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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: VIOXX PRODUCT
LIABILITY LITIGATION

Docket No. 05-1657
Section "L"
New Orleans, Louisiana
Wednesday, August 17, 2016

THIS DOCUMENT RELATES TO:

JO LEVITT V. MERCK SHARP & DOHME CORP.
2:06-CV-9757

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

APPEARANCES:

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P R O C E E D I N G S

(WEDNESDAY, AUGUST 17, 2016)

(MOTION PROCEEDINGS)

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5 (OPEN COURT.)

6 THE COURT: Be seated, please. Good morning, ladies and
7 gentlemen. Let's call the case.

8 THE DEPUTY CLERK: MDL 1657, *in re: Vioxx Products*
9 *Liability Litigation.*

10 THE COURT: Will counsel make their appearance for the
11 record, please. First for the plaintiff.

12 MR. McCLAIN: For the plaintiff, Kenneth McClain, your
13 Honor, for Ms. Levitt.

14 THE COURT: Okay, Mr. McClain. For the defendant.

15 MR. BOEHM: Good morning, your Honor, Paul Boehm for
16 Merck.

17 THE COURT: Okay. This is a matter that grows out of the
18 Vioxx litigation. Ms. Jo Levitt indicates that she consumed Vioxx
19 in accordance with a prescription given to her by her doctor. She
20 claims that over the period she's had some issues, cardiovascular
21 issues, and she's filed suit against Merck. This grows out of the
22 MDL litigation.

23 The motions before me today, I have a number of *Daubert*
24 motions, but counsel has given me well-crafted briefs on each side,
25 as well as depositions, as well as the reports of the doctors or

09:51:26 1 the individuals that are the subject of *Daubert* motions, and I
09:51:33 2 really don't need any oral argument on that. I understand it and
09:51:36 3 I'll be ruling on that.

09:51:38 4 But there is another motion and that is a partial summary
09:51:43 5 judgment motion regarding Ms. Levitt's business losses; in addition
09:51:53 6 to personal injuries and in addition to medical expenses, she
09:51:58 7 claims various business losses. And Merck takes the position that
09:52:05 8 as a matter of law, these losses are not recoverable. The
09:52:10 9 plaintiff takes issue with that and feels that they are. So I'll
09:52:14 10 hear from the parties now.

09:52:17 11 MR. BOEHM: Good morning, your Honor, this is Paul Boehm.
09:52:19 12 As your Honor is aware and just referenced, there are five motions
09:52:22 13 before the Court. We have seen and I am mindful of the Court's
09:52:25 14 order asking that we focus on Merck's summary judgment motion, and
09:52:28 15 we propose that we start with that. My partner Ms. Horn will spend
09:52:32 16 whatever time the Court would like addressing that motion.

09:52:35 17 We did just want to note that we are also prepared to
09:52:38 18 discuss anything that might be on the Court's mind or questions
09:52:41 19 with respect to the expert-related motions, in particular if the
09:52:44 20 Court has any preliminary views or questions that could lead to the
09:52:47 21 denial of those motions, we would appreciate the opportunity to
09:52:50 22 address those issues or questions.

09:52:52 23 At a minimum, your Honor, we did not receive your order
09:52:56 24 until we were on the tarmac to leave Washington yesterday
09:53:00 25 afternoon. We prepared some materials in connection with our

09:53:03 1 anticipated argument on those expert-related motions that I would
09:53:05 2 like to hand up to the Court.

09:53:06 3 THE COURT: Okay, that's fine. And also send a copy to
09:53:09 4 the plaintiff so that they have it.

09:53:11 5 MR. BOEHM: We will e-mail those right away. Thank you,
09:53:14 6 your Honor.

09:53:15 7 THE COURT: Okay. Good.

09:53:17 8 MS. HORN: Good morning, your Honor. Elaine Horn from
09:53:20 9 Williams and Connolly here on behalf of Merck on the motion for
09:53:23 10 partial summary judgment as to damages. Specifically as to
09:53:27 11 business damages that Mrs. Levitt seeks to recover in this case.

09:53:31 12 And as you know, this is the last case, last personal
09:53:35 13 injury case; and one of the reasons that we're still here is that
09:53:37 14 there is a vast disparity between the parties' views as to what
09:53:41 15 types of damages can be recovered in this case.

09:53:43 16 Ms. Levitt would like to recover for certain businesses
09:53:47 17 that closed after about eight years after her cardiac events, and
09:53:51 18 it's Merck's position that Missouri law does not permit that.

09:53:54 19 Now, just a handful of key facts that are pertinent to
09:53:58 20 this particular motion. Mrs. Levitt had her cardiac events in
09:54:03 21 March and May of 2000, those are the events that are the subject of
09:54:06 22 this particular litigation. And at that time she had an ownership
09:54:10 23 interest in several different businesses. She had a 50 percent
09:54:15 24 ownership in a business known as Chocolate Soup Retail, which is a
09:54:19 25 corporation that owned a chain of high end children's clothing

09:54:23 1 stores, there are 14 different locations in major cities across the
09:54:26 2 country; she owned a 45 percent interest in a holding company that
09:54:30 3 also owned a corporation called Chocolate Soup Manufacturing, which
09:54:36 4 was the company that actually created clothing that was based on
09:54:40 5 Mrs. Levitt's designs; and then that same holding company also
09:54:44 6 owned a hotel in Lincoln, Nebraska that she had purchased from her
09:54:49 7 father some years ago.

09:54:50 8 Now, all of those businesses continued to operate for
09:54:54 9 eight years after she had her events. They did not close until the
09:54:58 10 2008-2009 time period, which was the same time period which you may
09:55:03 11 recall there was a great recession, financial crisis, lots of
09:55:07 12 economic difficulties in the country at that same time.

09:55:10 13 So we raise a number of issues in our brief. I would
09:55:13 14 like to focus on two of them, either one of which would warrant
09:55:18 15 granting Merck's motion. The first is that there was a clear case
09:55:22 16 that we cite in our brief that as a general rule a personal injury
09:55:27 17 plaintiff cannot recover for lost profits in business in a personal
09:55:30 18 injury action.

09:55:31 19 THE COURT: And we're dealing with Missouri law here
09:55:33 20 because that's where she lives and that's where the drug was
09:55:36 21 consumed.

09:55:38 22 MS. HORN: Correct. And there is a limited exception to
09:55:44 23 that general rule in which lost profits can be used as a proxy for
09:55:50 24 a personal injury plaintiff's lost earning capacity, and it's that
09:55:54 25 limited exception that's the focus of dispute here. The Levitts

09:56:00 1 would like to squeeze within that exception, and the undisputed
09:56:05 2 facts in this case clearly show that that exception does not apply.

09:56:10 3 And the key element of that particular exception is that
09:56:14 4 the plaintiff must make a substantial showing that the businesses
09:56:18 5 for which she seeks to recover lost profits did not rely on in any
09:56:27 6 significant fashion on invested capital or the labor of others.
09:56:30 7 And we cite numerous cases that talk about that. And here that's
09:56:34 8 the determining factor because we have companies that employed
09:56:38 9 hundreds of people, all across the country. She very well, as they
09:56:42 10 have put out in their briefs, she was one of the founders and much
09:56:46 11 of the clothing operation was based on her designs. But it was not
09:56:49 12 a sole proprietorship, it was not a one-woman show. And she may
09:56:54 13 have been the most important person in the company, but it still
09:56:57 14 required hundreds of people.

09:56:58 15 And you can look at the plaintiff's response to our
09:57:00 16 statement, our Rule 56.1 statement, statement of undisputed facts,
09:57:04 17 and the admissions in there clearly show that that exception does
09:57:07 18 not apply.

09:57:08 19 THE COURT: How do you see the exception tailored? Is it
09:57:12 20 that the plaintiff must show that it was not personal services
09:57:20 21 predominating?

09:57:21 22 MS. HORN: Well, it's two: She must show that personal
09:57:25 23 services dominate and make a substantial showing that invested
09:57:29 24 capital and the labor of others was relatively insignificant. So
09:57:34 25 as applied here, you would need to show that the millions of

09:57:37 1 dollars invested in these business and the labor of hundreds of
09:57:41 2 other people across the country was relatively insignificant to the
09:57:44 3 operation of this business. And her own admission showed that
09:57:47 4 that's just not the case.

09:57:49 5 In the statement of Rule 56.1 statement she admitted that
09:57:53 6 the multiple family businesses relied on the labor of hundreds of
09:57:56 7 other individuals, that was her response to No. 10 and No. 17. She
09:58:00 8 admitted that hundreds of individuals performed functions, and I
09:58:06 9 quote, "necessary to keep the businesses running." That's response
09:58:09 10 to No. 18. And she admitted that both the hotel and the clothing
09:58:14 11 businesses utilized substantial invested capital, that's response
09:58:17 12 to No. 19. And those issues alone take this case outside of the
09:58:21 13 exception. And so for that reason alone, Merck's motion should be
09:58:24 14 granted.

09:58:24 15 But there's another reason that independently warrants
09:58:29 16 granting the motion. And that's under Missouri law: To recover
09:58:32 17 lost profit, you must show with reasonable certainty there is a
09:58:36 18 connection between the lost profits that you seek to recover and
09:58:38 19 the alleged wrongful conduct of the defendant. So in this case
09:58:42 20 Mrs. Levitt needed to show with reasonable certainty there is a
09:58:44 21 connection between the cardiac events she suffered in March and May
09:58:49 22 of 2000 that she attributes to Merck and her businesses closing
09:58:53 23 eight or nine years later. And she offers nothing but speculation,
09:58:57 24 there's no reasonable certainty. She can't point to any facts that
09:59:01 25 support with reasonable certainty that those businesses would have

09:59:02 1 survived a worldwide economic crisis.

09:59:05 2 And, in fact, here, Mrs. Levitt has designated an expert
09:59:11 3 to opine on damages. And he does, he provides a full report. And
09:59:15 4 he testified that there is no basis to distinguish Mrs. Levitt's
09:59:18 5 business from the hundreds of other similar businesses that closed
09:59:22 6 during the same time period. So since she can't point to any
09:59:26 7 reasonable -- any facts that showed reasonable certainty that there
09:59:29 8 is a connection, that's another reason to grant our motion.

09:59:32 9 THE COURT: Okay. Thank you very much let me hear from
09:59:35 10 the plaintiff on those issues.

09:59:38 11 MR. McCLAIN: Yes, Judge. Judge, you've heard more about
09:59:44 12 this case probably than you've wanted to. And I appreciate the
09:59:52 13 Court's willingness to let me appear by phone, as you told me you
09:59:57 14 would in court two weeks ago.

10:00:00 15 THE COURT: Yes.

10:00:00 16 MR. McCLAIN: Ms. Levitt, this is a very unique
10:00:03 17 circumstance. This Chocolate Soup company that she started and was
10:00:10 18 the driving force in, you know, like Reggie Jackson said, she was
10:00:17 19 the straw that stirred the drink. It was a very big deal here in
10:00:26 20 Kansas City when it was running full speed, and she was the belle
10:00:33 21 of the ball in the media in regard to its creation and its vitality
10:00:42 22 and its effect on the local community of entrepreneurs here, and Jo
10:00:49 23 Levitt was the reason for that excitement. She was the designer of
10:00:54 24 the clothing that was involved, she was the motivator of the other
10:01:03 25 individuals involved in the enterprise. And so this is not the

10:01:12 1 type of situation that is talked about in the cases where one
10:01:13 2 individual is not consequential to the overall success of the
10:01:19 3 business. In fact, she was the business. And when she was taken
10:01:22 4 out of it, the business failed.

10:01:24 5 The suggestion by Ms. Horn that it required millions of
10:01:29 6 dollars of capital is correct, it was her money. The business was
10:01:36 7 started with \$5,000 and it was not a situation where it was a
10:01:43 8 public offering of stock or some other things that these cases talk
10:01:48 9 about, this is money that was generated by the company and put back
10:01:53 10 in; but also borrowed by she and her husband, which ultimately
10:01:58 11 forced them into bankruptcy.

10:02:01 12 So the investment part of this actually goes in her favor
10:02:05 13 as the cases discuss this issue in terms of her overall necessity
10:02:10 14 to the success of this business.

10:02:12 15 In addition to that, the fact that they had hundreds of
10:02:16 16 employees is true from time to time, but those people were
10:02:22 17 relatively at low levels of the success of this company. And the
10:02:28 18 executive -- people that were, you know, employed to sew or to work
10:02:34 19 in the retail stores or other things that they operated, not to
10:02:40 20 denigrate their contribution because they did have some, but those
10:02:43 21 contributions were easy to replace. Much easier than Ms. Levitt.
10:02:47 22 And the people in the executive decision making said we were really
10:02:55 23 responding to what Jo told us to do.

10:02:57 24 That's what the accountant said, that's what her husband
10:02:59 25 said, and it's demonstrated by the fact that when she was taken out

10:03:04 1 of businesses it collapsed. It was a slow collapse but it was
10:03:09 2 because she had built up a substantial infrastructure around her.
10:03:13 3 But when she was not able to adjust to changing market conditions
10:03:18 4 because she no longer had the strength and vitality to do it, and,
10:03:24 5 you know, extensive discussion about her lack of energy caused
10:03:28 6 projects that used to be done in a short period of time because she
10:03:32 7 worked 70 to 90 hours a week, seven days a week before these heart
10:03:38 8 events that it would take months and months and months to do simple
10:03:43 9 tasks that she used to do in a short period of time.

10:03:46 10 So the testimony from our witnesses has been that, in
10:03:50 11 fact, her inability to react caused the company to fail because it
10:03:56 12 could not adjust to the changing circumstances that were
10:04:00 13 surrounding her.

10:04:03 14 THE COURT: But, Counsel, but your opponent says that
10:04:06 15 your expert said that he felt it was too speculative. How do you
10:04:10 16 deal with that?

10:04:11 17 MR. McCLAIN: Well, Judge, what he said was that as an
10:04:15 18 economist, I am not able to differentiate within this business
10:04:24 19 other businesses that I see from a paper analysis. But Ms. Levitt,
10:04:28 20 he said, may, in fact, be able to do that; and I am relying upon
10:04:32 21 her to discuss those damages, those are not within the scope of
10:04:35 22 what I am able to do.

10:04:39 23 So we fall back, Judge, on -- and she points out and as
10:04:43 24 you've recognized on a number of these issues, you know, a Judge in
10:04:47 25 Missouri may be in a better position to judge these things than

10:04:52 1 would appear on the surface. I can remember -- I was trained at
10:04:57 2 the University of Michigan Law School. When I first heard judges
10:05:03 3 telling me from the bench that a plaintiff can always testify to
10:05:06 4 their own damages in Missouri -- and in fact, that was on the bar
10:05:09 5 exam -- as a matter of Horn book law, it sounded foreign to me.
10:05:14 6 But it is so ingrained in our law, Judge, that it comes tripping
10:05:19 7 off the tongue of everyone that practices here.

10:05:21 8 And looking at the cases, Judge, you can see that
10:05:27 9 throughout -- and I just would give you an example. This is a 2006
10:05:33 10 case and we didn't cite it because it wasn't the focus. But I am
10:05:37 11 going to give it to the Court if that would be okay over the phone.

10:05:40 12 THE COURT: Yes, go ahead.

10:05:42 13 MR. McCLAIN: The case is *Parshall v. Buetzer*, and it's a
10:05:47 14 Court of Appeals decision, Western District of Missouri, July 11,
10:05:54 15 2006. The Southwest site is 195, SW 3d, 515, 2006. It was joined
10:06:06 16 in by our chief justice currently Judge Breckenridge on our Supreme
10:06:13 17 Court, so it's pretty current law, I think, on this issue. And
10:06:17 18 reiterate this point, you know, here is the quote I would cite you:
10:06:22 19 "A business owner's testimonial evidence sufficient to provide the
10:06:26 20 trier of fact with a rational basis for estimating damages to the
10:06:29 21 plaintiff, including lost profits is sufficient."

10:06:34 22 So in other words, the testimony of a business owner
10:06:37 23 about their lost profits is even being sufficient in Missouri
10:06:42 24 without the need of an expert. And here we have a woman who
10:06:47 25 testified, look. At the start of this case my businesses were

10:06:51 1 worth \$20 million. I can support that by the fact that I submitted
10:06:55 2 financial statements to banks who lent me money based upon them
10:06:59 3 after reviewing all of the statements that I provided to them, and
10:07:02 4 following my illness I was bankrupt. And she can document all of
10:07:09 5 the different iterations of financial statements that were provided
10:07:12 6 to the bank thereafter, which she ties to her illness.

10:07:16 7 So I think that there is a sufficient basis that is
10:07:19 8 contemporaneous with the events, documented with statements and
10:07:26 9 other things from the bank files during this time period, which
10:07:30 10 she, frankly, attributes to her illness, as do the other people
10:07:35 11 that were involved with the actual business at the time.

10:07:39 12 Now, Dr. Ward says as an economist, that's something that
10:07:46 13 I am not able to do, but you can establish that through the
10:07:49 14 testimony. I am going to leave that to the plaintiff. And that's
10:07:52 15 how I deal with that issue.

10:07:54 16 THE COURT: All right. Let me hear a response. He says
10:08:01 17 that it's a question of fact because the plaintiff's going to say
10:08:05 18 that I am a key person, it's my personal services predominated, and
10:08:12 19 that all of the capital was my own.

10:08:18 20 MS. HORN: Well, let's start with the last piece, all of
10:08:21 21 the capital was my own. The source of the capital isn't the issue,
10:08:25 22 it's the fact that the profits that are generated from the business
10:08:28 23 are a return on capital and not a return on the individual's labor.
10:08:32 24 The cases in which this exception applies where you can use profit
10:08:36 25 as a proxy for earning capacity, this is where the business is all

10:08:40 1 about that person. So like where you have a solo practitioner as
10:08:44 2 an attorney or doctor. The cases that we cite, we had cases where
10:08:47 3 you had have very small construction company of ten people where
10:08:50 4 the main person was the plaintiff and that wasn't enough, that was
10:08:55 5 too much, there was too many people too much capital. Here we have
10:08:58 6 hundreds.

10:08:59 7 THE COURT: Or a doctor, for example, a doctor's office.

10:09:02 8 MS. HORN: Correct, if you take the doctor out, the
10:09:05 9 business is all about that particular personal service.

10:09:08 10 I am not familiar with the specific case that Mr. McClain
10:09:12 11 referenced, but I know that cases that we found which talked about
10:09:17 12 whether or not a business owner -- the fact that a business owner
10:09:20 13 could testify to the value of his or her company, those were
10:09:23 14 largely cases in which the business itself was a party. And so
10:09:27 15 here we're at the threshold question of not how much you want to
10:09:31 16 value the business at, but whether or not you even get there,
10:09:34 17 whether or not these are the type of losses that you can pursue
10:09:39 18 under on individual personal injury.

10:09:40 19 And under Missouri law they're not, they're just not.
10:09:42 20 And there is a very limited exception and it's not just that the
10:09:46 21 fact that Mrs. Levitt was so important, we are not trying to
10:09:50 22 dispute that.

10:09:50 23 I'll take a step back. Mr. McClain started by staying
10:09:54 24 Ms. Levitt was like the star that stirred the drink. Well, that's
10:09:57 25 good but you still need the drink. Like you still need the people

10:10:00 1 to actually cut the clothes, make the clothes, sell the clothes,
10:10:03 2 you need people to do whatever they were doing with the hotel. And
10:10:06 3 she could be Wonder Woman but she couldn't do all of that by
10:10:09 4 herself.

10:10:10 5 And so all of these millions of dollars in profit that
10:10:12 6 they wanted to recoup that required the capital and labor of
10:10:15 7 others, and because of that it's outside of the exception.

10:10:18 8 THE COURT: All right. I understand both positions. Do
10:10:21 9 you want to respond to that case that he mentioned? Do you feel
10:10:26 10 that that's necessary? Do you feel it's necessary to respond?

10:10:31 11 MS. HORN: No.

10:10:32 12 THE COURT: Okay. While I've got you all, give me your
10:10:35 13 thinking on Dr. Edelson (VERBATIM).

10:10:48 14 MR. BOEHM: Do you mean Dr. Egilman, your Honor?

10:10:50 15 THE COURT: Yes. I am familiar with Dr. Egilman, but I
10:10:55 16 would like your thoughts on that.

10:10:57 17 MR. BOEHM: And, your Honor, as I mentioned, we brought
10:10:59 18 with us some slides that we prepared in anticipation. We will not
10:11:02 19 by any means go through all of these slides.

10:11:05 20 THE COURT: Just Dr. Egilman's. You can hand those out.

10:11:13 21 MR. BOEHM: And we e-mailed those to Mr. Thomas.

10:11:17 22 MR. McCLAIN: We can't get them to download.

10:11:24 23 MR. BOEHM: I think we sent two versions, one is the full
10:11:27 24 size and one is cut in half so it's small enough that it should
10:11:31 25 come through. We can try again, we'll do that now.

10:11:35 1 THE COURT: I just need Dr. Egilman. Dean, can you put
10:11:38 2 the screen down?

10:11:49 3 MR. BOEHM: I am not anticipating using -- putting any
10:11:52 4 slides up on the screen, your Honor, unless you would like me to do
10:11:53 5 that.

10:11:53 6 THE COURT: No, that's okay.

10:11:54 7 MR. BOEHM: I was just going to direct your attention to
10:11:57 8 certain slides on the hard copy that I provided to you.

10:12:00 9 I want to focus on two specific arguments that plaintiff
10:12:05 10 has made with connection with Dr. Egilman. And of course any other
10:12:05 11 that are on the Court's mind.

10:12:08 12 I'll direct the Court's attention to slide No. 4. The
10:12:13 13 first plaintiff's argument that I wanted to address: The idea that
10:12:16 14 Dr. Egilman already has been accepted as an expert in other Vioxx
10:12:32 15 cases, and I guess the implication being that that is -- stands for
10:12:36 16 his qualifications to testify in this particular case.

10:12:39 17 To be clear, Dr. Egilman has been designated and has been
10:12:45 18 permitted to testify in one Vioxx case, that was the *Ernst* case,
10:12:49 19 which plaintiff's counsel correctly pointed was the first Vioxx
10:12:53 20 trial that took place in 2005 in Texas state court. Plaintiff did
10:12:57 21 not in their opposition brief, however, mention the appeal of that
10:13:00 22 case. The appellate court singled Dr. Egilman out and specifically
10:13:06 23 rejected his testimony.

10:13:09 24 Dr. Egilman in that case was testifying based on the
10:13:12 25 presumption that the plaintiff had experienced myocardial

10:13:16 1 infarction. His report was focused on myocardial infarction data,
10:13:21 2 his opinions were based on myocardial infarction related data and
10:13:25 3 information, and he expressed opinions on that basis. The
10:13:28 4 appellate court said that was an unwarranted assumption and because
10:13:35 5 of that, his testimony should be rejected. In fact, we have on
10:13:38 6 slide 5 of what you have in front of you an excerpt from the
10:13:41 7 opinion in that matter. The same thing is happening here.

10:13:46 8 Plaintiff --

10:13:47 9 MR. McCLAIN: Can we just stop. This is catching me by
10:13:50 10 surprise in light of what we were told to prepare for and in light
10:13:54 11 of the fact that this was not -- you can't download what they sent
10:13:57 12 us and it's not cited in their brief.

10:14:00 13 MR. BOEHM: Actually it is cited in our brief.

10:14:02 14 THE COURT: Well, let's do it this way. Don't refer to
10:14:06 15 any documents, just tell me your argument just from the
10:14:12 16 standpoint --

10:14:13 17 MR. BOEHM: Sure, that's fine, your Honor.

10:14:18 18 In that opinion, the Court determined that Dr. Egilman's
10:14:21 19 opinions were not appropriate because he was relying on assumptions
10:14:25 20 about myocardial infarction in a case where the plaintiff did not
10:14:28 21 experience myocardial infarction.

10:14:29 22 In this case Dr. Egilman concedes that Ms. Levitt did not
10:14:34 23 experience myocardial infarction. He expressly testified in his
10:14:37 24 deposition that she did not have a myocardial infarction, but
10:14:41 25 rather that the injury that he had identified was that of unstable

10:14:47 1 angina.

10:14:48 2 THE COURT: Doesn't that go to his conclusions and not
10:14:52 3 excluding him from testifying?

10:14:54 4 MR. BOEHM: Your Honor, no, it doesn't. It goes directly
10:14:56 5 to his methodology. An expert who is relying on data that
10:15:02 6 concerned one particular type of cardiovascular injury to express
10:15:05 7 opinions about a different type of injury goes directly to the
10:15:10 8 issue of methodology. That is an unsound and unreliable
10:15:15 9 methodology to express opinions, particularly causation opinions,
10:15:19 10 about an entirely different injury. Dr. Egilman should not be
10:15:22 11 allowed to testify to a jury using data and documents about
10:15:27 12 myocardial infarction when he himself agrees that Ms. Levitt didn't
10:15:30 13 experience that injury.

10:15:31 14 And that's the same kind of issue that was identified by
10:15:34 15 the appellate court in *Ernst*. And we're asking the Court to
10:15:39 16 exclude Dr. Egilman's opinions about myocardial infarction data or
10:15:42 17 relying on analyses of myocardial infarction data in this
10:15:46 18 particular case.

10:15:46 19 Now, plaintiff's counsel has suggested that Dr. Egilman
10:15:53 20 can look at something called acute coronary syndrome and that
10:15:57 21 stands in for unstable angina, the event, the specific type of
10:16:01 22 event that Ms. Levitt experienced. Nobody actually disagrees in
10:16:07 23 this case that acute coronary syndrome and unstable angina are two
10:16:13 24 different things. Acute coronary syndrome, as plaintiffs say in
10:16:18 25 their own opposition brief with respect to Dr. Egilman, is a

10:16:23 1 combination of three separate coronary outcomes; including unstable
10:16:30 2 angina, which plaintiff Jo Levitt had, myocardial infarction and
10:16:35 3 sudden death. I am reading verbatim from page 23 of the
10:16:40 4 plaintiff's opposition brief. They say the same thing on page 26
10:16:44 5 of their opposition brief. Dr. Egilman also says acute coronary
10:16:48 6 syndrome is actually just an umbrella term that refers to multiple
10:16:51 7 coronary events. They are not the same thing.

10:16:53 8 And the Fifth Circuit has made it clear that it is
10:16:57 9 unsound methodology to use a composite end point to try and reach
10:17:03 10 causal associations or conclusions about a particular type of
10:17:06 11 injury. There are two cases that we cited in particular in the
10:17:09 12 brief, one is the *Burleson* case, one is the *Allen* case, they're
10:17:13 13 cited in the briefs, they're on slides 14 and 15 in what's been
10:17:17 14 provided to the Court. We urge the Court to read those opinions.

10:17:22 15 Those are cases where plaintiff is alleging that causal
10:17:25 16 associations had been found as between an exposure and cancer stood
10:17:32 17 in for causal associations between an exposure and a particular
10:17:37 18 type of cancer. The Fifth Circuit said, no, you can't do that.
10:17:42 19 You have to look at the specific type of injury. And that's
10:17:45 20 exactly what we have here. And Dr. Egilman concedes he has not
10:17:49 21 looked at unstable angina.

10:17:51 22 Now, the plaintiffs have suggested that it wasn't
10:17:53 23 possible for them to do that because of the way the data was
10:17:55 24 collected. That's just incorrect for the reasons that we've said
10:17:59 25 in the -- stated in the brief. And Dr. Egilman himself in his

10:18:02 1 testimony said that that could have been done, that Dr. Madigan had
10:18:07 2 the data to do that. He just did not ask Dr. Madigan to do it in
10:18:13 3 that way, he asked him to look at the composite end point, which as
10:18:15 4 you know includes sudden death and myocardial infarction.

10:18:22 5 THE COURT: Was he involved in the treatment? I wasn't
10:18:25 6 clear as to whether or not he was involved in the treatment of Jo
10:18:28 7 Levitt.

10:18:29 8 MR. BOEHM: You know I was confused by that when I read
10:18:30 9 the report the first time as well. Your Honor, Dr. Egilman had no
10:18:34 10 involvement in the actual treatment of Ms. Levitt. He does purport
10:18:38 11 to have met with her on an occasion and had a conversation with her
10:18:42 12 about, you know, how she is feeling now and what's going on in her
10:18:45 13 life.

10:18:46 14 THE COURT: Did he refer her to anybody for treatment?

10:18:49 15 MR. BOEHM: I'm sorry, would you say that one more time?

10:18:52 16 THE DEFENDANT: Did he refer her to anyone for treatment?

10:18:56 17 MR. BOEHM: No, he did not, your Honor. We asked him
10:18:57 18 that question, he did not refer her to anyone for treatment.

10:19:03 19 Now, the last point I would make with respect to
10:19:07 20 Dr. Egilman is this idea that because he's been accepted in a
10:19:09 21 variety of other litigations as an expert talking about a variety
10:19:12 22 of different subject matters, then that shows that he is qualified
10:19:16 23 to talk about a host of issues in this case. Your Honor -- in
10:19:22 24 particular, plaintiff points us to the example of his work in the
10:19:25 25 popcorn lung litigation, the so-called popcorn lung litigation that

10:19:29 1 Mr. McClain is involved in. We would advance the idea that his
10:19:35 2 work in that case actually illustrates the problem. In that case
10:19:40 3 Dr. Egilman purports to be a specialist in occupational medicine
10:19:44 4 with a particular specialty in occupational lung disease. In this
10:19:49 5 case, of course he says he has a particular specialty in vascular
10:19:53 6 biology and cardiology and psychiatry and state of mind and
10:19:58 7 warnings and marketing and the law.

10:20:03 8 The point is you can't just take an expert's word for it.
10:20:07 9 That's particularly true for an expert who is claiming to be a
10:20:10 10 specialist in virtually every area where an expert testimony might
10:20:14 11 be called for in this case.

10:20:17 12 I'll just use one example: The regulatory opinions.
10:20:22 13 Dr. Egilman is by no measure an expert in the FDA. The cases that
10:20:27 14 Dr. Egilman's counsel has cited in their opposition brief stand for
10:20:31 15 the undisputed proposition that there are such things as FDA
10:20:36 16 experts. But those people invariably are individuals who have
10:20:40 17 spent many years working in the regulatory process at the FDA or in
10:20:44 18 one instance somebody who spent many, many years leading the
10:20:47 19 regulatory department of a pharmaceutical company involved in this
10:20:53 20 industry.

10:20:54 21 This is illustrative of a pattern, and I am happy, your
10:20:57 22 Honor, to discuss any one of these areas: Psychiatry, neurology,
10:21:01 23 vascular biology, marketing, and so on.

10:21:04 24 THE COURT: No. I've got it. Thank you. Let me ask the
10:21:08 25 plaintiff to respond to anything. From Dr. Egilman, what's your

10:21:12 1 view as to, first, whether he's qualified; and if so, on what?

10:21:18 2 MR. McCLAIN: Judge, you know, yes, we think he's
10:21:21 3 qualified and we lay that out for the Court. He has written eight
10:21:25 4 peer reviewed articles on Vioxx. Eight peer reviewed articles
10:21:29 5 which shouldn't, you know, according to the *Daubert* case itself is
10:21:36 6 the hallmark of an expert, that he relies upon peer reviewed
10:21:40 7 literature, he wrote it.

10:21:42 8 You know, he did testify and I think that the Court
10:21:46 9 correctly identifies the issue, whatever the Court of Appeals says
10:21:50 10 about what was accepted or not accepted goes to the evidence and
10:21:54 11 the weight of the evidence and is left to the trial judge to
10:21:57 12 decide, not at this stage to decide he is not qualified. The Court
10:22:00 13 did not say he wasn't qualified to testify in that case.

10:22:05 14 So, you know, Judge, just to back up regarding his
10:22:10 15 qualifications. Dr. Egilman received his medical education at
10:22:15 16 Brown University, he went on to receive a master of public health
10:22:22 17 from Harvard, and worked for the National Institute of Occupational
10:22:28 18 Safety and Health as a uniformed officer in their epidemiology
10:22:34 19 section before going into practice and becoming a professor at
10:22:40 20 Brown University Medical School where he currently still teaches.
10:22:47 21 His involvement has extended into publishing chapters on warnings,
10:22:54 22 particularly on warnings related to drugs. And so, has
10:23:01 23 demonstrated expertise in general medicine involving epidemiology
10:23:12 24 and including warnings and as they relate to the process of
10:23:17 25 approval of drugs, which he has published some extensive literature

10:23:22 1 on.

10:23:24 2 Page 4, Judge, of our brief as an example, of the brief
10:23:32 3 entitled Plaintiff's Opposition to Defendant's Motion to Exclude
10:23:35 4 Dr. Egilman, you know, he has twice testified before Congress on
10:23:40 5 the proper conduct of medical research, including design and
10:23:44 6 informed consent, corporate responsibility to test products and
10:23:48 7 publish study results as well.

10:23:51 8 So we think that he has *Daubert* permissible credentials
10:24:01 9 to testify and has testified extensively about Vioxx and studied
10:24:09 10 it, in addition to his testimonial credentials.

10:24:15 11 So you come down to the specific opinions that they want
10:24:21 12 to challenge that he renders regarding acute coronary syndrome and
10:24:26 13 its relation to MI, which they agree that their studies demonstrate
10:24:33 14 a causal link between MI's and Vioxx. The problem with their
10:24:38 15 argument is that their own internal data from their own studies --
10:24:41 16 and this is what Dr. Egilman points out -- includes both MI's and
10:24:45 17 unstable angina -- in other words, acute coronary syndrome --
10:24:51 18 undifferentiated in their own data.

10:24:52 19 And so it was impossible for them to differentiate
10:24:56 20 between those two events within their own data at the same time
10:25:04 21 they were advocating its use to the general public. And both of
10:25:08 22 our experts, other experts besides Dr. Egilman agree with
10:25:12 23 Dr. Egilman's analysis of the data as it relates to acute coronary
10:25:17 24 syndrome, which includes both MI and unstable angina.

10:25:21 25 So he explained this extensively in his deposition, it's

10:25:24 1 not an off the cuff opinion, it is based upon an epidemiological
10:25:28 2 review of their own data and the conclusions drawn therefrom.

10:25:33 3 So once again, Judge, this goes back to the initial point
10:25:38 4 that you discussed. This is a question for the trial judge in
10:25:42 5 regard to admissibility after hearing the testimony about the basis
10:25:46 6 of the opinion that he draws, not something to be decided on the
10:25:48 7 papers; because he does have a basis to opine and the credentials,
10:25:56 8 you know, that should make his opinion admissible in this instance.

10:26:01 9 THE COURT: Okay. All right. I've read his depositions
10:26:09 10 and I've got it, and the other material, too, that you all have
10:26:13 11 sent to me. I mean, I have a package of it that I've been going
10:26:17 12 through, and I really -- I understand the issues.

10:26:23 13 Okay. Let's leave it at that. I'll be ruling on it
10:26:27 14 shortly. This case, I want to try to get it back to the judge as
10:26:31 15 quickly as I can for you all so that you can try the case. It's
10:26:35 16 been a long time. I know counsel for both sides have been working
10:26:39 17 on it hard and have been trying to resolve it. Not every case can
10:26:46 18 get resolved unfortunately, and that's just the way it is.

10:26:49 19 MS. HORN: Your Honor, we did have one more question
10:26:51 20 about the motions in limine schedule. In our proposed schedule we
10:26:55 21 had a little astrict where we asked if it would be possible to have
10:26:59 22 the motions in limine be due 30 days after whenever you rule on
10:27:03 23 these pending motions?

10:27:05 24 THE COURT: What's the motions in limine?

10:27:07 25 MS. HORN: We haven't filed them yet. We wanted to wait

10:27:10 1 until we saw how the case played out after you ruled on these
10:27:15 2 motions.

10:27:16 3 THE COURT: All right. But, you know, for the most part
10:27:19 4 if I can help either side on motions in limine to make it easier
10:27:23 5 for you, I'll do so. But the motions in limine oftentimes are best
10:27:28 6 handled by the judge who is going to try the case, but I'll do
10:27:33 7 that. I'll let you file them so that -- and if the plaintiff has
10:27:38 8 any motions in limine that you want me to deal with. I guess I've
10:27:43 9 been with this case so long now I may know as much about it as any
10:27:48 10 judge, so if I can be of help or service to either one of you all,
10:27:53 11 I'll do that. But we have to get this case back to trial because
10:27:57 12 it looks to me like it has to be tried.

10:28:00 13 MR. BOEHM: Your Honor, the Court's current order has a
10:28:03 14 deadline for motions in limine that is I believe September 17th.

10:28:06 15 THE COURT: Okay.

10:28:07 16 MR. BOEHM: What Ms. Horn is suggesting is that rather
10:28:10 17 than necessarily stand by that particular date, it would be helpful
10:28:12 18 to us to have rulings on, for example, Dr. Egilman and whether he
10:28:16 19 is going to be able to testify about myocardial infarction.

10:28:19 20 THE COURT: That's fair, I'll do that, 30 days after I
10:28:21 21 rule on it. I'll give you all an opportunity, both sides, if you
10:28:23 22 have any motions in limine that you need me to deal with, send
10:28:27 23 them. If I can, I'll do it; if not, then I'll just send it to the
10:28:32 24 judge that I am sending your case to. Thank you very much.

10:28:35 25 MR. McCLAIN: Judge, could I ask one thing before we get

10:28:37 1 off the phone?

10:28:38 2 THE COURT: Sure.

10:28:39 3 MR. McCLAIN: Judge, I would point out, and I'm sure the
10:28:42 4 Court's aware, we lay out in our briefs what opinions we're seeking
10:28:48 5 from him and which ones we're not. The defendants have stated in
10:28:53 6 their pleadings they want you to rule that he can't testify about
10:28:54 7 the things we're not asking him to testify about. I would prefer
10:28:58 8 that that not be done, because you know how orders get misused all
10:29:02 9 over the place; and if we're not offering him on those opinions, I
10:29:05 10 would prefer that we just have a stipulation we are not offering
10:29:08 11 him to offer opinions about those areas as opposed to the Court
10:29:11 12 ruling he can't offer opinions on things we're not seeking to have
10:29:15 13 him offered, if you know what I mean.

10:29:17 14 THE COURT: Let's do it this way. Why don't you meet
10:29:20 15 with counsel and see whether or not you can do a stipulation. If
10:29:23 16 not, then I'll deal with it.

10:29:26 17 MR. McCLAIN: All right.

10:29:27 18 THE COURT: If you can enter into a stipulation that both
10:29:30 19 of you all are comfortable with, then that's fine. If you can't,
10:29:34 20 then I'll rule on it.

10:29:35 21 MR. McCLAIN: All right.

10:29:36 22 MR. BOEHM: Thank you.

10:29:37 23 THE COURT: Let's get together soon on it, two weeks
10:29:41 24 enough for you?

10:29:42 25 MR. McCLAIN: Oh, yeah.

10:29:43 1 MR. BOEHM: Yes, that would be great, thank you, your
10:29:45 2 Honor.

10:29:45 3 THE COURT: Let me hear from you, then, in two weeks and
10:29:47 4 then I'll rule on it if you can't reach it.

10:29:50 5 Oftentimes a stipulation is sometimes better because the
10:29:58 6 Court that you're going to be trying the case before will have the
10:30:04 7 benefit of a stipulation as opposed to interpreting my ruling. So
10:30:10 8 give it a shot. If you can't, I'll rule on it.

10:30:14 9 But let me hear from you all within two weeks as to
10:30:17 10 whether or not you're able to have a stipulation. Otherwise, I'll
10:30:20 11 deal with it. Okay?

10:30:21 12 MR. BOEHM: Yes, your Honor.

10:30:22 13 MR. McCLAIN: Thank you, Judge.

10:30:23 14 THE COURT: All right. Folks, thanks very much. Thanks
10:30:25 15 for coming down. And I heard you well on the phone, so you came on
10:30:28 16 just as if you were here.

10:30:29 17 MR. McCLAIN: Well, thank you, Judge. I appreciate -- I
10:30:33 18 have to be down in Clinton, Missouri for a pretrial this afternoon
10:30:37 19 or I would have loved to have been there.

10:30:39 20 THE COURT: All right. Thank you. The court will stand
10:30:41 21 in recess.

10:30:41 22 (WHEREUPON, THE PROCEEDINGS WERE CONCLUDED.)

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