UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: VIOXX PRODUCTS LIABILITY LITIGATION	*	05-MD-1657
	*	Section L
Relates to: 06-CV-9757	*	March 17, 2015

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ORAL ARGUMENT BEFORE THE
HONORABLE ELDON E. FALLON
UNITED STATES DISTRICT JUDGE

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PROCEEDINGS

(March 17, 2015)

THE COURT: You may be seated, please. Good morning, ladies and gentlemen.

Call the case, Dean.

THE DEPUTY CLERK: MDL 1657, *In re Vioxx Products Liability Litigation*.

THE COURT: Counsel make their appearance for the record, please.

MS. HORN: Elaine Horn from Williams & Connolly on behalf of Merck.

MR. MCCLAIN: Kenneth McClain on behalf of plaintiff, Levitt. Mr. Thomas also is here, Judge, and he will argue the second motion that's going to be up, I think, as counsel at least anticipates argument.

THE COURT: Okay. Fine.

MS. HORN: Also, we have Emily Pistilli from our firm.

THE COURT: We have two motions for summary judgment today. This is in the *Vioxx* matter. The individual was taking Vioxx and in the pleading claimed that they had a heart attack as a result of taking Vioxx.

There is an issue of the specifics of the complaint, the original complaint, in that -- there are two motions for summary judgment. One motion for summary judgment

10:55

is that the complaint indicates that the individual plaintiff had a heart attack and there's no proof that they had a heart attack and there's no doctor that will say they had a heart attack. The plaintiff takes the position that the heart attack comment in the pleading is broader, to include cardiovascular incidents, and that they feel they have a doctor who can discuss cardiovascular incidents and its relationship.

The second motion for summary judgment has to do with the learned intermediary defense. Vioxx is a prescription drug and it must be prescribed by a doctor. The claim for lack of warning is really focused on the treater, the prescriber, what the prescriber knew, could have known, should have known, did know. This prescriber indicates that he would prescribe it again, that he felt it was a good drug, and as I understand *sub silentio* would be angry that it's been off the market, would prescribe it again if it were indeed on the market, and in fact he prescribes Celebrex presently.

The plaintiff takes the position that, number one, he has another doctor who, while is not prescribing, has initially seen the plaintiff and that that doctor -- I'm not quite sure will testify because nobody knows. Apparently they haven't taken his deposition yet. He points to the fact that there are two doctors.

Secondly, he takes the position that the learned intermediary doctrine has been abrogated because of the direct

10:57

advertisement to the consumers. This is a Missouri case, however, and I've been unable to find any Missouri law that takes that position, although I am aware of several other states that have done so. Louisiana has not. I don't know what Missouri would do. I think it would be hard for me to even make an *Erie* guess on it.

That's the issues as I understand them.

MS. HORN: Well, Your Honor, you have clearly summarized both motions succinctly. Our plan today was to address the latter motion first, the one dealing with the learned intermediary, and then we can move on to the second one.

THE COURT: Have you found any case that deals one way or the other with learned intermediary from Missouri?

MS. HORN: I believe there's an Eighth Circuit case which says that they have not recognized it, and that's as close as we have. I'm sorry, that Missouri has not recognized the direct-to-consumer exception to the learned intermediary. They clearly have the learned intermediary doctrine.

THE COURT: Is this a case that I should send back to Missouri? How do you feel about that?

MS. HORN: For that purpose?

THE COURT: For the purpose of summary judgment. Any more discovery needed here?

MS. HORN: Well, where the case stands now is when we

10:58

filed our first motion, the expert discovery had started, had not been completed, and so the discovery was stayed pending resolution of various motions. So at this point we would still have to wrap up expert discovery. Then depending on how the Court rules on the injury motion, there may be additional fact discovery that would have to take place. In terms of what a Missouri court would do, as we note in our papers, that's a minority view, that there's a direct-to-consumer exception.

THE COURT: That's true. That's true.

MS. HORN: So there's that.

THE COURT: I think to some extent it may be realistically urged that it's a growing minority, but that may be more optimism than fact. As more of the television time is taken with advertising, not necessarily Merck, I see judges focusing a little bit more on that. It's still a minority position, and I don't have any Missouri case that says they would recognize it.

MS. HORN: Not today and certainly not back during the time period that we are referencing.

THE COURT: I agree with that.

MS. HORN: You have summarized the basic facts. I just want to highlight a couple that we feel are particularly relevant to this motion. We have the issue regarding who prescribed Vioxx to Ms. Levitt.

THE COURT: Did Hartman prescribe Vioxx, the first

11:00

guy?

MS. HORN: She testified that she originally got some Vioxx from Dr. Hartman. At the time that she showed up in Dr. Katz's office, however, she was no longer taking Vioxx.

THE COURT: He wasn't treating --

MS. HORN: Right. Then the original prescription had been on an as-needed basis and she wasn't taking it. When she started seeing Dr. Katz, he put her on a treatment plan that included daily use of Vioxx, 25 milligrams a day. So there's a clear distinction between what happened with Dr. Hartman and what happened with Dr. Katz.

Dr. Katz testified that he examined Ms. Levitt and he made his own independent assessment and his own medical judgment to prescribe Vioxx to her. He is the one that continued to prescribe Vioxx to her until 2002, when she stopped taking it.

THE COURT: Have you all taken Hartman's deposition? How do you know that he wasn't treating her or doing that? Is that what she said?

MS. HORN: We have his records. We did not depose Dr. Hartman. No one else is offering any affidavits from Dr. Hartman indicating that he would do anything other than what Dr. Katz did.

THE COURT: Okay. Let me do this. Let me hear a response to that motion, and then you can come back and argue

11:01

the second motion. What's the second motion?

MS. HORN: No, the second motion is the -- we are doing them in reverse order. The first motion we were planning on arguing on was the learned intermediary. Then the one that we filed last year we were going to argue second, unless you want to do it the other way.

THE COURT: No, that's fine. Do you have anything to say on learned intermediary? I'll give him an opportunity to respond and you an opportunity to rebut on learned intermediary, and then we will go to the next motion.

MS. HORN: Just to highlight on learned intermediary, we submitted Dr. Katz's testimony. Dr. Katz's testimony is very clear that he would prescribe Vioxx if it were being sold with the black box. This Court has already addressed a similar issue with the Louisiana AG action in which the issue is whether or not the state would pay for Vioxx. The evidence showed they continued to pay for Celebrex with the black box, so there's no reason to believe they would be different with Vioxx. There's no other competing evidence as to Dr. Katz's testimony. So that, we believe, shows that there is no proximate cause.

THE COURT: What about the argument the plaintiff makes that the learned intermediary -- that he has other theories of liability other than warning, that it's defectively designed or defectively manufactured? Learned intermediary, of

course, is not really helpful in those theories. It's helpful in a warning theory because that's who you have a duty to warn. How do you deal with that argument?

MS. HORN: To the extent that there are any claims alleged that do not turn on what the warnings were, specifically design defect, as we cited cases in our brief, with design defect, in order to comply, to say that it's not defective, the manufacturer would have to change the actual formulation of the drug. That's dictated by what the FDA has approved or not approved. There are several cases that say that in that circumstance, a design defect claim is preempted.

THE COURT: We know that the *Bartlett* case deals with the generic. I'm not so sure the law is as clear in the nongeneric as it is in the generic. In the generic, Justice Thomas takes the position that they can't change it and so they are stuck with the FDA's approval. You can't do anything. I'm not so sure that the nongeneric, meaning Vioxx produced by Merck, whether the law is as clear as it is in the generics.

MS. HORN: Well, in terms of the actual formulation, when you have a distinction in the preemption context between the brand and generic that has come up with labeling and there's this provision where a manufacturer can arguably change the label and then go get approval afterwards, they can't do that with actually changing the drug. They can't suddenly

11:04

decide they are going to make a different chemical compound and sell it under the same license. You can't do that.

The courts have actually looked at that issue as it applies to the branded context and have reached the conclusion, which is the logical conclusion, that you can't do that on either side of the fence. So that's the first problem with the design defect.

Second, there is no evidence currently in the record from which a reasonable jury could find that Vioxx, if it had had an adequate warning, if the issue is not warnings, that it was unreasonably dangerous. There just isn't that kind of evidence in the record, and there's no affirmative evidence as to go into any other claim that the plaintiffs have.

Even though it's our motion, they have the burden to come forth with some evidence for their claims. They have made various assertions about what some people may or may not say at trial, but that's not what we have right now.

THE COURT: Let me hear a response.

How do you see the learned intermediary? Is there any case in Missouri that says --

MR. MCCLAIN: Yeah, there are a couple, Judge, we point you to. *Krug* is a Supreme Court of Missouri case. What *Krug* holds -- and that's *Krug v. Sterling Drug*, 416 S.W.2d 143 (Mo. 1967). Under Missouri law, the doctrine only applies when the defendant actually warned the doctors of the risk. If

11:06

appellate did so fail to warn the doctors of the risk, it's liable regardless of anything the doctor may or may not have done.

THE COURT: This doctor says that he is aware of the risks and he would do it again.

MR. MCCLAIN: Let me read you the actual testimony. That's what they said about it, but let me read you the testimony about it because it's not what they thought it said or said it said. It was a little different than that.

Also, Judge, there was a case that we cited to you. It was one of the only cases that got out of the MDL. It was up and down to the Eighth Circuit and the MDL panel. It was a class action against Merck for the cost of the drug. It was under the Missouri Merchandising Practices Act. We cited to the decision, and it was a trial court decision.

The court held (as read): "The Court further notes that given the mass direct-to-consumer advertising alleged here, the fundamental justification for the doctrine that patients rely solely on their doctors to choose which prescription drug they take simply may not exist in this case."

That was the *Perez v. Wyeth* case that was cited as 208 WL 4771525. The case was certified as a class. It went up and down. It was removed twice. It went to the Eighth Circuit and back, and then they settled it. That was the opinion of the court that the direct marketing would

11:07

vitiate the warnings under Missouri law based on *Krug* and the other precedents that the court found.

If that's an open issue as far as you are concerned, we would suggest that Judge Phillips, who has this case back in Kansas City, would be in a better position to assess that perhaps than the Court, or at least equally in a better place.

THE COURT: I understand. That case, it's an iffy situation. I understand.

Tell me about the fact that -- you were going to read me something about Dr. Katz.

MR. MCCLAIN: Yeah. Dr. Hartman first prescribed Vioxx to Ms. Levitt in August of '99. Dr. Katz's note for her, when he first treats her, was to continue current meds, including Vioxx, in December of 1999.

In fact, the prescription for Vioxx was always controlled by Dr. Hartman. For example, when she switched from Vioxx to Relafen, Dr. Hartman did this on his own, without including Dr. Katz in the decision.

THE COURT: Did he continue to see her even though Katz was there?

MR. MCCLAIN: They were both treating her at the same time.

THE COURT: I see.

MR. MCCLAIN: Now, their entire motion is premised on

11:09

this false notion that it was Katz who was her sole prescribing physician and the decision to prescribe Vioxx was his alone as a matter of first instance. This is an affirmative defense under Missouri law, and I want to address that because that's a point they contend with us on in the reply that we just got a couple days ago. It's clearly an affirmative defense, and they have the burden on this.

Now, in addition to that, Ms. Levitt herself says that if she had known the risks, she wouldn't have taken Vioxx. So that plays into this question on learned intermediary as well.

Dr. Katz himself says, "I always tell my patients the risks when I know about them."

She says, "I was very concerned about heart-related problems, and I wouldn't have taken it."

So there's a causation issue in this regard, which is what the whole learned intermediary doctrine is about.

Ms. Levitt herself says, "I'm the one who was making the decision based on what I knew."

Dr. Katz says he didn't tell her because he was unaware of the risks; but if he had known, he would have told her.

She says, "I wouldn't have taken it."

So that's something to consider in this regard as well.

11:11

THE COURT: Does anybody know what Dr. Hartman's position is on this?

MR. MCCLAIN: No. We asked to take the deposition and they opposed it. You know how we got in this case. She had been *pro se*. We got in when discovery was closed. You opened discovery for very limited purposes. We tried to take Hartman's deposition. They wouldn't allow us to do it. We do have his records and they are enlightening. Let me just tell you about some of them.

Here's what the testimony shows, and there's a conflict in it. I'm sorry. I'm trying to find my note, Judge.

THE COURT: What's your recollection of it?

MR. MCCLAIN: There is some very good -- and maybe it's in the note of the -- here it is. I'm sorry.

That's what I'm looking for. Yes. I'm sorry, Judge. It was in my notes on the reply. Here it is. I apologize.

Here's what they say in this regard. They wrongly claim that Katz testified that he exercised his own independent judgment. Merck claims that Dr. Katz testified that he exercised his own independent judgment in determining that he would include Vioxx in his treatment of Ms. Levitt.

Merck cites page 27 of the transcript where Dr. Katz was asked that, and they asked him to assume for a moment that when Ms. Levitt came to see him, she was not

11:14

currently taking Vioxx. That was the basis upon which they then cite and say it was his independent judgment. They go on on that page, if you will look at it, and they ask him this question (as read):

"**QUESTION:** Did you base your decision to prescribe Vioxx to Ms. Levitt on your own assessment and evaluation of her and what you thought would work best for her?

"**ANSWER:** Yes.

"**QUESTION:** So if a prior physician had prescribed Vioxx to her at an earlier time, that did not influence your decision to prescribe Vioxx to her; is that correct?

"**ANSWER:** Probably the best answer to that would be yes and no in that if she felt she were doing well with Vioxx, I would probably say we should continue it. If she said she wasn't satisfied, then I would make a change. I'm looking actually at her initial visit on October 11."

This is Dr. Katz testifying, looking at his notes.

"Even though I don't discuss it in the rest of her visit, it appears that at registration on October 11, 1999, that she noted that she was taking Vioxx on an as-needed basis."

So this suggestion that they make that she wasn't taking it is just not correct. That was Dr. Hartman's prescription.

11:16

"**QUESTION:** What are you looking at to determine that?

"**ANSWER:** That's the flow sheet of medications on October 11, 1999. Under Vioxx, it appears that she was taking one. She said one a day."

Now, it was Ms. Levitt's original plaintiff profile that she filed in this case that it was Dr. Hartman that prescribed it to her. It was the amended plaintiff's profile that she said that it was both Hartman and Katz that prescribed it to her jointly, not one or the other. So the evidence is contrary to what the defendants claimed.

In fact, this is additional testimony from Dr. Katz. This is at page 44 of his deposition. This was, of course, taken *pro se*. This was before we ever got involved in the case. They noticed this up when the woman was *pro se*.

"From my records, I didn't write her a prescription on that date" -- that's the first date that he saw her -- "which suggests to me that she was going to be taking the 25-milligram Vioxx that she probably had already received from Dr. Hartman. Because my first prescription for Vioxx is dated December 27, 1999, and from a review of the records, we have already mentioned she indicated that she had Vioxx from Dr. Hartman."

So the testimony is at least a factual issue that needs to be decided not on summary judgment. That is a

11:18

matter of their affirmative defense. You also have to consider, I think, in this regard, in regard to Dr. Katz, several things.

One, he was a paid expert of Merck's. They produced the records. We have got over and over again thousands of dollars that he was paid by Merck as a paid consultant. There's many cases -- and we cite some of them -- that if you are a paid consultant, that vitiates or can vitiate the learned intermediary doctrine as it applies to the individual who is a paid consultant. He has a conflict of interest in that regard, and the jury at least has a right to consider that. Katz was so well-known and such a relied upon figure at the multidisciplinary meetings they even made a poem about him on Vioxx. So it's not like he was a disinterested party in this regard.

It goes on from there in terms of his decision. He says on the one hand that he wouldn't have changed the prescription, that he liked the drug and it was a good drug and would have stayed with it, but there's evidence contrary to that, Judge.

The fact of the matter is that Dr. Katz stopped prescribing Ms. Levitt Vioxx in April of 2002, the very same time that Merck added the enhanced cardiovascular warning on the drug. Now, Dr. Katz claims this is just a coincidence, that it was not a label change but instead a change in

11:19

insurance that led him to stop prescribing Ms. Levitt the Vioxx, but we have testimony that disputes this.

Ms. Levitt herself says the pharmacy never offered her to continue filling the prescription out-of-pocket, something it always does when there's an insurance change. Additionally, she never received a notice from the insurance company that it was not allowing Vioxx to be utilized, which it always does when it disapproves a drug. Finally and most importantly, she was directly told by the pharmacy this was not an insurance change, but it was a doctor's change of the drug.

Now, credibility questions on Dr. Katz's testimony about why he did certain things are for the jury, we would suggest. In fairness to him, he said this was 13 years ago and his recollection was kind of fuzzy. That's at page 103. He testified incorrectly about when he started her prescription. At first he said October of '99, but then he corrected himself and said December of 1999. As we say, the jury gets to consider whether or not the fact that he is a paid expert might be influencing his recollection of these events.

So for all these reasons, Judge, we think that this learned intermediary doctrine is not a good defense in this case, at least it's not supportable on summary judgment. One, we don't think Missouri law supports it. Two, we think that there are factual issues surrounding this, particularly Dr. Hartman's original prescription and whether or not he was

11:21

involved.

Regardless of what any doctor testifies, Ms. Levitt herself has testified, "Had I had known, I wouldn't have taken it." And Dr. Katz says that if he had known, under the informed consent doctrine, he would have told Ms. Levitt about the risks. So we have factual issues all over this motion that we think preclude summary judgment.

As you point out, we have other claims as well, and those other claims we don't think are vitiated by this regardless, including the failure to test before marketing. That, certainly everyone recognizes, clearly exists.

Regardless of what you say about label change or change of the defective design, I think that your reading is correct, that as to the maker of the drug, not a generic, that there's no limitation on their ability to change the formulation if they find it to be defective. I don't think that there is that limitation. There wouldn't logically be any limitation on the inventor of the drug, who finds that there is a defect, to change that from harming people. I can understand the logic on the generics. That makes sense because they are simply following the FDA approval.

THE COURT: Is there any evidence at all that it was defective?

MR. MCCLAIN: Well, other than it's unreasonably dangerous. Under Missouri law, that's the test, its

11:23

unreasonable danger, and that alone is enough to make it defective.

THE COURT: There's always some side effects of drugs. That's the way the warning is. Even aspirin will give you problems with your stomach.

MR. MCCLAIN: Sure. They concede for this motion, Judge, they didn't warn. They say assume that for the purposes of this motion, so we have to take them at their word. They are not asking you to assume they warned. Katz doesn't say that he was warned except with the enhanced warning, when he stopped prescribing it.

I think that the question of unreasonable danger is a jury question. The question of failing to test before submitting it to the FDA is another live issue, as well as a negligence claim, which we cite that Sixth Circuit case that says even if you have a preclusion in some regard, there's no bar to proceeding on your other tort claims.

That's the *Wimbush* case, a Sixth Circuit case, 2010, which is at 619, in which the court held that claims against drug makers, even where the drug maker has complied with the FDA regulations, because there's no impossibility between complying with state law duty to exercise reasonable care in leading up to placing a drug on the market and complying with the federal government's process for approving drugs, they approved that cause of action, which we have pled

11:24

in our complaint. So we have claims which survive regardless.

As you point out, this is an issue which could be decided by the Missouri court, and we are hopeful to be able to go back there for trial at some point. We tried mightily to settle and didn't make any progress. We would like to resolve this case at some point and ask your help in doing that. Thank you.

THE COURT: Any response to this? Then we will go to your next motion.

MS. HORN: Just briefly, Your Honor, on the point about who prescribed Vioxx when and why. Counsel started reading the testimony of Dr. Katz from page 44, and I just want to continue because I think that is relevant. Starting on page 44, which was already read so I won't repeat it, continuing onto 45, he starts in the middle of his testimony (as read):

> **"ANSWER:** Because my first prescription for Vioxx is dated December 27, 1999. And from my review of the records, we already mentioned that she indicated that she had Vioxx from Dr. Hartman.
>
> **"QUESTION:** But that she was not taking it?
>
> **"ANSWER:** Correct.
>
> **"QUESTION:** Did you know why she was not taking it at the time she came to see you?
>
> **"ANSWER:** No. I don't have any mention why she

11:26

wasn't taking that regularly.

"QUESTION: But then based on your assessment and evaluation or examination of Ms. Levitt, you determined it was appropriate for her to start taking it daily?

"ANSWER: Correct."

Keeping with that, on the letter from her very first visit with Dr. Katz -- Dr. Hartman referred Ms. Levitt to Dr. Katz, a rheumatologist. He in turn writes a letter back to Dr. Hartman dated October 11, 1999. He described everything that happened. The very last paragraph (as read):

"She was given informational materials regarding fibromyalgia. She was advised to start Vioxx at 25 milligrams daily with food and to take amitriptyline regularly at 25 milligrams nightly."

So we don't dispute that she had had some Vioxx at some point, but she was not taking it 25 milligrams a day daily at the time that she went to see the rheumatologist. She had not been diagnosed with fibromyalgia before she went to see Dr. Katz. As treatment for that specific condition, he prescribed Vioxx and some other things.

On the point about Dr. Katz being a paid consultant, the evidence in the public record is that he was a clinical investigator for the ADVANTAGE trial. To say that that makes him into a consultant, that that would bias his prescribing behavior, there's no evidence of that. To the

11:27

extent that he has been paid as a speaker, he testified at his deposition -- and it's also noted on the CV that's attached to the deposition -- he has done it for many different pharmaceutical companies, including direct competitors of Merck, in the COX-2 market. To suggest that is going to sway him one way or the other, there's just not evidence of that.

On the point about Dr. Hartman's deposition and not reopening discovery, without going into the details of that, I do note there's nothing preventing the plaintiff from talking to Dr. Hartman now. We don't have any other affidavit or anything else from Dr. Hartman.

Then the final point, Dr. Katz stopped prescribing Vioxx in April of 2002. To rebut the cites that we have to Dr. Katz's records, his contemporaneous records, and his deposition transcript, they have submitted a new affidavit for Ms. Levitt from 2014 where it says all the things that counsel explained. That's not what she said at her deposition.

We go through in our reply brief and set out the page citations to that portion of the deposition where we discuss why she stopped taking Vioxx. She didn't have a recollection of why she stopped taking it. When she was confronted with the record showing in the doctor's medical records that the insurance was no longer going to pay for it, she acknowledged that that must be the reason. There are numerous cases that say you can't come back years later at

11:29

summary judgment and submit a contrary affidavit. We think that the evidence would support a summary judgment here.

THE COURT: How about the second motion? This is the motion where the complaint was filed in 2006. At that time, if I remember, paragraph 36 or so took the position that the proximate cause was a heart attack suffered in June of 2001. Now the plaintiff takes the position that it's broad enough to include other cardiovascular incidents as opposed to just a heart attack. How do you see that?

MS. PISTILLI: Yes, Your Honor. Thanks. Emily Pistilli from Williams & Connolly representing Merck on this first motion for summary judgment.

Yes, as Your Honor summarizes, the central issue in this motion is that originally in the complaint and then for almost eight years afterwards, until she withdraw Dr. Schapira as an expert, Ms. Levitt was consistent in alleging that Vioxx caused her to experience actually two heart attacks in that 2000 time frame. The fact and the expert evidence that has since been developed by the parties to date establishes that she did not actually have any MI.

As you point out, Your Honor, the plaintiff would ask the Court to accept the original allegations in the complaint as being broader and to encompass other cardiovascular injuries. But as you are aware from the course of this litigation, the specific allegation of an MI or heart

11:31

attack is reference to a specific arterial thrombotic event and it's not a generic term for all cardiovascular injuries.

There are other instances in this litigation of other types of cardiovascular-related injuries -- for example, congestive heart failure -- that are cardiovascular-related injuries that have not been lumped in as a heart attack. It's a distinct injury.

THE COURT: What does she claim she has now?

MS. PISTILLI: There are a number of different events that are pointed to. I believe the most distinct phrasing of the injury would be exacerbation of cardiovascular disease or exacerbation of coronary artery disease and then with reference to angioplasty that she had performed at the time she alleged the heart attacks, angioplasty and the placement of a stent, as well as a bypass surgery, a CABG surgery, but without any reference to heart attacks in those medical records.

As a legal matter, as Your Honor captured in your remarks, under Missouri law, as in other states in this type of complex medical injury, there's expert testimony that would be required at the summary judgment stage to sustain the burden. While Ms. Levitt has a number of other experts, Dr. Schapira, who has been withdrawn, was the only expert who was designated to opine on her allegations that she suffered MI's caused by Vioxx. With his withdrawal last year, after his deposition was rescheduled twice, she has no expert witness who

11:32

is currently designated to support her claims that Vioxx caused her to experience MI's, the injuries that were alleged in the complaint. That lack of expert evidence warrants summary judgment in favor of Merck.

THE COURT: Is there any expert at all that says something about the cardiovascular incidents?

MS. PISTILLI: The experts do speak about the other events that are reflected in the records. Our position, Your Honor, is that Merck was entitled to rely on the complaint. The principle to notice pleading would dictate that Merck is entitled to rely on the complaint that this is a heart attack case.

Notably, the other injuries that they have raised, the other cardiovascular ailments were not inconsistent with having a heart attack. So up until the withdrawal of Dr. Schapira, it was not apparent and Merck was not on notice that they were, in fact, abandoning this; that this was no longer a heart attack case but was instead a generalized allegation about cardiovascular disease.

Merck would suggest that the discovery in this case would have been different. Different discovery and expert decisions would have been made if this was a matter of generalized cardiovascular disease rather than a heart attack.

Just a brief example. As you know, Your Honor, the APPROVe study, the data that led to the withdrawal of Vioxx

11:34

from the market, the data in that study related to specifically MI's, heart attacks, the specific thrombotic event that was alleged in her complaint.

The expert that Merck has designated in this case was an expert designated to opine on her heart attack claim. If instead it's a case about generalized heart/CV ailments without reference to a heart attack, there would have been other discovery. Should Your Honor rule that way on this motion, there would need to be other discovery to explore those.

THE COURT: Who drafted the pleading? Was she *pro se* at the time?

MS. PISTILLI: She was not *pro se* at the time of her complaint being drafted. The dates are pointed out in one of our pleadings, but she has had three separate sets of counsel and so she has been *pro se* for periods of time.

THE COURT: Okay.

MS. PISTILLI: I just wanted to reiterate that point, Your Honor. The thrust of the plaintiff's response to our motion is that Merck has been aware that there have been these other references to CABG surgery, the stents, the angioplasty along the way. It's Merck's position that until she actually withdrew the expert who was supporting her heart attack claims, there was no notice to Merck that this was no longer a heart attack case but that instead that they viewed the heart attack

11:36

allegations as a broad shorthand for cardiovascular disease.

THE COURT: Okay. All right. I understand your issue.

What's the response?

MR. THOMAS: Danny Thomas for the plaintiff, Your Honor.

THE COURT: What's the exact statement? I think it's 32. What does 32 say?

MR. THOMAS: Averment 32 of the pleadings, sir?

THE COURT: Yes.

MR. THOMAS: I do believe it does state two heart attacks.

THE COURT: Okay.

MR. THOMAS: If I could address a couple of things really quickly, and then I will go to address some of the finer details of the briefings.

The reference we were abandoning the heart attack claims after we withdrew Schapira, it's a little misleading. First of all, Schapira only references one heart attack in his report alone. It is my understanding that she was in the process of having a heart attack the very first time when medical doctors intervened, and then she had a heart attack the second time. We are not abandoning the heart attack claim by any stretch of the imagination by withdrawing Schapira, and we aren't abandoning the heart attack claim in

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our response to summary judgment.

I don't know where that understanding is coming from. It's not supported by the records. It's not supported by the discovery. It's not supported by the expert reports. This is why we keep saying we oppose the motion to stay. We wanted our experts to explain their positions. But the stay was granted, and I understood why.

This is why we filed a motion to reopen discovery, so we could depose the cardiologist. That was opposed for strategic purposes, and I understand why. I understand the Court's ruling. I asked the Court to reconsider it again in light of the mess that we are dealing with right now.

When all this started, Merck's sole point of contention was we did not have an expert to testify as to heart attack. We withdrew Schapira for strategic reasons. We believed that we had enough expert and medical records to satisfy our burden of proof.

To make things easy, before I even get into the argument, we can just redesignate Schapira. The case has been stayed for a year. There have been no expert depositions. No harm, no foul. We don't have to do that. We would like to do that just to avoid, again, this mess and let the case be decided on the merits, because I think that's what everybody is entitled to.

11:38

The sole point of contention was we don't have an expert. When we replied to that and said, "We do have an expert," they said, "Well, now you are changing the position and you're changing the theory of recovery." Not true. Merck has been on notice of plaintiff's claims of injuries via our filings, our expert reports, plaintiff's deposition testimony, and her supplemental plaintiff profile form.

The supplemental plaintiff profile form came out in 2009. Nowhere did it mention heart attacks, and I will go into a little bit more detail about that. Plaintiff's complaint satisfies the federal notice pleading standard which requires only a short and plain statement showing entitlement to relief under 8(a)(2).

Plaintiff has sufficient expert testimony to support her claims, both through her retained expert, Dr. Egilman, and her treating cardiologist, Dr. Rosamond. His letter came in 2010, I believe, Your Honor. Dr. Rosamond is qualified and permitted to testify as to issues pertaining to his treatment of plaintiff. No expert report is required under Federal Rule 26(a)(2)(b) from Dr. Rosamond. Even though he gave one, he is not even required to do one. If the Court will recall, he wrote a *Lone Pine* letter to His Honor before my firm was involved again. Essentially, what I think we are dealing with here is a premature *Daubert* attack on Dr. Egilman before he has even been deposed.

11:40

Let's talk about --

THE COURT: Is he a cardiologist, Egilman?

MR. THOMAS: No, he is not, Your Honor.

THE COURT: What is he?

MR. THOMAS: He is a board-certified internist.

MR. WILLIAMS: Internist?

MR. THOMAS: Yes, sir.

Again, plaintiff's supplemental profile form was submitted by plaintiff herself -- and she should be commended for this -- in September of 2009. The attorneys that originally filed her lawsuit and filed her original PPF handled unknown numbers of cases, and they filed generic pleadings and generic discovery. When she was handling the case herself *pro se*, doing everything she could to survive, she took it upon herself to file a supplemental PPF, and here's what she had to say about her injury.

Oh, here's what she says in her deposition, and then I will get to that. In her deposition she says (as read):

"Oh, I'm sorry. I did have a PPF first. ASC, arthrosclerosis, MI. Stents less than three months ASC/MI CABG. Reduced ejection fraction. New plaque in arteries not there less than three months before diagnosis of very aggressive heart disease."

They have been on notice since 2009, and now they are trying to tell the Court that they made discovery

11:41

decisions based on just the petition? Did they not read the supplemental plaintiff profile form? What discovery decisions did they make? The only discovery they did was to take plaintiff's deposition, plaintiff's husband's deposition, the deposition of Dr. Katz -- they deposed none of the other cardiologists -- and a psychiatrist and a business associate. That's the only discovery they did.

They haven't made an offer of proof as to what other discovery they would have performed. They haven't made an offer of proof as to what other expert they would have retained. Merck deposed plaintiff on the contents of her supplemental amended PPF. For 50 pages of deposition testimony, they asked her questions about it.

She responded directly to questions about her injury saying, "I thought I was going to die. I mean, because all the sudden I have aggressive heart disease, and I never had aggressive heart disease in my life."

Talking about the letter from Dr. Rosamond, I stand corrected. I think it was 2010. I think my notes are wrong. I think that letter came in 2010.

Dr. Rosamond states, "I think it is likely that Vioxx therapy contributed significantly to the aggressive presentation of her coronary artery disease." They have a right to rely on that as well, Your Honor, and they should have relied on it.

11:43

Plaintiff's expert, Dr. Egilman, wrote in his report, "Her Vioxx use thus was a significant contributing factor for her heart disease during and after Vioxx consumption." Merck cannot come before the Court and feign surprise that plaintiff has alleged injury of heart disease and not merely heart attack when it's been on notice for over five years. Notice pleading, that's what federal pleading is all about. Plaintiff's' complaint complies with federal notice.

As opposed to the cases cited by Merck -- and that's important for the Court to understand. Merck hasn't cited a single case on point for its contention. Plaintiff is not seeking to assert a brand-new claim. She's merely expanding upon the description of her claim.

If she was asserting stroke or diabetes or some of these eyeball deficiency, vascular deficiency cases, that's a new claim. It all stems or circles, and always has, around the events of March 10, 2000, the stent balloon to LAD, and May 26, 2010, double bypass due to restenosis. She's always identified these dates. They are consistent. Whether you call them heart attack, aggressive heart disease, whatever it is, it's these two dates that have been at issue with regard to Vioxx.

THE COURT: When did the CABG happen?

MR. THOMAS: The CABG happened, Your Honor -- I believe that was May 26, 2000.

11:45

Merck claims that once plaintiff withdrew her expert, she no longer has expert testimony to support her proximate causation claim. This ignores again the report of Dr. Egilman, the letter authored by her treating cardiologist, Dr. Rosamond.

I think all four of the cases cited by the defendant -- the *Trasylol* case, the *Baycol* case, the *Brickey v. Concerned Care of Midwest* case, and the *Kipp* case -- are all distinguishable. We have identified why they are distinguishable in our pleadings, and I'm not going to go over that with the Court again.

This isn't a case where we completely failed to designate expert witnesses to testify as to causation or where all the relevant expert testimony has to be stricken. That reminds me -- or has been stricken, excuse me.

That reminds me, Your Honor. Under Rule 15(b), they have acquiesced to an amendment by litigating the issue. Under Rule 15(b), if the issues have been litigated by express or implied consent of the party, we believe that they have acquiesced to an amendment via the supplemental plaintiff profile form, which they deposed plaintiff at length about, Dr. Rosamond's letter, and again plaintiff's deposition. All these speak to aggressive coronary artery disease presentation, coronary artery disease, and aggressive heart disease. We brought this up in our pleading, Your Honor, and they had no

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response to it, that they have acquiesced to an amendment to the pleading.

To the extent that they believe that they have not acquiesced or the Court believes that the pleadings or the discovery and the claim is not in comport with the original petition filed back in 2006, the Court has discretion under Rule 16(b) to allow an amendment. Again, there's no prejudice here, Your Honor. We are just trying to get the case decided on the merits. They have made no offer of proof as to how anything would have changed. If they want to reopen discovery, we would love to.

THE COURT: Okay.

MR. THOMAS: I have nothing further. Thank you very much.

MS. PISTILLI: Just a couple of points in response. The first thing I would mention is the plaintiff seems to be going back and forth about whether they are actually alleging heart attacks as the basis of this claim or if this claim excludes heart attacks but relates to the other manner of cardiovascular events that are mentioned in her records and in her pleadings.

They suggest today that maybe there is actually evidence of a heart attack. Merck's position is there is not evidence in the record of a heart attack, and Merck set that evidence out in the pleadings submitted to this Court. The

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evidence they mentioned today was not mentioned in their responsive pleadings.

They mention all their other experts. There is no expert other than Dr. Schapira that says she had a heart attack and that her heart attack was caused by Vioxx.

On the issue of whether Merck could have acquiesced to an amendment and whether an amendment should be permitted now, I would disagree that Merck did not have a response to the argument about acquiescence. We have cited, Your Honor, the *Moody* case.

There's case law setting out that if documents and statements are out in discovery that are not inconsistent with the well-pleaded claims that are in the case, a party does not acquiesce to amendment by failing to object to that evidence when it comes in. We have cited those cases in the brief, so we believe that we have responded to that assertion.

THE COURT: Okay.

MS. PISTILLI: We obviously disagree strongly that there would be no prejudice with an amendment being allowed at this time, 14 years into the *Vioxx* litigation, nine years into this case, with discovery having been taken in this case for many years. We submit that there would be substantial prejudice to Merck and also that it is just an end run around the pleading requirements and the conduct of earlier discovery in this case that we have been pursuing for these years.

11:50

A similar notion with respect to the suggestion to redesignate Schapira. To suggest that there is no prejudice when we had extensive preparation for Dr. Schapira's deposition, it was rescheduled multiples times, and then extensive briefing on this motion, certainly there is prejudice to Merck to just get a do-over and go back to the start as if this never happened.

THE COURT: Okay.

MS. PISTILLI: Lastly, on Dr. Rosamond and Dr. Egilman.

On Dr. Rosamond, Merck's position is that his *Lone Pine* letter, he is not -- the testimony he would be offering in this case as the plaintiffs put it forward is not the testimony based on a treating physician's impressions of his patient. It's opinions formed subsequent to his treatment of the patient, of Ms. Levitt, and a report would be required. We have cited cases in our brief to address that.

Dr. Egilman does not support that she had an MI. He addresses her cardiovascular claims for two paragraphs in his very lengthy report, Your Honor.

Lastly, on the point of discovery, the suggestion that we should have anticipated the abandonment of the MI claim and that we wouldn't have done anything differently, Your Honor, a claim regarding the general state of Ms. Levitt's cardiovascular health would bring into the case a

11:51

much broader look into her lengthy cardiovascular history and also additional fact and expert discovery about her other noncardiac health problems -- fibromyalgia, for example -- that would have appeared to have generated symptoms that could erroneously be characterized as exacerbated cardiovascular disease. It's one of the examples of a discovery issue that we pointed out in our briefing.

THE COURT: Is there any evidence that any of those other problems are causally related to Vioxx?

MS. PISTILLI: That was another point that I had alluded to when I first presented, Your Honor. Unlike the situation where expert testimony is presented on Vioxx with an MI, this raises the question of what evidence is out there that Vioxx could lead to the increased incidence of coronary artery bypass grafts, of stenting. As you touched on, Your Honor, it is not the situation where there is well-tried territory in that regard. We are not aware of that, and we haven't had experts address that because this is a heart attack case. Thank you.

THE COURT: Let me look at this again from what you all have told me, and I will be ruling on it very quickly. Thank you very much. I appreciate your briefs and argument. The Court will stand in recess.

THE DEPUTY CLERK: All rise.

(Proceedings adjourned.)

11:53

* * *

CERTIFICATE

I, Toni Doyle Tusa, CCR, FCRR, Official Court Reporter for the United States District Court, Eastern District of Louisiana, certify that the foregoing is a true and correct transcript, to the best of my ability and understanding, from the record of proceedings in the above-entitled matter.

s/ Toni Doyle Tusa
Toni Doyle Tusa, CCR, FCRR
Official Court Reporter

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