should be aware that plaintiffs in going through the initial exhibits that they are offering No. 267, which I think your Honor has Exhibit C, we have culled those documents to less than 100. So it might well make it a lot easier to address what they are.

THE COURT: Maybe more than I needed to do. We will

is at issue. And the person making that opinion and formulating that opinion is part of the case. Who is giving the opinion? What is their history for veracity, credibility, things of that sort all come into play more so than physical fact people who you can cross-examine on where they were and that kind of thing, physical facts. So most of the 401 objections I don't think are applicable to experts. I think everything is pretty much relevant to experts.

However, I think there the issue really, the focus is on 403. Whether or not this is cumulative, whether it is prejudicial, whether or not it is too confusing to the jury, whether or not it has some problem that upsets the way that the jury process the information. So the 403 is the issue for the experts.

With regard to this particular matter, the first item that the plaintiffs seek to introduce them to me to be the grave men of that report, and I am not talking about a 901 authentic type, I'm not talking about things like getting into evidence but just the substance of it. It seems to me to be dealing with children primarily. And we are dealing in your particular case with an adult. Most of the reports that I have read focuses on kids in the first issue.

The second document which you attach as B, I think Exhibit B, seems to me has some elements in it that focus on notice generically about the drug focus, on the fact that 60

the relevance standpoint. I can make some decisions on 901 admissibility. I can make some decisions on questions of privilege and so forth. The relevancy is more difficult for me to deal with.

It is helpful, however, to have motions in limine on it because it gives me some opportunity to have thought it out a little bit more, to have thought it through and be able to circle it for my ruling and then have the ruling more meaningful and more consistent. So I don't have any problem with motions in limine. But my rulings on relevancy generally are withheld until the case proceeds so that I can put it in context, because it doesn't make any sense, relevancy, when you take it out of context.

With regard to this particular issue before me, also let me say that with question of 401 and 403 having said that, I look upon experts in a different way than I look upon regular witnesses. A witness who is an eyewitness, they can have a lot of baggage that they carry. And although to some extent their character is at issue, what they say and the physical facts of what, where they were and what they saw and what their eyesight is and things of that nature are more significant than their character or their past or their baggage or whatever it is.

Experts, on the other hand, haven't seen anything. They make an opinion from what's been told to them or what they have reviewed or what they studied. So their opinion is what

again there are probative issues in Louisiana of prior reliability and efficacy. Are we not to be allowed to be able to use evident that's reliable, trustworthy and evidence that these plaintiffs need in the presentation of the case? I have been sitting here and I want to go back, and I hate to do this but the last sentence I made when I made my argument was that if the court rules in the favor of the defendants, the only cause of action that the plaintiffs will have is their warnings case, and I just wanted to clarify that for the record, because if I didn't say that, that's what I meant to say.

THE COURT: I thought that's what you said.

MR. AMEDEE: Thank you, your Honor. And I just ask for 54B because if that is the only cause of action, knowing fully there may be others that might exist, the item and expense associated with the trial would be, I don't think it would be advisable. And it is, in fact, a first instance case, case of first instance. I mean we, Mr. Irwin is right, there are no other cases out there especially in Louisiana that addresses it.

THE COURT: Okay. Let me make just a couple of general comments about evidence. First of all, the issue of relevance for the most part I look upon it as being contextual. And it is hard to exercise a relevance argument out of a proceeding. It is generally or has to be put in the proceeding at the time it is offered and so forth. To get some meaning out of it from

of the adjusted CPMP concluded regarding efficacy. It says (reading) Cisapride looks therapeutic in the indications of GERD. Regarding safety date from electro-physiological studies, clinical studies, spontaneous reporting and epidemiological studies show that Cisapride is associated with the risks of cardiac QTC and sudden cardiac death. That's what these cases are about.

The vast majority, if not virtually all of the materials relied upon by this agency in making their determinations were submitted to them by Janssen. They didn't just put them out in the air. So it represents the findings of a European publication agency. So subject to the exception, and it is admissible as a public record, relevant and reliable in establishing plaintiff's claims that he in carrying his burden, which we know now to be a strong one under the LPLA, the same can be said for the other document, the IKS, which is the counterpart of the FDA, and it also rendered an opinion that's relevant and reliable and probative of plaintiff's claim. You went into the document. I was going to read a quote from it, but I won't because there are findings in there that our experts relied upon that can be used in cross-examination of the defendant's experts and their witnesses that are probative in the case of the plaintiff's.

Now, there is one other item than foreign correspondence and this is Janssen's own competence. Once

this way. I mean it is a nice preview of what we are going to be faced with at trial, but I don't think it is the type of thing that you rule in or out at this point. Thank you, your Honor.

MR. AMEDEE: I will be brief, your Honor. You know, for two decades Janssen has, in fact, had and their counterparts total control of this drug, the information concerning this drug. Dealing with this foreign body, with that foreign body, with the FDA, we find out a few years ago that this drug had some serious side effects, might well be defective. Consequently we have to embark upon our task of finding experts. These experts have to rely upon certain documents. Dr. Stuppy did, in fact, rely upon the CPMP opinion in this evaluation of the efficacy and risks associated with the use of this drug. Whether or not Janssen was bound by it has no bearing on whether or not an expert for the plaintiffs can, in fact, rely upon it in the formulation of his opinion. Their opinion for Cisapride is relevant in that it is probative and reliable information that support plaintiffs' contentions and proving their case.

The LPLA, it addressed lack of efficacy, addressed risk/benefit analysis, and it also addresses alternatively designed probability, all of which the plaintiff has to prove in order for it to be successful in their cases.

I would like to quote from the document regarding all

they find out somebody slipped to know that they should put skid-proof material down on the floor or loading platform?

In the context of this trial, when the trial was taking place, your Honor, as a line officer rather than somebody that's scrambled eggs that ponders over decisions for weeks and months and does it just like this (snapping fingers), you can make a decision whether it is admissible or not admissible as the flow of the case goes on. I think these motions are make work. They are ill-advised as motions in limine. They are things that trial lawyers and trial judges deal with on a daily basis. To sit here and argue right now whether we weren't bound by the federal regulation our subsidiary company which is wholly owned by or parent company and that knowledge wasn't imparted to us and therefore that evidence should be excluded and we should have blinders on as to everybody that was going in front of us, all of these things, these warnings, these red flags coming up that they missed the target is going to occur during the flow of the testimony.

Your Honor can rule whether or not this is a notice issue or feasibility issue, whether it is remedial, whether it is a report from a foreign government, whether it is an adverse report, whether it is whatever it is. If it contributes to the knowledge that these defendants had or could have had, it would be relevant in the context of the trial. And it is I believe just ill-advised to deal with them on a motion in limine in

not regulatory documents. They don't make it either under 44.1. These documents are going to be offered for one reason only: So that somebody can stand up and tell a jury that some European government after some presumable broad study has come up with something conclusive and isn't it terrible. In fact, the European agencies had no authority whatsoever over Janssen Pharmaceutica. We answer to the FDA and that's who we were supposed to. Thank you, Judge.

THE COURT: All right, thank you.

MR. LEVIN: What I have to say is generic applies probably to 90 percent of the motions, maybe all of them, except causation motion. So I will just address it once. I have been in your court now for two or three years. I haven't seen you try a case. Heard a lot about it. But I remember when your Honor was down here trying cases. These issues are the issues that lawyers in court deal with at trial. In the context of the delivery of the briefs, all of these issues go to feasibility and notice. We are very sophisticated. We are handling a MDL pharmaceutical case. But it really boils down to whether you could have put a rail on those steps that a person could have held on to so they wouldn't have slipped. Or maybe some skid-proof substance on a deck of a vessel. And they do it afterwards. And if they did it afterwards, was it feasible for them to have done it before? And did somebody else slip and did somebody else slip and how many times did

contribution to the evaluation of the safety of Cisapride.

Comments of that sort the plaintiffs argue are informational and that the worldwide distributor of the drug should have responded to this type of information. How do you deal with that?

MR. CAMPION: First, your Honor, in fairness to the defendants, the appeal that the defendant took which led to the issuance of that document turned on a request for approval for dyspepsia. And the matters that you just brought to my attention I don't believe really address the basis of the appeal taken back in the Swiss matter.

Second, matters with respect to notice in that should be the basis for it come down to this: The defendant sought and obtained from the FDA and presented materials to the FDA. The FDA drew its own conclusions about the efficacy again and again and again. I know there is another argument out there about which product is more efficacious, but we are bound by the FDA. Our obligation is to the FDA. It is the FDA who regulates us, not someone whose name I don't know.

The document has nothing to do with what the appeal was all about and there is something basically unfair about that. And obviously at the end one would argue the balancing point now and I will finish the argument in the brief, and we expected the various customary hearsay arguments under 803(5) and 803(6) and 807. These are not business records. These are

So we have the business then of two separate agencies which have no control whatsoever over Janssen. Judge, there is some language there which you will find one way or the other that if you put that before a jury they will have no understanding whatever as to what this is. Janssen was controlled by the FDA and answers to the FDA. It sought approval by the FDA. That was the ruling agency that matters.

Finally, your Honor --

THE COURT: Before you leave that document, help me out with this reference in it. The date you mentioned was prior to the, there is some comment in the document at page 11, and it says it is displeasing that a medicinal product for such wide use with which potential life-threatening cardiac side effects have occurred and for which finding exist have such sparse human data. And it says also in the same page a total of 348 reports were analyzed. Of these 210 or 60 percent were serous QT, 40 of the matters for which -- then it says approximately 60 percent of all 348 cases originating in the United States.

Another one they said something about on page 13 no validation studies have been carried out. There is another reference here on page 14, it says to summarize it must be said that no estimate of incidents can be derived from these studies, that the reliability in the informative power of Cisapride studies with regard to serious cardiac during the use of Cisapride are very weak. And those studies make no valuable

A. Correct.

Q. Do you agree you have no expertise on any of the European countries which have regulations about Cisapride?" And his answer was "yes."

Your Honor, for all of these reasons, the issuance of a document which bears a date two years after this product was taken off the market, three years after Mr. Diez death and the injuries to Ms. Brock were advanced, there is no basis on the grounds of relevance.

Now, the second document was the so-called IKS. It is a product of the Intercontinental Cantone drug-controlled office. It is an agency of the Swiss government. It is one of those agencies that may or may not simply want to play by whatever IMEA says. The only document they have before you is a document from July 1999, and I can concede that is prior to the date of defendant Diez' death.

But what does it hold? It holds simply that a particular indication for GERD, which was sought by a Johnson & Johnson affiliate, not the defendant in this case, not Janssen Pharmaceutica, for functional dyspepsia was not approved. That's what it says. That's its holding. There is a lot of talk about this they came to that conclusion. The fact remains that GERD still remained an indication in Switzerland a second-line treatment in 1999, and GERD was a second-line treatment in America in 1999.

Answer: "No."

"Q. Have you any information whatsoever in your career of the European regulatory agencies or pharmaceutical regulatory agencies?" Answer: "No."

"Q. Do you have any greater understanding of the European regulatory agencies than you have of the FDA?

A. No.

Q. Do you know who the person, who the persons were who participated in rendering the opinion that you saw on the screen?"

The doctor had said that the only thing he knew about this is that when he went to the computer, he went on the WEB and up popped this screen. And his answer to that was "no".

"Q. Do you know how much time finally they spent doing whatever it is that they do to come to the opinion that you saw on the computer screen?

A. No."

Page 101:

"Q. You have no expertise in pharmaceutical matter?

A. Correct.

Q. Doing your inquiring for your expertise, you don't know what the EMEA is?

A. Correct.

Q. Do you agree you have no expertise on how the EMEA came to their opinion?

in two words. I believe we have laid out in the brief. The first is before the year 2000 and before we took the product off the market, and every single foreign country that is Europe, had their own regulatory agency. In the year 2000 as part of the Europeanization they created this agency called a CPMP, which is different from the EMEA, and at the end of the day the European-wide organization does not have FDA authority. What every opinion comes down to when we study this is whatever you are going to study are not binding on a single country. So the existence of this opinion has no regulatory effect in Europe. Each European country chooses to accept it, it can.

Now, with respect to what the EMEA opinion is, there is no evidence whatsoever beyond this piece of paper that says yesterday I did get this from Stuppy about the EMEA to see if in some fashion he was going to bring evidence to the table that would make it relevant to this dispute. It is formally stated in the motion papers of the opposing motion supposedly prefiled by plaintiff that Dr. Stuppy is not a regulatory expert. So I asked him a few questions to see whether or not he can bring anything to the court which would bring life to that document for you. I will just read a couple of questions and answers.

On page 99: (READING) "Do you have any information whatsoever as to how EMEA, or whatever it is, studied the subject that was the basis of the opinion that it issued?"

FDA. And there is no dispute about the fact that during the time Janssen was selling Propulsid in the United States it had received FDA approval in 1993 from the FDA that the product was safe and efficacious when used in accordance with package inserts, and on six separate occasions from 1995 to the year 2000, six additional approvals were received from the FDA for Janssen for various changes in the product insert, product warning, all of which concluded that the product as labeled remained safe and efficacious. In view of the FDA approvals, those are common to all of the foreign regulatory issues.

As to this CPMP document, I offer the following additional arguments, and by those arguments, I think by themselves should be sufficient to enable the court to deny use of the evidence of foreign regulatory matters simply on the ground that of their relevance. As to the CPMP, the document to which counsel wishes to present to the jury and have presented in some fashion through Dr. Stuppy, is a document that bears a date of 2002, more than two years after the drug was taken off the market in the United States. The conclusions reached in that document address matters which go beyond the scope of this case. And this, we turn our attention to the issue of what is the CPMP.

And while there is no federal foreign regulatory expert offered by the plaintiffs, what is the foreign regulatory scheme? The foreign regulatory scheme, your Honor, described

too much time for lunch because I'm boring enough.

THE COURT: All right. Anything we have to do before? If not, we will --

MR. IRWIN: Are we going to take up the forum regulatory matter? We can do that in five or six minutes, Judge.

MR. CAMPION: We have filed a preliminary motion to exclude all evidence respecting foreign regulatory matters.

THE COURT: Let's get that one for a moment.

MR. CAMPION: Judge, the foreign regulatory matters fall into three categories. Number one, documents which counsel have come to call the CPMP, okay, 2002 opinion. The second matter is called the IKS document, and the third is some internal memoranda from Janssen. This is addressed in this motion.

It is also addressed in a motion reading Dr. Dupuy, who I believe is the only plaintiffs' witness who is prepared to speak to the issue of the foreign regulatory matter common to all issues is the following: That the plaintiffs have not advanced a single foreign regulatory expert witness to address for the jury or for the court any of these matters.

Second, there is not dispute about the fact that these foreign regulatory agencies, of which I will speak, had no authority agency to which Janssen Pharmaceutica manufacturing and sale in the United States was obliged to answer was the

the law now and that's why we think this is a court question.

THE COURT: Okay, fine. Thank you very much. I'm going to take the under advisement. I'm not going to rule from the bench on it. Give me some logistical advice from the standpoint of the other motions that we have. Do you want to take a break for lunch and come back, or do you want to go with the motions?

MR. IRWIN: That's fine with us. We have a couple of motions that I think could be addressed in a little, matter of a couple of minutes. There are a few more that will take 10 minutes or so perhaps on each side.

THE COURT: All right. Let's take those. We will go until 12 o'clock. We will take a break and see where we are.

MR. IRWIN: When we come back, we are going to go until 12 now, and then I think what we would like to do, your Honor, is mindful of your Honor's comments this morning about the Diez causation motion for summary judgment, Mr. Murphy would like to address the court on that briefly and address some of our what we think are some issues involved in that.

THE COURT: All right.

MR. MURPHY: I'm not one of those two-minute guys and so I'm going to need more time than the 15 minutes, and I would appreciate going after lunch.

THE COURT: All right.

MR. MURPHY: But I would pray, your Honor, I don't need

factually supportable. That's number one.

Number two: I believe that much of the argument concerning the LPLA and the suggestion that the language is ambiguous, which I do not agree, would be an argument that is better made to the legislature without changing LPLA.

Next, I still heard and the court has still heard no cases cited to it from any jurisdiction in this country providing a precedent for drug-to-drug comparison as a reasonable alternative design. There are many states, most states, in fact, have a reasonable alternative design requirement as part of the equation of design liability. No other states have reported and cases where you can use another drug as another product for alternative design.

In 54B we would agree with the 54B ruling provided it comes after a verdict. We think that we ought to proceed with our trial on way or the other. And then after that we certainly agree that 54B would be appropriate.

And then finally in response to your Honor's question that it was suggest, yes, your view of liability is that this drug's risks outweigh its benefits. And that is the question to be presented to the jury. And then it should go off the market. And that is precisely what the law in Halphen was. That was the law in Halphen. Was asbestos unreasonably dangerous per se such that its risks outweighed its benefits and it should be off the market. That was the law. It is not

under the reading of the statute as Mr. Irwin would want the court to read the statute.

Now, while we are messing around in Louisiana with this issue, we have states that do not have these issues. And as much as I tried to have general verdicts, we have very few courts that allow general verdicts. So if we could remand cases to the various other jurisdictions and start seeing what other jurisdictions are doing with certain cases, some of those questions will be helpful in answering the specifics of the jurisprudence in Louisiana. And then maybe we could develop the end game or maybe that is developmental in the end game. Thank you, your Honor.

THE COURT: Thank you. Let me hear from defendants.

MR. IRWIN: Five comments or five points briefly, your Honor. Argument was made that if this aspect of the claim, the design aspect of the claim is dismissed, then they have no claim available to them. And I don't understand that, because they certainly have a warnings claim available to them. But in some respect it feels a little bit like to me that they are almost conceding the warning claim, that the warnings have gone to the doctor; the doctor is apprised of the risks. And when the suggestion is made that no claimants in Louisiana who use drugs have no claim available to him or her if this motion is granted, overlooks the existence of that warning claim and suggest to me in this case that that warning claim is not

would not have killed Mr. Reed. Mr. Diez if he did not die as a result of this injection and did not cause Ms. Brock prolonged sustained fatigue, that is the case.

So if the court decides in the defendant's favor after all the work we put in, I would ask that the court certify this as a 54(B) and give us the opportunity to file any state proceedings. The problem I have here is that this will take away half of Mr. Diez's cause of action and a substantial half. And it will also affect thousands of cases here in Louisiana. If this is accepted in the position it is accepted, the only causes of action that plaintiffs in Louisiana and quite possibly lots of states will have is a warnings case. And I just don't think that is the status of the litigation. The tort system is drug therapy; sale of drugs is void in that manner by our tort system.

THE COURT: Okay, fine. Do you have another comment?

MR. LEVIN: I know I am out of turn. A question that your Honor asked, and I will be very brief, is your Honor asked what are we to do if FDA says it could be on the market and Buckman says we can't question the FDA. Fortunately we have the lover verdict. The FDA does not preempt, never preempted drugs and really doesn't preempt medical devices. I mean, there are minimum standards. They do not do their own testing. They rely on the defendants for testing, and there is not federal preemption under the FDA. Where there is preemption is

be an easy task in this case. But our burden is one of those four. We know two of them don't apply.

And in a warnings case, especially in a case with a drug like this, that probably between letters to doctors, label changes, you have dozens of them over a seven-year period that we have heard the term label fatigue. The could very well be that this particular drug you couldn't give an adequate warning, and doctors just got tired of seeing them.

So what to do with this big conglomeration of confusion? You look at the product itself, and you do a risk/benefit analysis with the requirement that alternative design existed. The question if for the court and for all of these courts is whether or not that alternative design can be alternatively designed drug. We know there were plenty of those out there.

THE COURT: Another product?

MR. AMEDEE: Alternatively designed product.

THE COURT: Right.

MR. AMEDEE: That's what I like to call it but same product. So I have to join in with Mr. Levin. Counsel for defendants and I were wondering as to whether or not the court made a definitive statement, and I don't think that the Reed case required it. In this case and in the Brock case and Diez and Brock obviously there were alternatively designed drugs that could have been given to these two people that first off

THE COURT: But if we create in society a FDA, we tell the FDA it is your job to tell us what's proper to get on the market, and then we tell the tort system there is a requirement to warn, there are going to be several problems with drugs by their very nature of various drugs that the drug is a dangerous thing. But we are going to require them to make certain warnings on the label, and if they fail to make the warning, then people have a claim. But it is up to the FDA to tell whether or not something is appropriate for the market. That's their theory. What's wrong with that?

MR. AMEDEE: That bootstraps the defendant, I mean the plaintiffs' complaints because we can't, we don't have a cause of action as to that relationship with the FDA and the defendant. And we don't have a cause of action at least here in Louisiana and the vast majority of states for the promotion of the drug. You have to show it is defective. You have to show that --

Some states have the prudent manufacturer test, the consumer expectation test, which I think Louisiana does kind of lean toward, although it is not set for in the Act. And all of those establish the fact that you have to show a drug was or a product was defective when it left the manufacturer's control.

We did away with the negligent standard here. If we could have a negligence standard in this case, I wouldn't be standing here arguing about this right now because that would

business in the sense if they can't they can't change their pill because it is their pill and that's patented. It is with A, B, and C chemical and that's the chemical composition of their pill. They can't manufacture it with A and B because somebody else has a patent on that particular drug. So what do they do then?

MR. AMEDEE: They get in the market like Janssen did because that's when you get to the balancing. Once it becomes a fact, Judge, that this product is so unreasonably dangerous, then they have no alternative but to take it off the market, put it into some program or something of that nature.

You mentioned these drugs that are extremely dangerous: Chemotherapy, age drugs that borders on this concept of common K, the restatement. We don't have that. And it looks like these defendants are retreating to that position. With this drug when they have FDA statements that it could have a condition that could have been life threatening that could be treated with Tums, they are going to hide behind the fact that since you can't tell us how to redesign this drug, we are fr4ee to keep it on the market as long as we could, until the handwriting was on the wall, avoid advisory boards, committees, this, that and the other facts and say, okay. We better get out of this. I don't think that the Louisiana legislature intended that. I certainly don't think that society has made that judgment.

So along came the new product, the screw. The court said show us a better screw. I think in the amicus that was filed by the PSC they said you can make a screw longer, fatter and have different thread bars and most importantly even change to titanium.

It is not the case with drug therapy. Drug therapy is drug therapy. Whether a pill is round, whether it is square, oval, you take it the same. It goes through the same mechanism going into the body, and you don't redesign it by a method of injection. Some people can't swallow a pill so they have to take it intravenously, but it still has the same metabolic reaction when it enters the body.

THE COURT: What makes it defective in your view? Is it defective because the risks outweigh the advantages?

MR. AMEDEE: Your Honor, that's what our Act says we have to show, that a product is unreasonably dangerous in its alternative design requirements. Then we have to do a risk utility analysis, that its severity of risks are outweighed by its benefits and that an alternative design existed which was feasible, and the manufacturer could afford both economically feasible and could be manufactured feasibly.

THE COURT: How can they do that? They can't manufacture another drug because they have a patent on that particular drug just as there is a patent on Cisapride or Propulsid. So they can't manufacture it. So they are out of

the drug got into the doctor's possession. As to how the drug was promoted, all those honorariums and conventions. So we have to look at the drug. That's all we can do is look at whether or not the drug is so defective as the statute says when it left the manufacturer. That's what that cause of action says.

We also have to look as to whether or not when it left the manufacturer there was an alternative design. So what this argument is about: It is not about risk/benefit. It is not about unreasonably dangerous. It is really about whether the court will accept an alternative design drug to satisfy those requirements. Now, the defendants have tried to bootstrap, and rightfully so -- not rightfully so, but understandably so, the pedicle screw cases as being applicable and have cited Theriot and a number of other decisions and here in the Eastern District. The pedicle screw device utilizing a spinal device using pedicle screws is a multi-component device that has rods, it has a bar, it has fasteners and has screws. The alternative design that the plaintiff in that particular case set forth -- I wasn't involved in that case, but I was involved in the pedicle screw cases, was a clamp. You got a clamp over here, a screw over here. These two things are machined differently. These clamps have been used for many, many, many years, back into the '30s, '40s, back in the Herrington rod that was hooked with clamps.

did they take the docs to nice places and entertain them for Cisapride? They do that. Did they take them to seminars and invite their wives and children to some nice places? They did that. Did they give them stock options? They do that. Did they give them honorariums? They did that. Did they ghost write articles for them and pay them to sign the articles? They do that. Others look at the articles that were signed by somebody that they thought was prominent not knowing that is ghost written and prescribe the drug.

Is there a learned intermediary defense there? Perhaps the jury would say no. All of these real concepts, the facts of the particular case would develop in a trial. And the fact finder, as the fact finder mostly does would make the right judgment. All that and we would be back to where the legislature said the law should be: Pre-Halphen, not the law that Mr. Irwin wants this court to adopt.

THE COURT: All right. Thank you. Any response?

MR. IRWIN: Should I wait until Mr. Amedee goes?

THE COURT: Yes.

MR. AMEDEE: I had an argument all planned, but the arguments really opened so many doors. The Buckman case does, in fact, prohibit a plaintiff in Louisiana from presenting evidence regarding how the drug got on the market. Louisiana's law limiting the causes of action to four as your Honor has stated limits the plaintiff from presenting evidence as to how

because my doctor told me to take this product. So isn't that, does it from the defendant's standpoint they say that if you include in the concept of alternative products a different product, then that in effect introduces into the area of design the intermediary defense, because the person who picked that product is a learned intermediary, and they did everything they could to inform this learned intermediary. The learned intermediary understood it and said notwithstanding those risks I believe this is the product. So they are off the hook. We have always had a learned intermediary.

MR. LEVIN: We have had this defense before.

THE COURT: In design or in warning?

MR. LEVIN: In warning.

THE COURT: Does this mean that it is part and parcel of design?

MR. LEVIN: As you play conceptually through with it, you just can't separate all these different concepts by themselves completely. At some point they all become a soup and they mesh together. As we lawyers know, and the plaintiffs' bas has dealt with the learned intermediary, I mean, perhaps your Honor might adopt the Perez case in New Jersey which says that if you have direct promotion on television, you don't have a learned intermediary perhaps.

Perhaps if the jury in looking at the learned intermediary defense would look at how they promoted the drug,

then it goes on to say that the person who alleges defective design has to prove that there is alternative design out there. So your burden is to show there is alternative design, you in effect are showing the existence of another design as opposed to alternative design, in a sense that it is a different design. So the question then is whether it is an alternative, whether the issue in the drug cases whether alternative design includes different design or different product.

MR. LEVIN: It has to, your Honor. Because it makes no sense if it doesn't. And that's why there has not, the Theriot decision did not really get involved in that, and it was a product, but it nevertheless touched consistently on what we are discussing here for a prescription drug.

But with a prescription drug, the alternative design it must be another product. My God, we played with the molecules and isomers. And I were to say that we have spent $16 billion like they spent to develop Cisapride, and we now have an isomer that's better and the hydrogen rings in different positions, if that's what an isomer is, they would be arguing, well, I changed the product; it is no longer the molecule that is the product and is uniquely designed. It just can't be that way.

THE COURT: And then the question that you are confronted with and that's the Catch-22 in a situation is that when there is a different product then you ask the plaintiff, well, why didn't you take that product? And he or she says

different because in drug liability you are not only dealing with a regulated industry as you are with medical devices, but you are also dealing with chemistry, not mechanics, not the make of a steer4ing wheel as to whether the steering wheel can collapse on impact or not collapse during impact. You are well beyond that. You are in a very, very sophisticated area. You can't have alternative designs. And if your are, if that's the law that you must have an alternative design in Louisiana, then you have given the pharmaceutical industry a free pass to do whatever they want to do. They can mislead the FDA, not report adverse reactions, not report deaths, not report injuries, not report what they see of a product in foreign countries, mislead the FDA plaintiffs. You can't go into the FDA. Buckman prevents you from doing that.

Plaintiffs, you can't show that you create this benefit with another product and alterative design when it comes to drugs. It would have to be another product, because the Louisiana legislature said you can't do that. I don't think that that's the case, your Honor. I don't think that's the result that's judicious. I don't think that's the result that any fair reading of the statute and the jurisprudence of Louisiana dictates. So that makes me --

THE COURT: Share with me your view on how you get there. You have got a statute that says there are only four areas of liability, and one of those is defective design. And

be the result of this particular statute.

So where do we go from here other than your Honor writing an opinion? I would suggest, your Honor, that is your have -- I think it is a monumental situation. I think this is a very, very important thing, and it certainly has an impact on the jurisprudence in Louisiana and probably elsewhere. Because other legislatures are looking to other statutes with regard to tort reform and want to know how they are being interpreted by the Couar courts. I have no crystal ball as to how your Honor will rule, but I suggest that there be appellate review, 1292(B) or probably if you were to agree with Mr. Irwin a 54(B) dismissal, and we would get it up. I am not familiar with Louisiana practice to know whether your Honor has the ability to ask the Supreme Court of Louisiana to interpret the legislative system. I'm not sure that you do or you don't. But I know the Fifth Circuit does.

Perhaps with the suggestion to the Fifth Circuit to do this, because this is not the first. This is going to come up over and over again in all drug liability cases. And the courts have always handled drug liability differently than widget liability. 402 is a wonderful concept, but the restatement of torts is comment. It is there for drug liability. And the restatement of torts third doesn't even touch alternative design in drug liability. It has some other onerous provisions, but it recognizes that drug liability is

constitutional. And the Supreme Court of the United States said just that in Squid v. Kerr Magee when they tried to read out of the Price-Anderson Act the claim for punitive damages. And the Supreme Court said I can't believe the legislature intended to take a right away without giving something in return. And as such punitive damages remained under the Price-Anderson Act and under Soquid.

Now, when you take this statute coupled with the Buckman opinion in the Supreme Court, which says you cannot prove PLC, Plaintiffs Legal Committee v. Buckman, you cannot prove fraud on the FDA. You can't show that the defendants attempted to mislead the FDA. You are in the tort section. The FDA regulatory commission has nothing to do with it. It is up to them to enforce their own rules. It has nothing to do with tort liability. If you coupled Buckman along with the reading that Mr. Irwin wants you to make of this particular statute, the Louisiana claimants who took Cisapride, for that matter any other drug, would be out of court and are out of court, and I don't think that's what the governor intended. And it doesn't appear to be what Mr. Kennedy intended. It doesn't appear to be what Mr. Moore, who represented the Louisiana Trial Lawyers, intended. It only appears to be what the industry wanted that statute to accomplish. And I can't believe that we as a society as advocates on one side in court and the Fifth Circuit and the Supreme Court would allow that to

having this different product. And I don't think that issue was before the Louisiana State Legislature when they discussed several bills in one siting and have a 20-something page record of the same. It just wasn't there.

As I read the legislative history and the comments that were made by Mr. Kennedy who was representing the governor and the governor was concerned about jobs in Louisiana and having some sort of tort reform, if that's a concept, and proposed that a terrible thing happened in Louisiana. There was the Halphen case. And suddenly we want to go back to traditional tor concepts with regard to 4002 A cases, and the way to go back is to adopt this statute with alternative design, and we can overcome the ramifications of the Halphen. Well, there was drug liability in Louisiana before the Halphen case. And there was the intent of the legislature was for there to be drug liability after the passage of that statue. And the reason you don't find any cases on defective design is narrowed to be argued the way we are doing here in other jurisdictions is they are not faced with that particular statute and trying to somehow fit in or fit out, fit without that statute. But that's what we have in Louisiana.

And I do believe that when statutes are ambiguous and when statutes are applied the way a party wants them to apply would take a right away without a quid pro quo, that the statute has to be read in such a way that the statute becomes

record. The plaintiff's attorney failed to show for the argument, was called to court and God Bless the Fifth Circuit. They waited for him to get in his vehicle and get to the court and argue before them. That would not have happened in my jurisdiction in the Third Circuit.

And in Reed I do not believe you had a proper record before you, and the PFC did not address it because in the February 3, 2003 transcript, a fair reading of that transcript at least the way we read it is that your Honor was looking at something that was very, very case specific with regard to the symptoms and the treatment of the Reed plaintiff. And the products liability statue in Louisiana was not up front in your Honor's reading at that time. I believe that's the way I read your Honor. Your Honor knows better than I do because you wrote the opinion.

But if Mr. Irwin is correct, then there can be no drug liability in Louisiana. None whatsoever. We re not -- I believe that hooks and other types of screws, rods, are alternative products. And Theriot was wrongly decided, because the record hadn't been made properly by expert testimony in Theriot. But even that is a far cry from Cisapride, a chemical that has a molecular composition, has hydrogenics that are unique, patented and only as to itself. And I don't know how you can tamper with that particular molecule to make an alternative design without changing the molecular molecule and

certain products, especially those that are heavily regulated will be available to the public through certain, in certain limited ways. And this would include prescription drugs, and that those drugs so long as they are permitted to be available and are accompanied by proper warnings, while they may be very dangerous to many people and many circumstances, does not make them defectively designed. They are what they are. They are designed to embody those risks. Those risks are a direct result of those designs, that design which cannot be changed without changing the product.

THE COURT: Okay, thank you. I understand your argument. Let me hear from the other side.

MR. LEVIN: Good morning, your Honor. Mr. Amedee has allowed me as amicus to go first. I'm not going to be as case specific as he is. I do not share Jim Irwin's views especially when they come to drugs. I can't believe society or the legislature in Louisiana made the judgment that has the ramifications that Mr. Irwin attributes to them.

Your Honor is faced, despite the Theriot case -- am I pronouncing it correctly? Because I say Dalbert for Daubert -- it was the three pages. Your Honor's Reed case I believe came up as an aside and wasn't as fully developed. As your Honor in begriming to think about this, and counsel are going to aid you in the thought process, in Theriot it is no excuse for the opinion, but that court, the Fifth Circuit, did not have a

regulatory authority authorities are going to permit it to remain the market, that that risk/benefit equation and that if doctors are going to elect to use it, presumably they have been fully informed of the risks and benefits in the product labeling, that the responsibility would then not be with the manufacturer of that drug. I don't know that there is any case, there is not case anywhere that suggests that there is negligence against that manufacturer merely because that drug happens to be "more dangerous" than other drugs that might treat HIV, treat cancer.

THE COURT: Your position is that as long as, you meaning the manufacturer, advise of the risks you can manufacturer any drug with any risks as long as there is some benefit, even if it is overwhelmed by the risks if you advise the physician, and he is fully or she is fully informed of that risk and you require that it be a prescription drug?

MR. IRWIN: Yes. And that presumes that the drug is properly on the market and permitted to be labeled in that way by the FDA.

THE COURT: You would shift the responsibility then to the FDA rather than the tort system, is that what you are saying?

MR. IRWIN: No, no, your Honor. I don't mean to be, I don't think it is a shifting of responsibility. I think it is a, I think it is a judgment that we have made as a society that

appropriately.

And every drug in one respect or another could be called a dangerous product, every single one of them all the way from aspirin on up. And in our society and our laws recognize that certainly with respect to prescription drugs that we want those judgments made by professionals. And they will make those judgments about risk and benefits. So, yes, there are dangerous drugs and there are dangerous products on the market. And alternative designs to those products to not result -- I should say -- let me rephrase that. We don't judge the dangerousness of those products based on the availability of other products that may be less dangerous. What we require is that those products be appropriately labeled.

THE COURT: I can see, for example, a manufacturer manufacturing, say, a drug with 99 percent of risk and one percent advantage. But if it cures AIDS and there is no other drug on the market and those risks are described, maybe that's okay. Twenty, 30 years hence when there is four or five or six other drugs on the market that equally cure AIDS but don't have that 99 percent risk, does that drug then become defective or does it simply mean that the prescriber may be negligent for prescribing a drug with that many risks when there are other drugs out there that don't have the risks?

MR. IRWIN: Maybe. I don't think that drug becomes "defective". I think we made a societal decision that if the

determining its efficacy, and if you conclude that its risks outweigh its benefits and it should be "off the market" and you can do that by looking at the risks and benefits of other drugs by comparison, then you can find that this product is unreasonably dangerous.

That is the exact point that was being made by Chuck Moore in the transcript that we present to your Honor last time where Chuck Moore made the observation that the LPLA could change the law under Halphen as it relates to products that cannot be redesigned. That's what he was saying. You cannot redesign a product; then the LPLA may not have a cause of action, effectively have a cause of action for that product.

And that's a fact, Judge. If you can't redesign it, if it is incapable of redesign, then there is no alternative design. And I think that's what we have got here. I cannot redesign Cisapride without making something other than Cisapride.

THE COURT: Can you manufacture a defective, a dangerous product and then everybody recognizes that it is a dangerous product, and nobody has a claim because there is only one product?

MR. IRWIN: I think you can, and I think you do. I think the manufacturers of a dangerous product label them, because sometimes the dangers are apparent and sometimes they are not apparent. And they are supposed to be labeled

of a pedicle screw from stainless steel to titanium and not change the product, it is still a screw, still does exactly the same thing, if you change the Cisapride and it is no longer Cisapride, it is no longer a screw. That is why Dr. Eckberg doesn't get on the witness stand in any state in this country and suggest to the jury that they can consider Metoclopromide as a design for Cisapride, not anywhere. And that is why the pedicle screw cases went the direction that they did.

Initially they felt like alternative treatment cases, but they were also advancing different design theories as well. So, your Honor, we believe that the analysis that Theriot has is correct. If you use that same analysis and apply it to a witness like Dr. "X", who proposed to use a different product, then it applies.

And finally, with respect to the LPLA, it gets us back to the other issue. Although I do believe this firmly, it is a balance question. It involves drug regulation, the FDA and decision by surgeons. But if you focus and narrow this down with LPLA, which we do eventually, if you go back and look at this issue, the way they present their case and the way they want to present this case and the way Your Honor analyzed the issue in footnote three in Reed, basically what they want to do is to take us back to Halphen.

And they want to say to the jury you can determine whether this produce is unreasonably dangerous just by

arguments drifted into the ideas of design. And so then the plaintiffs would advance that the design argument, the "designing argument" that, look, those pedicle screws are unsafe when you put them in the lumbar pedicle. And a safer design -- and this is where it became determinative -- they said a safer design would be hooks or a safer design might be a rod that wouldn't expose the patient to these risks of nerve root irritation. Or they even said a safer design might be for the surgeon to use a bone graft and use the person naturally rather than using hardware at all. And the courts saw through that particular line, and they say those are alternative treatments, or they are different designs, they are not a pedicle screw -- they are not a screw.

Now, some of the plaintiffs did advance or at least tried to advance the traditional same theories involving the pedicle screw, and they said, well, this pedicle screw was defectively designed because it is made out of stainless steel. This screw would be of better design and it would not corrode as much if you made it out of titanium. Bingo. There is alternative design. Exact same screw to be used by the surgeon, the exact same way, no more. How the surgeon chooses to use it, but they change the composition of it, but they hadn't changed the product.

Now, that is very relevant to what we are dealing with here. Because if you change, if you can change the composition

particular case --

MR. LEVIN: Not that case.

MR. IRWIN: Not that case. He and I were in for a long time up in Philadelphia, but what all of those cases involved was the decision by doctors to take an orthopedic bone screw and implant that orthopedic bone screw in a lumbar pedicle in a location from which it was not labeled for use for an implant by the FDA for an indication. And the argument went, of course, that there was grounds of maybe promotion for use. That was the thrust of those cases.

There were also arguments made that the pedicle screw system was unsafe and that lost of extra risk, because if you screw the pedicle screw into the lumbar pedicle, you invited risk of another root damage; whereas, if you took that exact same screw and if you screwed it into the sacrum, into the sacral path where there was not these nerve roots, you would not expose the patient to the same damage. In those cases the court said, well, that was a choice of "treatment" by the doctor as to where he or she chose to put that pedicle screw. Whether the pedicle screw was chosen by the doctor to be put into the sacrum or whether it was chosen by the doctor to be put into the lumbar pedicle, it was a choice of treatment.

But other arguments were advanced by the plaintiffs to try to salvage those cases and to keep them from being dismissed on summary judgment. And that is where those

that these pharmaceutical cases around the country were determined on that basis, we would se it reported. We would see it in the Fifth Circuit. We would see it in Novartus, in the Stone v. Novartus case. We would see it everywhere where the parties have litigated and presented theories of liability about, well, was the Lamasil, which was the drug used in the Stall case, was the Lamasil safe enough in comparison to another fungus drug? We have heard that that would have ben litigated forever in the Stall case. We would hear it in all of our cases. We would have courts of appeal addressing it, the risks of the design of all sorts of drugs and comparing them to what was the safety profile of a different drug. And we don't do that because it is not an alternative design. That is the reason, your Honor.

THE COURT: Okay. In the Theriot case the court, the Fifth Circuit said that when the argument is that you should be or use another medicine or place another device, in that particular case that that would be the call of the doctor as opposed to the patient. But does that case say that it's not alternative design, or does that case say that it is the learned intermediary's decision and that is the proximate cause?

MR. IRWIN: I think that case says it is not alternative design. What we were dealing with in that case, and Mr. Levin and I have handled them to the bottom of that

So it is not threat the LPLA does not apply conceptually drugs, it just says that if you are going to say alternative design, you are going to have to do it in certain ways. And it can't be by using a different product. You can't change the molecules. That is no longer an alternative design.

Our classic alternative designs are the kind that you described this morning in chambers when we had the other discussion. It is the kind that I described. I think we have our Reed argument when we talked about the Brown v. Ferral Gas, which was a case that the plaintiffs cited, where that case involved a custom smoker. It was a propane-fired smoker. And the question was whether it could be redesigned or apply a hot valve that could shut it off. Those are all classic design cases.

And what we are dealing with here is a question about whether Rezulin is an alternative design for Cisapride. That's the bottom issue. Are we going to allow it in this case? That's the issue. And as a practical matter, are we going to allow in this case Dr. Eckberg to get up on the witness stand and tell the jury that it is feasible alternative design to Cisapride to Rezulin? And I don't propose to go into the qualifications of him because he is not a drug designer. I only make that point to show just how off in left field that really is.

Because if that were the case, if that were the case

THE COURT: Treatment?

MR. IRWIN: -- different product, you can call it a different treatment, you can call it a different product. It is not a new design. A new design as the commentators have analyzed, whether it is the third commentary to you, two commentary or one law review article, they fall into three or only three categories of the drug. If you want to suggest that Volmax or Cisapride or Metoclopromide can be delivered a different way, either in time release or injection or might make it --

THE COURT: Syringe as opposed to pill?

MR. IRWIN: Yes, sir. That is one of the three. The other is dose. If you can suggest that a safer dose would be a different design, that would be another. And the third is if it is like a good example is a vaccine or an influenza virus.

Apparently an unknown vaccine which is mentioned earlier by the World Health Organization, it is a recipe that's used of three viruses that they select, those are the only tree ways that you can present an alternative design. If you go to a different drug, Rezulin is not Cisapride.

And that is exactly what the court said. It said the only active compound is a chemical compound known as Triazolan. As a scientific constant Halcion is incapable of being revised, modified or re-defined or alter the chemistry of Riazolan molecule would be to create a new compound and a new product.

drug? I mean, how does the plaintiff go about proving it?

Let's assume as the Product Liability Act in Louisiana says that defective design is one of the four theories, and then 2800.56 says a product is reasonably dangerous in design if at the time the product left its manufacturer's control 1) there existed an alternative design for the product that was capable of preventing plaintiff's damage. So that's one of the elements that the plaintiff has to prove in a defective design case.

There is no provision in the law of Louisiana that says drugs are excluded from product liability. So I assume that drugs are covered by products liability. And if they are covered by products liability, it seems like unless there is a specific exclusion for drugs under the defective design, then they are covered by the defective design theory. And if part of the defective design theory burden on the plaintiff is to prove an alternative to that particular drug, now do they do it other than by showing that there is another drug capable of treating the condition that is available? How do they do it otherwise? Aren't you in effect saying that sub se lento there is no defective design case for drugs in Louisiana?

MR. IRWIN: There is, and in three categories those are ones we described in our brief. It would be, the difference is I think, forgive me for being over simplistic, but what they are suggesting in not a different design but --

we look to find cases, but it is not a surprise that the plaintiffs have not directed us to one case in America where there has been a design claim for drugs where you compare drug to drug -- you made drug comparisons -- there isn't a single case. They cited six cases which we clearly distinguished the last time, and I won't go through those again.

They didn't purport to try to respond to those distinctions that we made in our reply brief. None of those cases involved drug-to drug comparison, not a one. One state did involve a comparison of adermidicid or herbicide to another chemical, but none of them involved drug-to-drug comparisons. And that is at the very heart of this question. And that is why I suggest to your Honor the drugs are different because of the role of the FDA and because of the role of doctors. That is the overriding fundamental really conceptual issue here.

Then we can talk to LPLA, and it doesn't make any difference whether we are talking about Mrs. Brock or Ms. Reed or Mr. Diez, they are all going to have different side effects. They are all going to have different benefits, and they are all going to experience different risks with whatever medicine that they use.

THE COURT: But is your argument focused on the fact that the learned intermediary defense is not only available in warning, it is available in defective design as opposed to the argument that an alternative is not or may not be a different

should not have such dire side effect as sudden death, arrhythmia or prolonged QT interval, and if it does as is the case with Propulsid, the drug is defectively designed. And I do think that that is their argument, but it is not the law.

That is not the law in this state. It is not the law under the LPLA. And for that matter, Judge, and I think this is the most important thing, it is not the law in any state in this country. And the reason it is not is simply because we are dealing with drugs. And we can talk about the law, and I am really more skilled to talk about them today, but fundamentally what they have said is we made societal and regulatory decisions and opinions about the handling of drugs in other societies; therefore, the FDA make regulatory decisions about what drugs are going to come onto the market, it makes regulatory decisions about what drugs will go off the market.

The analysis the FDA applies is not at all the same as what a jury might apply. And drugs are used by individual based on prescribing decisions by doctors who make risk/benefit determinations about whether patient A would be better on Rezulin or might be better on Asofax or patient B might be better on Propulsid or might do better with Xantac.

For these reasons that is why drugs are different. And, therefore, it is no surprise, and I guess maybe a little troubling and why we lawyers like to go to the library because

left with the suggestion that we could start with the design motion.

THE COURT: That's fine.

MR. IRWIN: Is that acceptable?

THE COURT: Yes.

MR. IRWIN: Your Honor, I will avoid repeating as much as I can the discussion and comments I made at the rehearing. Some of them I think necessarily need to be recited to some extent here. We would suggest that although I guess in some respects that is an unusual question and certainly and interesting question, we think it is a question that has a clear answer. The issue or rather the argument that the plaintiffs make is that Propulsid is unsafe and should not be on the market and that there are other, more effective drugs to treat GERD, and they would suggest that these other, more effective drugs are alternative designs for Cisapride, IAH blockers and Anaside and Rezulin. They say they have less dangerous side effects, and they would suggest that that balancing test would permit a presentation of a liability question to the jury, that the jury would be able to make a judgment about the design to other drugs.

Your Honor sort of capsulized the issue in a footnote in your Reed opinion where you said, and this is footnote three, the thrust of plaintiffs' complaint seems to be that a drug design for the treatment of a gastrointestinal problem

to amend the order to make it clear that my ruling applies to only those three cases, reserving everybody's right to urge or to defend on the other areas. Okay, anything more on the MDL?

MR. IRWIN: Next month, your Honor?

THE COURT: Yes, let's get a date then. The 25th, April 25th is convenient. I'm going to be trying some cases in Laredo, Texas the following week, so I will be out of town.

MR. IRWIN: Okay with defendants, your Honor.

MR. WRIGHT: That's fine.

THE COURT: Before we leave, is there anything further from the state liaison, anything further from the states?

MR. ARSENAULT: No, your Honor.

THE COURT: Okay. We will take a break at this point and come back for motions in limine. Court will stand in recess.

(COURT RECESSED AT 10:32 A.M.)

P R O C E E D I N G S

(Court reconvened at 10:42 a.m.)

THE COURT: Okay, we have some motions before the court. I understand that the parties would like to decide the order or have some ideas on the order of the motion. I will take them up in whatever way you want to take them up.

MR. IRWIN: I believe our discussions this morning we

three of that minute entry was that the paragraph should not apply to any matter other than the three cases cited. And I believe there is not disagreement as to that either. However, the PFC is very concerned about the scope of that motion, and it should be limited. We have filed with the court two declarations. I have the original declaration here to present to the court of Mr. Buchanan to substitute into the record should the court want that or need that. But the PFC prefers that no findings as to what was contemplated, negotiated or should be produced in connection with PFC discovery should have been ruled upon by the court. And it is specifically electronic calendars and information was contemplated, and we did not want that record to hang out there to the prejudice of others who may, in fact, desire to get some electronic discovery. I believe that's the only issue that's really in dispute.

MR. IRWIN: We concede that the resolution of the hearing that you held on December 23rd applied to Brock, Zeno and Diez. If the MDL ever wants to bring the issue before you for resolution, we will then re-address the same matters and also address the question of cost. And with respect to that argument, on the day before Christmas Eve, Judge, I know it was as to those three cases.

THE COURT: I understand the issue, and I will deny the motion for reconsideration with the exception that I am going

THE COURT: Motion to reconsider the January 2nd minute entry.

MR. DAVIS: Your Honor, that matter is set for hearing today. We have had a number of discussions over that. The PFC filed a motion for reconsideration in addition to the one that was filed specifically in the Diez case. The Diez case also has a motion for reconsideration. If your Honor would like the PFC to give its comments on that, I can be brief.

THE COURT: All right.

MR. DAVIS: The memo that we filed on behalf of the PFC spells it out. There are two matter that were exchanged between counsel, and I think you will -- I say counsel, I mean defendants' liaison counsel and plaintiffs' liaison counsel, and you will find that there is not disagreement as to the fact that the minute entry that was entered by this court on January 2nd relating to a motion to compel is limited in application solely to the three cases, Diez, Brock and Zeno.

We also agree that the findings of the court were based upon matter submitted in connection with the motion and in oral argument of counsel. And the findings are without prejudice to the plaintiffs' steering committee. That's based upon the fact that that motion was filed solely in connection with those three cases, and the replies were solely in connection with those three cases. And the PFC was not a party to that motion.

The court's intention specifically as to paragraph

informed in about or within one month, by the time the next conference comes. We have the results of two trials. We are going to see the issue starting to play out. The end game committee is not dead, it just isn't too active because people are involved in other things. Mr. Zimmerman and Mr. Levin are not the only participants. Mr. Preuss and I once again are going to sit down with the -- I guess it is going to be desirable to look forward to a conference in chambers with you and members of the plaintiffs' side of the end game planning committee to see if there is something that can be done with that.

Your Honor, I have nothing else to say.

THE COURT: Okay. Well, I have said enough. I think that my feeling about the MDL is that it is a good concept, but it has a timeline to it. And once the timeline is past from the standpoint of discovery, then it ceases to be a help to the litigants. And we just have to then focus on what to do with the cases thereafter. One way is to send them all back; the other way is to send them back to states in some kind of sequence. Another way is to try some of the cases here. There are various way of doing it. But you all need to focus on that. And by next month we will set up some kind of end game committee meetings with the court, and we will see if we flesh it out.

MR. ZIMMERMAN: Thank you.

solution, they should not have the benefit of the MDL holding onto the cases so that they can deal with them one at a time for the next 22 years. They ought to just go back and let's see what happens. Otherwise, they ought to come to the table with your good offices and try to resolve this globally. But so far they have shown to indication whatsoever of doing that.

THE COURT: Does the defendant want to speak on that? I don't want to have you just one side be heard.

MR. CAMPION: Well, your Honor, we have made clear to the plaintiffs with respect to their proposal that there be some global resolution of 40,000 plus or minus cases, we are not going to do it. We have told them in the clearest possible terms that we will not enter into some program in return for something in an affidavit that this plaintiff will receive "X" dollars, "Y" dollars or "Z" dollars. It is pretty obvious that we are going to move toward a couple of QT trials. There is not doubt about that. Whether it is here, there or someplace else I don't know. Probably it is best for all if it is here, because something may come of that. I doubt very much whether my colleagues on the plaintiffs' bar will ever agree about the fact issues in the QT cases, especially other cases will never be put in the litigation and all cases they control will disappear. It is not going to happen in the real world, may not happen because of any number of reason.

Nonetheless, I guess we are all going to be pretty well

Then I can meet with the end game committee and talk about these matters. You have got to focus, the end game committee has got to focus on how to resolve the cases that are not resolvable by mediation. And through some creative ways it can be done. But you have to get together and talk about them and make sure that your clients are protected by them. But we have got to have some finality on these cases soon.

MR. ZIMMERMAN: We can create things by ourselves, your Honor. We can't even make things with our good offices unless there is some degree of creativity on the defense side. And we can't force them to do what they don't want to do. So just sending a case back here and a case back there is playing by their binary rules. They don't want to deal with it globally, and they have a right not to want to deal with it globally.

So that all I can say is if they want to try cases, they want to handle them individually, God bless them. The more that go back and the more cases that they have to deal with at the same time, the better off all of us will be. Because to send them back one or two, three times is the best thing in the world for the defendant. It goes on forever. And they get a verdict here so they blame it on Mississippi. Another verdict comes in in Michigan. They have lousy laws. So the plaintiff blames it on Michigan.

It isn't going to work out unless the defendant wants to find a global solution. If they don't want to find a global

there is resolved. Taking your 1404 example, let's assume we try a case back here in your forum. Under that scenario of the case where it is not a death case and it is not a case that's "in the mediation program" but it is a case we argue about every day as to whether or not defendants want to settle it, we say, well, let's try it, let's try it. We get a verdict. What's the effect of that verdict? If we could have some understanding if it goes "A" or if it goes "B", something will happen. That will advance the process. But absent that, all we have done is try that case.

THE COURT: Yes.

MR. ZIMMERMAN: And that is where we are kind of hung up.

THE COURT: Well, I think that's part of what I'm trying to get everybody focused on. You have got so many creative ways of resolving the case of this sort, but you have to focus on them.

MR. ZIMMERMAN: And I believe there are, and I think possibly, your Honor, and I'm speaking a little bit out of turn maybe, but at some point we can sit with your Honor, both sides, and talk about some ideas. We have sat with each other talking about it. We have kind of gotten to this point where we are sitting each other down, but we are not getting too far.

THE COURT: Right. Well, that's why I suggested that you create end game committees and get somebody to focus on it.

way is to get a sample case for each of those particular areas and try them. If you want to try them in this court, then we have to think about how to try them in this court. If they are not filed in this particular court, I certainly can't take them under 1407, but I probably could take them under 1404 if they are sent back to me for some reason.

MR. ZIMMERMAN: They go back and come back.

THE COURT: Right. But they would go back and come back. This approach would realistically require a joint effort or agreement. I would imagine a court if it get a remand from me and an agreement from the attorneys that the court can 1404 it back to me, I would think a court would be willing to do this. But if one side says no, I want my briar patch, then I think that the local courts are going to be more reluctant to send it back. So that's a way of doing it.

If you have certain categories that you have problems on, see about resolving it either by sending certain cases to the forum state for resolution or having it sent back here under 1404 for resolution. And we go on with it. And that's a way of doing it, too.

But you have to be focused on that, because we are getting to the point now where I can't do much for you from the standpoint of discovery - it is about finished. And so we have got to think about how to resolve the cases at this point.

MR. ZIMMERMAN: But I guess there is resolved and then

THE COURT: All right. Bucky, do you have anything?

MR. ZIMMERMAN: I don't have much of a voice. What we have been really focusing on, your Honor, if seeing what the defendants and the plaintiffs can agree on in terms of resolving cases. We have not focused so much on how to package product for the litigants, going down the road on remand. We should have to spend some time on that.

But the process right now has two ways to resolve itself within this court: One is through individual mediations which are arduous and slow; and one is through any kind of resolution that you call global, which has been, seems to have been non-starter. We are still hopeful that something can be worked out in both of those areas. But it looks like we are going to have to wade through the trial to get any change in position. It is very easy for plaintiffs: We all want to resolve cases. And it is very easy for defendants to say we never want to resolve cases. But what we really need is, if there is some middle ground, we have not been able to strike it, and we keep trying.

THE COURT: Well, you know, there are a couple of ways of doing it. One is to try to carve out areas that you can mediate, and get to a point where you say these are the areas that we can't mediate. And so you have got to focus on resolution of those particular areas. There are two ways of doing that. One is to send them back to the states. Another

concept of MDL is to be of service to the litigants and to get you to a certain point. We can't have it become a black hole or something that the litigants lose total control over the case, and it just sits there and gathers dust. That's not good for the system; it is not good for the litigants, and it is terrible for the attorneys.

So we are getting to a point now where you have exchanges some seven or eight million documents. We still have some preliminary motions. We have a couple more areas that we need to deal with, and we have got to exhaust our opportunities in mediation.

But we are getting to the point at which you have to start thinking about the ultimate resolution of this case in other forums and how we go about doing it. Do we send them all back at one time? Do we take them on a case-by-case basis and send the New Jersey cases back first, the California cases back or something of that sort? Some kind of priority needs to be focused on whether we have any problems with class actions, state class action, whether that needs to be focused on. How do we package the evidence and send it back to the states? All of those sorts of logistical problems take a little more thought. You are the experts, and I am looking to you for some guidance.

MR. LEVIN: All of the above that you just mentioned, your Honor, we are just about there now.

MR. DAVIS: We have not heard from Verilaw since --

THE COURT: Are you still using those?

MR. DAVIS: Yes.

MR. IRWIN: They have been loving me lately, Judge. And I did see that. I saw something on my computer I believe yesterday or today that they have updated some aspect of the Verilaw as far as it is effective March 8th.

THE COURT: At the appropriate time we really need to all put our heads together and see what we have learned from this process and see whether or not we can make life a little easier in the future for all of you and your colleagues who have participated in this case. So let's keep good notes and see what we can do to deal with this later.

MR. DAVIS: Your Honor, the representatives of the end game committee from the PLC are present, Bucky Zimmerman and Arnold Levin.

THE COURT: Okay, fine. Let me hear from either one of you.

MR. LEVIN: I will be very short, your Honor. I speak only for myself. I am at the end of the process of the end game. I have some ideas for the end game which I will express when arguing the design issues. But it takes two to tango, and I have been dancing by myself.

THE COURT: What I had in mind with the end game committees is that you need to recognize the fact that the

Also, the forum court can do that and probably do it better if that's your approach. The MDL mediation process has to be in its approach more global. You have to look at cases and see whether or not those cases are able to be mediated, and if so, whether you can categorize those cases. And then once you categorize those cases, pick the best case and the worst case and establish some kind of goal post to which all the cases in that category should fit in between.

MR. DAVIS: Your Honor, the only other item is we have had some discussions with defense counsel regarding concluding or settling, and I believe that we will get those matters concluded rather soon.

THE COURT: All right. The trial schedule, I talked about the trial schedule with the Diez and Brock attorneys in the conference room, and I have got many pretrial motions that have been submitted. We talked about them in connection with the trial. Do we need to do anything more here?

The next one is thirteen, indemnity agreement.

MR. IRWIN: Your Honor, we have periodically received follow-up requests. When we do, and we can agree to assume the defense of the pharmacy. We do so and in accordance with the letter agreement, and when we execute those agreements, we send a copy to the plaintiffs liaison counsel.

THE COURT: All right. The next item is Verilaw. Anything on that?

much experts were paid and which experts were retained and various things of that sort that may have something to do with the work product of the attorneys.

MR. DAVIS: Your Honor, with respect to the declassified documents, since the joint report was prepared, and order has come out, and it has been complied with.

THE COURT: All right. And then eleven, mediation.

MR. DAVIS: Your Honor, we are on the plaintiffs side ready, willing and able to proceed to mediations.

THE COURT: Anything from the defendants?

MR. IRWIN: As are we. We have received some more materials, not only from Mr. Herman and related firms, but other firms. And we intend to take, resume discussions of mediation up again and do so right after these trials. And we are anxious to do so.

THE COURT: All right, fine. As I mentioned to you at the outset when you talked about mediation, the way that the MDL court can be a facilitating forum for mediation is if the parties will look at these cases or some of the cases or portions of the cases or whatever, hopefully all of that, but if you can't do all of them, you are going to look at the cases in which you can do it and seek some common ground in those cases. The MDL court is really not a forum in which you can look at each case individually and specifically. There isn't enough time to use that approach.

funds.

THE COURT: Okay. When you do that, I will put it under seal. And will you also be as specific as you can in the motion and also check with all the committee members, and in the motion indicate that they are agreeable to it. This information will be placed under seal simply because it involves some litigations costs, and it may be a personal privilege to the plaintiffs. And so it is just a private matter of the plaintiffs; and therefore, I am placing it under seal.

MR. DAVIS: Just to advise the court of one other matter. There is another check from a state case that's come in that Mr. Irwin is investigating, and we expect that that check will also be cleared up as to how much the amounts are or the deposit time. But it is one of the state cases that resolved themselves, and funds need to be deposited into the court, and I just bring this up so the court is aware that it is out there. But defense liaison counsel is on top of that and advised us that we will address it shortly.

THE COURT: While I said it is placed under seal, if anybody from the state liaison wishes to see the material or if any plaintiff wishes to see the material, they simple need to request it from the court, and I will give you an opportunity to look over the material. The reason it is placed under seal is simply because it has to do with litigation expenses: How

down the road by an individual or a particular matter, it can be addressed at that point.

MR. IRWIN: This might be something that might be appropriate for a pre-planned order. For example, since this information is preserved and since it may very well be within the case, specifically sales reps' conferences with the prescriber, it might be something that the first court would take up.

THE COURT: That's probably right. We ought to keep that in mind so nobody should destroy the hard drives. Let's retain them, and we will deal with that later.

MR. DAVIS: I will get back to your Honor on hard documents after Jim and I speak next week.

THE COURT: All right.

MR. DAVIS: The motion to compel we can pass on.

THE COURT: The next item is eight, 30(b)(6) depositions.

MR. DAVIS: With respect to the data base, the defendants produced the access data base, so we can pass that one.

THE COURT: Then the trust account, number nine.

MR. DAVIS: Your Honor, there has been deposited into the registry of the court the sums that are required under the pretrial order. The PLC would like to advise the court of its intention to be filing a motion to withdraw some of those

know what you all have worked out on the electronic information.

MR. IRWIN: With the court's permission, I would mention to the court that insofar as electronic production is concerned, my impression of the history of this is, and we will cross the bridge when we get to it if it comes time that we want to go to the time and expense of getting home computer records, and so I think now that's where we are in the meet-and-confirm question as to determine whether we do that and to determine how that expense is handled. And I think that's a question for our consultants. That's what the meet-and-confirm is about.

THE COURT: Yes. And you need to get with the consultants on that. And the way I see it working is for some program of sampling to be instituted to see whether or not there is anything that's worth the time and effort. So you have got to before you expend the time and effort and washing everything, you have got to just come in and see, make 10, 20, 30, whatever the appropriate sampling is and test that and see whether or not it is worthwhile. And then if it is worthwhile, then we decide about how much cost it is going to take and how much time it is going to take.

MR. DAVIS: In addition to that, one of the items that we have discussed is keeping that electronic issue open even after the MDL may be concluded so if the information is desired

have conflicts between trials and discovery. So just be aware that we are moving into that hectic time, and I suspect it is going to get worse before it gets better.

MR. DAVIS: Your Honor, set for hearing today is a motion to compel production of documents of sales force. We have had discussions regarding that motion. That motion involves both electronic information, what we commonly call detail letters or sales reps had out in the field, as well as hard copy documents. We spoke about that earlier this morning, and defense liaison counsel has advised us that with respect to hard documents either those have been produced or they will be produced in response to the motion.

With respect to electronic information, we have agreed that we will discuss that further and some of the logistics that go into that. But we would like to get the hard copy documents taken care of now.

THE COURT: What's the response from the defendants?

MR. IRWIN: Your Honor, with respect to the hard copy documents, we believe that they have been produced. We will confirm to Mr. Davis in writing by the end of the next week with the court's permission that the hard copy documents have been produced.

THE COURT: All right.

MR. IRWIN: Is that acceptable?

THE COURT: Yes, that is. And at the same time let me

complete. Jim?

MR. IRWIN: Yes, that is correct, your Honor. We confirmed that in writing.

THE COURT: Okay.

MR. DAVIS: I skipped ahead to the request for admissions, and so we have already covered that. On January 24th PLC served upon defense liaison counsel a set of interrogatories, set number seven. We are waiting for a reply, and we spoke about that. Jim can advise the court on that.

MR. IRWIN: And we are working on that. And I would hope that we would have a response shortly, but I don't have a deadline at the moment.

THE COURT: What's a reasonable deadline on that, two weeks?

MR. IRWIN: Could I be permitted to report to Mr. Davis next week about that?

THE COURT: Let's do that. And Mr. Davis, let me know either by letter or something as to what the date is. Let me make a comment. I know we have trials and I know you have trials in California and maybe in New Jersey, New York and a couple of other states. But you have to anticipate some of that and both sides have to be able to have somebody who is continuing this discovery process while the trials are going on. You need a division of labor.

But now increasingly more and more you are going to

make sense.

So if you need a court order to get into a place, let me know and I will do it. Also, get me the name of the decision maker who is doing the scheduling with you. If necessary, I will order him to come to court and talk to me.

MR. DAVIS: Judge, I told the Degge Group counsel that I would get back to them within a time frame, but if the court had in mind, if you would like to give them some directions, I will.

THE COURT: I would like you to go as quickly as you can perhaps within the next two weeks, go and view the equipment. And depending upon what you need, bring it to me, and I will consider ordering them to produce it.

MR. DAVIS: Thank you.

THE COURT: Class certification. The parties indicated that that should be deferred until additional electronic discovery. Anything further on that?

MR. DAVIS: We will have additional discussions with defense liaison counsel.

THE COURT: Seven, the plaintiff and defendant respectively request for production.

MR. DAVIS: Your Honor, with respect to a major request for production, set number six, we have received on an ongoing basis documents. Defense liaison counsel has now advised us that the documents responsive to request number six is

The Degge Group was granted an extension until March the 12th. I communicated with counsel for he Degge Group. I have a letter if your Honor would like that letter, but in essence they have asked for additional time. They also told us that they believe they have 20,000 documents somewhere in North Virginia. I asked them what else they had. They have both electronic and hard copy documents.

I indicated to their counsel that your Honor typically has asked for the name of an individual who is there, the address, the telephone number, as well as indicated a desire to get the production sooner than later. The Degge Group has indicated that it will take well over a hundred hours of man time to assemble the material, and they don't think that they can get it until the end of April.

So I told them that I would report that to the court, and that following this conversation I would be able to get some directives from your Honor and will send some people to the Degge Group to try to lessen the burden if that's necessary. But we don't think that we ought to be expending a huge amount of dollars to get third-party subpoenas, albeit, they would like us to do so, I believe.

THE COURT: What you need to do is go there and take a look at the documents and see which documents you need. Because there is not sense getting 20,000 documents or thereabouts when you only needed a dozen of them. It doesn't

defendant to exclude those that are not. Let's try to do it the easier way.

MR. DAVIS: Your Honor, I think I have jumped out of order on some of these matters. I had inadvertently so that I can go back, and I apologize. I am on section five now. With respect to subpoenas duces tecum issue to Sines, also known as Nelson, we have communicated with defense liaison counsel, and we are waiting for a certification on that. I don't know where that stands right now.

MR. IRWIN: This involves a condition where there was a change in ownership. Certification was received from Nelson. I think it was Nelson. Certification was r3eceived, and the question was whether this person could certify the response for the, and maybe I'm messing this up a little bit, but maybe the former entity as well as the current entity. And we, John Winter is looking into that. I expect he will be able to confirm that certification for both entities, but one certification has been received. And the question is whether it is fully satisfactory.

THE COURT: Let's do that within a week.

MR. IRWIN: Yes, sir.

MR. DAVIS: With respect to a number of other third-party subpoenaed duces tecum that were issued, they are outlined in the joint report. MEDCOM has said they will get back to us as soon as we granted them an extension of time.

categories of documents that we thought we could agree on and admit 803-6 was satisfied. Some we felt were admittable and some we thought were not.

We have at this moment now set that aside because of the Diez trial. We think that the way to do this would be to follow this format: Basically would be to make a response by categories in this fashion, but it is going to take us more time. I remember your Honor suggested, I believe, when we spoke about this last time at one of our conferences that we make responses serially. For example, if we can be satisfied that some reports are satisfied, then we can identify all of those and make an initial response. At least we would get that out of the way. We think that is a sensible way of doing it. But right now we are working on the Diez trial.

THE COURT: Where are you with that, are you agreeable with that approach, or do you need it more quickly?

MR. DAVIS: We think we need it before then. It's been outstanding for quite some time.

THE COURT: Let's send the material that you have already gone through to him so that he has got as much as you have and let's continue on with that. I won't set any deadlines, but I am interested in getting it done post haste. Plaintiff attorneys have to get to me on that if you don't get it soon. What I will do is just declare that all such documents are business records and put the burden on the

defendants some requests for admissions that your Honor is aware of. That's been discussed at prior conferences. We have gotten no responses to any of those, and again, I remind the court that the states are looking to the coordination and I am very concerned just as I am about the Zipes material because that is going to impact a state case by having it produced so late. And I believe that these state lawyers are looking very much for this information.

THE COURT: Any input from Mr. Arsenault on that?

MR. ARSENAULT: I think Mr. Davis has been coordinating that activity and speaks authoritatively on that.

THE COURT: Let me hear from the defendants.

MR. IRWIN: Your Honor, at the present time we have no other cases set for trial other than Calbert and the Diez case. The request for admissions that we have been dealing with comprises, it consists of a request that we admit the business records status of 3,900 documents, 803-6. What we have done is my office has looked at a hundred of these documents that we have selected randomly. Some categories of documents readily satisfy the 803-6 requirements. Examples would be clinical research reports that are regularly kept in the ordinary course of business and prepared by us. Other documents clearly do not, and they would be documents like, say, for example, an e-mail with marginalia on it or something like that. As a result of that, what I call a pilot, we identified a number of

Calbert trial in California starting the exact same day. So I know we are all, it is important for us to stay on top of this, but I hope the court would recognize that our time frame right now is a little pressed.

THE COURT: What's your suggestion, Mr. Davis?

MR. DAVIS: With all due respect, that is an expert that's to be called in both of those trials, I believe. So it is very clear that the information needs to get in sooner rather than later.

MR. IRWIN: Well, your Honor, the discovery is over in our case here. In the Diez case, this has nothing to do with the Diez trial, nothing. Now, these things may be relevant to further cases down the line; they may be relevant to, once the cases are remanded as part of the court's remand order including this. There is no question but that Dr. Zipes received $600,000 from the defendants, and he has testified to that. And that would certainly be appropriate to ask him on cross-examination. But I think that it is not the same to say that this discovery is related to the Diez case. It certainly is not.

THE COURT: Okay. Let's have it a week after the Diez trial.

MR. IRWIN: Yes, your Honor.

THE COURT: Anything further on third-party subpoenas?

MR. DAVIS: Yes, your Honor. The PLC served upon the

whether or not a comprehensive reply from the expert of the defendants has been obtained. We have had some discussions and I understand that this material will be supplemented at some time, and I expect to receive that shortly. The PFC would ask that some time constraint be provided so that we can get this matter concluded.

THE COURT: What's the reasonable constraint from the defense standpoint?

MR. IRWIN: Judge, it is something we worked a great deal on. We have provided a great deal of information in response to these requests, including information consisting of a number of pages and material and references to Bates numbers of documents that have been previously provided. There was a concern expresses in the last letter about requesting more specificity in that response, and I told Mr. Davis that we would provide more specificity with respect to the large number of documents we identified. We are also going to update our response with respect to the total number of dollars paid to Dr. Zipes in connection with expert or consulting services he has done for J&J. I think your Honor will recall the number was in the neighborhood of $600,000. We will supplement that response.

The problem is, Judge, that my office is now preparing for this trial here, and the person who is really working most with Dr. Zipes is Fritz Zimmer, and he is preparing for the

objection with regard to the dismissal. I will dismiss with prejudice. I will award costs, but the costs are to be paid at the end of the case and are to be taxed as court costs in the amount of $200 per case. Anything further on that issue?

Service list of attorneys is number four on the agenda.

MR. IRWIN: As is customary, your Honor, we have the service list of attorneys, and I will present a copy to you, your clerk, Ms. Lambert, and to Mr. Davis and to Mr. Arsenault.

THE COURT: Okay.

(COUNSEL HANDS DOCUMENTS TO DEPUTY LAMBERT AND COUNSEL DAVIS AND COUNSEL ARSENAULT.)

THE COURT: The next item is five, third-party subpoenas duces tecum. Any report on that from the plaintiffs' committee?

PLAINTIFFS' COMMITTEE REPRESENTATIVE: Your Honor, with respect to third-party subpoenas duces tecum that have been issued, I will begin with the one that was issued to Dr. Douglas Sykes back in February, February 7th. The PFC got some documents that were responsive. We have had ongoing discussions with defense liaison counsel, and your Honor is certainly aware. I have those. We have not gotten a response to the most recent communication, which was a February 19th letter wherein we outlined a request that the items that are specifically responsive to the subpoena be identified and a certification be provided as well as an understanding as to

responses from two plaintiffs. We would ask that the court, we withdraw the motion to dismiss with respect to these to plaintiffs. We would ask that the court award us costs in the amount of $250 per plaintiff to be paid by these plaintiffs for forcing us to file this motion and write all of these letters. These two plaintiffs are Juan Jose Olayda and Lawrence Williams. Catrice Burrell was subject to the motion. She filed a PPM timely but did not submit authorizations. We, therefore, reserve our motion with respect to her. We understand from Mr. Murray's office and Mr. Amedee's office that they will be getting us those authorizations. When they get us those authorizations, we will withdraw that motion.

Finally, there was an opposition that was received in the Bowden matter, and the plaintiffs are Delores Dowden, Emma McClain, Thelma Masters, Debra Rocket and Jewel Sherrill. They have filed an opposition asking for more time. We oppose that. We think it is too little, too late, and we would ask that the court grant our motion with respect to those individuals. Now, Mr. Davis tells me another opposition may have come in this morning. I don't know about that, but he and I will discuss that and report to the court accordingly.

THE COURT: I understand the plaintiffs' committee objections to the dismissal in particular and argues that it be given without prejudice. And with regard to costs, they object to the costs being awarded at this time. I will override the

motion. Our position and the documents supporting it are a matter of record and have been discusses with the court before. I did want to recite to the court the status of the responses to the motions as we appreciate them. I have some names to read into the record. We will than after this hearing submit to the court and in due course to plaintiffs liaison counsel an order providing for our suggested disposition of this motion as it relates to those people who have responded and those people who have not responded. So if I may proceed, I would read into the record those names.

THE COURT: All right.

MR. IRWIN: The following, there were 52 people that were the subject of this motion. Judge, the following 20 individuals actually had sent PPMs to Drinker, Biddle's office, and the PPMs that weren't sent to Drinker, Biddle's office and our motion crossed in the mail. Therefor, we are satisfied that these were timely, and we will withdraw the motion to the following 20 individuals: Robert Beasely; Vernel Daniels; Robert D. Mosantos, Jr.; Sandra Dickerson; Rachel Douglas; Ronald Guillory; Robert Curbesky; Shaday Odom; Brandon Rader; Leonardo Ramos; Florence Riven; Ethel Rogers; George Smith; Eugene Sodo; Jane Stanley; Kerry Thomson; Roy Wagner; Joy Waters; Bennie Weld; Valerie Whitworth; Don Wilson and Michael Wilson.

Since filing the motion, your Honor, we have received

litigation. Let's keep an eye on that, okay.

The second item is the state of the liaison counsel. Is that where we are?

MR. WRIGHT: Mr. Arsenault will report to the court on that.

MR. ARSENAULT: No development there, your Honor.

THE COURT: Again as I do all the time, I tell you that I am interested in your access to all of the documents that's discoverable here and also to make sure that your trials in your states are proceeding. And if there is anything that we can do to facilitate that from the MDL, I need to know it so that I can at least focus on it. I don't want the MDL to stop you from proceeding. State Liaison Counsel have been very valuable in helping to coordinate the state and MDL proceedings. One of the problems we have in MDL is that everybody goes their own way and there is no coordination. Through your efforts, we have had some coordination and the court appreciates that.

The third item is the patient profile form and authorization.

MR. IRWIN: Your Honor, paragraph three of the joint report recites the status of the receipt of the patient profile form. We have before the court today a motion, the second motion of this kind, with respect to 52 plaintiffs who failed to timely furnish PPMs. I don't proposes to go over that

of the hard copy documents. And the PSC questions whether or not everything has been produced that's been requested. So there are some issues that are hanging out there, and we are in the process of discussing those.

THE COURT: The reason that I am focusing everybody's attention on this is that one of the purposes of the MDL, one of the reasons for the MDL is to provide one forum so that everything can take place within this forum. After that period of time, then the MDL court has to begin divesting itself of the cases so that the cases can go their own way either by settlement or by trial or by some other mechanism so that there is some resolution. It gets to the point where the MDL forum is counterproductive after you have used it for its intended purpose. So everybody has got to be conscious of that. I don't want to just keep a case here because I have it. I want to keep it here as long as it is serving a purpose for the litigants. But once it ceases to serve the purpose for the litigants, then we have to get rid of the case and get it back so that it can be resolved.

Having said that, there are some issues that the court can deal with. There may be some Dauber issues; there may be some class action issues. There may be some other common issues and also the MDL can supply a forum for mediation for those cases that can be mediated. But after we have done that, we have got to get on our way about getting finished with this

addressed, and it is expected that will be resolved by the conclusion of this Monday.

THE COURT: Okay. So discovery then will be finished at that time. Is that what you are talking about, both of you?

MR. IRWIN: There are a couple of outstanding motions, Judge, that relate to some requests for production of No. 7, which we will touch upon. And there is a motion with respect to the production of home computer records of the sales reps that we will discuss, but it is our impression that by and large, yes, we are nearing conclusion.

MR. WRIGHT: Mr. Davis is in contact with Mr. Irwin. May he say something to that matter?

THE COURT: Sure. Let me hear from Mr. Davis.

MR. DAVIS: Your Honor, Leonard Davis of the Herman Mathis law firm. The PSC is not sure whether or not discovery is yet complete, although I have every reason to believe what Jim says as to the production will occur. We have some issues regarding CDs containing e-mails that have been produced. We discussed that with defense liaison counsel. I expect that this will be addressed, but it has been some time, and it has been hanging out there that some of these electronic issues have been discussed.

With respect to the hard copy documents, there is set for today a motion to compel on the sales rep documents. That is just not limited to electronic documents. That's also part

P R O C E E D I N G S

(FRIDAY, MARCH 7, 2003)

(COURT CONVENED AT 9:38 A.M.)

THE COURT: Be seated, please. I apologize for being 20 minutes late. I was conferring with liaison counsel, and we had some matters that took us longer than usual. Counsel, make your appearances for the record, please.

MR. WRIGHT: Your Honor, I'm Bob Wright, one of the members of the PSC. I would like permission to stand in for Mr. Herman.

THE COURT: Yes.

MR. IRWIN: Good morning, Jim Irwin for the defendants.

THE COURT: Okay. We are here today first in connection with the monthly report regarding the MDL status. I will hear from the parties I have been presented with a joint report. The first item on the agenda is an update of rolling document production, electronic discovery.

MR. IRWIN: Your Honor, the report recites the status of the document production, which as we know is about complete. There had been a few more electronic documents produced, a handful of part-copies documents from Titusville, New Jersey. The total number of documents now pages now exceed seven million. There are still a couple of issues involving deciphering some additional documents, but these are being

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MR. AMEDEE: Thank you, your Honor.

THE COURT: I'm here.

MR. IRWIN: I mentioned this to Mr. Amedee. Bench books are to be delivered to your office Tuesday.

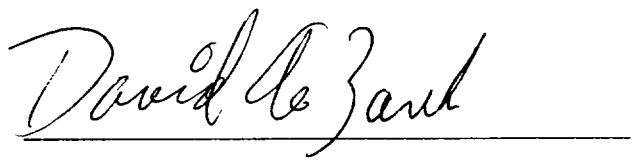
THE COURT: We can go off the record on this. This is just logistics.

(HEARING ON VARIOUS MOTIONS IN THE MDL CASE CONCLUDED AT 3:25 p.m.)

REPORTER'S CERTIFICATE

The undersigned certifies, in his capacity of Official Court Reporter, United States District Court, Eastern District of Louisiana, the foregoing is a true and correct transcription of his Stenographic notes taken Friday, March 7, 2003.

New Orleans, this 11th day of March, 2003.



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