

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA

In Re: VIOXX PRODUCTS	*	
LIABILITY LITIGATION	*	MDL Docket No. 1657
	*	
This document relates to	*	New Orleans, Louisiana
Case No. 05-4046:	*	
	*	
EVELYN IRVIN PLUNKETT, et al	*	February 8, 2006
	*	
versus	*	
	*	
MERCK & CO., INC.	*	
* * * * *	*	

AMENDED RULING OF THE COURT  
FROM VOLUME III OF THE  
JURY TRIAL BEFORE THE  
HONORABLE ELDON E. FALLON  
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For the Plaintiff:	Beasley Allen Crow Methvin Portis & Miles
	BY: ANDY D. BIRCHFELD, JR., ESQ. LEIGH O'DELL, ESQ.
	234 Commerce Street Post Office Box 4160 Montgomery, Alabama 36103

For the Plaintiff:	Levin, Papantonio, Thomas, Mitchell, Echsner & Proctor
	BY: TROY RAFFERTY, ESQ.
	316 South Baylen Street, Suite 600 Pensacola, Florida 32502

1 Appearances, (Continued):

2 For the Plaintiff: Gainsburgh, Benjamin, David,  
3 Meunier & Warshauer  
4 BY: GERALD MEUNIER, ESQ.  
5 1100 Poydras Street, Suite 2800  
6 New Orleans, Louisiana 70163

7 For the Plaintiffs: Herman, Herman, Katz & Cotlar  
8 BY: RUSS M. HERMAN, ESQ.  
9 820 O'Keefe Avenue  
10 New Orleans, Louisiana 70113

11 For the Defendant: Bartlit Beck Herman  
12 Palenchar & Scott  
13 BY: PHILIP S. BECK, ESQ.  
14 TAREK ISMAIL, ESQ.  
15 SHAYNA S. COOK, ESQ.  
16 54 W. Hubbard Street, Suite 300  
17 Chicago, Illinois 60601

18 Official Court Reporter: Cathy Pepper, CCR, RPR, CRR  
19 Toni Doyle Tusa, CCR  
20 500 Poydras Street, Room HB-406  
21 New Orleans, Louisiana 70130  
22 (504) 589-7778

23 Proceedings recorded by mechanical stenography, transcript  
24 produced by computer.  
25



1 here with the instant motion.

2           But before Russ speaks and even pretermittting  
3 those downstream MDL-wide concerns, the Irvin plaintiffs  
4 request that the Court's -- or submit that the Court's rulings  
5 limiting the testimony of these two experts are rulings that do  
6 require clarification and which do warrant serious  
7 reconsideration on sound principles of evidentiary law. As we  
8 appreciate the analysis, Your Honor has concluded that neither  
9 Dr. Tom Baldwin, plaintiff's cardiologist, nor Dr. Michael  
10 Graham, plaintiff's pathologist, has brought to this case  
11 sufficient background and familiarity with Vioxx to qualify  
12 them to opine that Vioxx caused or substantially contributed to  
13 Dicky Irvin's heart attack and death. In other words, the  
14 Court is not excluding this testimony on the basis of invalid  
15 methodology in the Daubert sense, but rather, on the basis of  
16 the qualifications language in Rule 702, which requires that  
17 experts have sufficient, quote, knowledge, skill, experience,  
18 training, or education. And we do emphasize the disjunctive or  
19 because it is purposefully used. What qualifies an expert to  
20 address a specific causation question about Vioxx is Vioxx  
21 knowledge or skill or experience or training or education or  
22 any combination.

23           The Court's decision that Drs. Baldwin and  
24 Graham lack any such qualification regarding specific causation  
25 gives rise to at least two very basic concerns: Number one,

1 the concern is that the defendant is now allowed to control the  
2 outcome of the 702 debates because of its own historic handling  
3 of the information concerning Vioxx; and concern Number 2 is  
4 that Rule 702 is being interpreted in a way that is  
5 inconsistent with Rule 703, addressing the proper bases and  
6 allow bases for expert testimony.

7           As to concern number one, Judge, the question,  
8 simply put, is this: Should a defendant manufacturer allegedly  
9 deliberately concealing the CV risks of Vioxx benefit by virtue  
10 of an historical climate in which the medical community of  
11 practicing physicians does not know about the dangers of Vioxx  
12 until those dangers are disclosed through litigation. That is  
13 to say, it is unavoidably true that doctors do not bring to the  
14 table, do not bring to the case extensive, past knowledge about  
15 Vioxx. It was not until September 30, 2004, upon the removal  
16 of the drug from the market, that the medical community was  
17 provided with information from Merck upon which to determine  
18 that Vioxx causes MI'S or other cardiovascular injuries. The  
19 absence of such cardiovascular illnesses to Vioxx exposure --  
20 the absence of such information, rather, prior to September '04  
21 made it unlikely that any physician would have attributed a  
22 cardiovascular event to Vioxx exposure at that time. This  
23 Court necessarily has recognized that the illnesses at issue in  
24 this litigation necessarily occurred before the drug was  
25 withdrawn. Therefore, whether a proposed expert did or did not

1 diagnosis a cardiovascular illness outside of the context of  
2 this litigation must necessarily in this case, we submit, be a  
3 minor, not a major, factor in the Court's decision.

4           In this circumstance, Judge, we believe it is  
5 critical to allow 702 qualifications to be built not just on  
6 long years of experience with Vioxx predating its 2004  
7 withdrawal, but in the language of the rule based on knowledge,  
8 skill, experience, training, or education, which can, and in  
9 many cases will have to be built on a review of published  
10 studies, research, and learning developed since the withdrawal  
11 of the drug. This is especially important, of course, in the  
12 context of MDL trials as these trials are occurring  
13 simultaneous with discovery in the emerging science and truth  
14 about Vioxx.

15           We Are not suggesting to this Court that you  
16 lower the 702 bar. We are simply suggesting that you not set  
17 it so high as to require what is not, as a practical matter,  
18 available in the way of historic Vioxx expertise within the  
19 community of prescribing physicians.

20           Your Honor has also cited as a factor the lack  
21 of these physicians' experience with prescribing Vioxx. And  
22 yet, Vioxx as a pain medication would not typically be  
23 prescribed by cardiologists, much less pathologists, and at the  
24 same time, cardiologists and death cases pathologists have the  
25 relevant expertise in diagnosing the cause of cardiovascular

1 injury or a failed MI. And therefore, whether a proposed  
2 expert on causation did or did not prescribe Vioxx, again, is a  
3 factor which we submit must be of minor, not major,  
4 consideration.

5           The Court has also cited the fact that these  
6 experts are not -- do in the come to the table -- come to the  
7 case with experience in research concerning Vioxx. Your Honor,  
8 the clinical research on Vioxx largely was conducted by Merck  
9 itself, and it would therefore be unlikely that researchers  
10 affiliated with Merck would now step forward and be able  
11 available to serve as expert witnesses for plaintiff. Again,  
12 That is a factor which, in the context of this case, we submit  
13 must be a minor or and not a controlling or major  
14 consideration.

15           The second concern we have is no less important,  
16 and that is that 702 needs to be aread with 703 to be the basis  
17 for which are allowed expert opinions. 703 provides that an  
18 expert's opinion that the facts or data which support an expert  
19 opinion or the inferences from facts and data may be those  
20 perceived by or made known to the expert at or before the  
21 hearing. At or before the hearing. And if of a type  
22 reasonably relied upon, may not even be per se admissible into  
23 evidence. Of course, in this case, we do have admitted into  
24 evidence published studies, literature, clinical studies,  
25 epidemiological data.

1           We also now have, for the purposes of these next  
2 two experts, Drs. Graham and Baldwin, the sworn testimony of an  
3 expert that Your Honor has admitted, and that is Dr. Ray, who  
4 has submitted opinions which, in a hypothetical question,  
5 should be allowed to form a basis under Rule 703 for the  
6 causation opinion of both Baldwin and Graham.

7           So, again, we believe that, when you read 702 in  
8 connection with 703, neither Baldwin nor Graham should be  
9 disqualified simply because they are going to be asked a  
10 specific causation question, which is predicated on their  
11 knowledge of what is published, what is in learned treatises,  
12 and what has already been stated in this case by another  
13 expert.

14           Your Honor, we also point out what appears to be  
15 some inconsistency in the Court's rulings insofar as you did  
16 allow the testimony in the first trial of a pathologist,  
17 Dr. Bloor. Dr. Bloor testified as to specific causation,  
18 testified that Vioxx caused or substantially contributed to the  
19 death of Dicky Irvin. Dr. Bloor did not bring to the table any  
20 expertise beyond what the Court now seems to be requiring with  
21 respect to Baldwin and Graham. We don't think it was error to  
22 allow Dr. Bloor to testify. For the same reason, it would not  
23 be an error to allow testimony by Baldwin and Graham.

24           Judge, the final point, I suppose, to be made  
25 before Mr. Herman addresses you is this: But even though this

1 is not a Daubert issue per se, the Fifth Circuit in the Rushing  
2 case, 1999, said something which we think is very important to  
3 remind us of the importance of the jury's assessment in these  
4 cases involving experts; and it was this from Rushing: As long  
5 as some reasonable indication of qualification is adduced, the  
6 Court may admit the evidence without abdicating its gatekeeping  
7 function. After that, qualification becomes a issue for the  
8 trier of fact rather than for the Court in its gatekeeping  
9 capacity.

10 We believe that this jury is well equipped to  
11 weigh and assess the qualifications of these experts on  
12 specific causation. The Court should address this, obviously,  
13 at a threshold level, a minimal level, for the reasons I've  
14 mentioned, not emphasizing things like prescription and  
15 research experience.

16 These men are eminently qualified, Judge, to  
17 build upon what is known since withdrawal of the drug, to build  
18 upon what has been introduced into evidence in this case, to  
19 express those opinions, and then let the jury decide. If we  
20 want instructive verdicts in this litigation, we think it's  
21 important for this case and for later cases that a qualified  
22 expert be able to have their opinions weighed by the jury.

23 **THE COURT:** Thank you, Counsel. Do you want to  
24 respond at this time or do you want to have Mr. Herman speak  
25 first?

1           **MR. BECK:** I'll wait until Mr. Herman is done.

2           **MR. HERMAN:** May it please the Court. Judge Fallon,  
3 good afternoon. I appreciate, on behalf of the MDL, the  
4 opportunity to advocate before you. I appreciate that you have  
5 been, as all counsel in trial, that your day starts probably  
6 around 6:00 a.m., and ends around 8:00 p.m., and to this  
7 evening allow us to argue this issue. We appreciate it.  
8 Particularly after Your Honor has made some rulings, heard  
9 other argument on the same issues, and received other briefing.

10                   In Act 3, Scene 2, of Julius Ceasar, Marc  
11 Anthony says, "In facing the judgment of a Roman citizenry, I  
12 have not wit nor wisdom to persuade you." But, Your Honor, I  
13 am mindful of another Shakespeare quote which gives me some  
14 solace. It was a criticism by Shakespeare of his observation  
15 of judicial stare decisis. And what he said measure for  
16 measure is, "Do not make a scarecrow of the law and set it out  
17 to cause fear in birds of prey until they make it their perch,  
18 and let it keep one shape for time and custom." And what he  
19 said was that decisions, particularly when they involve  
20 justice, need repetitive examination.

21                   Advocates come to this Court, and you certainly  
22 have in this courtroom some of the most skilled advocates to  
23 present cases. And, Your Honor, it is daunting, difficult, and  
24 beguiling for me to advocate professionally about something  
25 which plaintiff lawyers feel so strongly. There was always a

1 great fear that Daubert would not only be a slippery slope but  
2 would eventually become a razor's edge that not only shaved the  
3 ability of small people and consumers to present their cases  
4 but a blade that would cut the jugular; a razor's edge.

5 Your Honor, in one sense, the MDL lawyers on our  
6 side see these rulings, most respectfully, to come out of a  
7 illusion created by the defendants. I have had occasion to  
8 address Your Honor indicating that only a third of discovery  
9 has been done in the case; that documents have been secreted;  
10 that science has been subverted; that doctors have been  
11 alienated. And as discovery goes forward, a clear picture of  
12 deception motivated by avarice comes forward.

13 Now, what does that have to do with Daubert and  
14 these rulings? The MDL was designed as a discovery mechanism  
15 to save the time and money of the litigants and the judiciary.  
16 It was not designed as a trial mechanism. And while I  
17 certainly recognize the power of this Court and other MDL  
18 courts to conduct trials, and I repeat, because of the delay of  
19 Merck phased with a multiplicity of state actions in asking for  
20 an MDL, we are now in a situation of acceleration, expedition,  
21 without full knowledge of facts.

22 The reality is that an expert, whether he  
23 studies for 8 hours or 80 hours, will never reach the degree of  
24 sophistication or knowledge of an advocate or a judge, who,  
25 with tenacity, devotes time, energy, and intellect with

1 grappling with a scientific problem or a medical problem that  
2 comes into a courtroom. The perpetuation of expert witnesses  
3 with full knowledge is a difficult task as it is, but when  
4 trials are accelerated and expedited and discovery is  
5 incomplete, then the experts that come in the courtroom must,  
6 of necessity, of necessity, base their opinions only upon what  
7 is known or knowable.

8           It is true, as Your Honor observed, that the  
9 lawyers in this courtroom know more than experts, but, you  
10 know, Your Honor, a learned lawyer once taught me that, in any  
11 given case, the lawyer's job is to know, first of all, to be  
12 taught by experts; and second, to know more. And the  
13 protection is that an advocate who is well prepared can  
14 cross-examine upon the vulnerabilities of the expert, and the  
15 vulnerabilities or alleged vulnerabilities of the experts we  
16 are to present in this case and every other case in the MDL are  
17 vulnerabilities that are exposed or can be exposed by  
18 cross-examination. They are not some ephemeral types of  
19 issues.

20           Now, let's look at what was known to plaintiff  
21 potential experts. What was known is that Merck's position was  
22 in what they claimed to be authoritative texts, literature  
23 studies, what any cardiologist would have looked at had they  
24 been asked to look at it, and indeed *The Merck Manual*, which is  
25 used all over the country in order for any physician to make a

1 differential diagnosis, you don't have to worry about Vioxx.  
2 If it's 50 milligrams and it taken for -- if it's not  
3 50 milligrams taken for 18 months, you don't have to worry  
4 about it. And they published it, you know. They gave that  
5 information in journals in the FDA. The FDA does not conduct  
6 epidemiological studies of its own. It's garbage in/garbage  
7 out, or truth in/truth out.

8           So what is a physician to do? What is missing  
9 here, most respectfully, is the fact that we lawyers will never  
10 approach a cardiologist who is board-certified or a pathologist  
11 in the ability to treat and do a diagnosis. We did not have  
12 four years of medical school, we did not have two or three  
13 years of internship and residency. We have not gone to  
14 specialized courses. We don't see thousands of patients in our  
15 law offices.

16           And what is a resident or a internist? What do  
17 they do? They don't know what Vioxx is. They don't know what  
18 Propulsid is. They don't know what shelley's heart valve is.  
19 They've got to go to a *PDR*. They've got to talk to other  
20 physicians. They've got to read the literature that's  
21 available, and then they make a diagnosis, and then they treat  
22 the patient. And we believe that that's what this is all  
23 about. This cardiologist is board-certified. He had to take  
24 tests. It's his discipline. There is no showing, number one,  
25 that he's intellectually depraved.

1                   Now, let's talk about the reality of conducting  
2 studies. \$3 million. Are plaintiffs across this country, we  
3 have to go out on our cases and we conduct the studies that  
4 Merck should have done in order to get experts to testify? I  
5 will tell you that I think that learned counsel opposes one  
6 of the most gifted courtroom lawyers that I've ever seen. And  
7 in his opening statement, says, well, Dr. Ray was paid 250,000  
8 by plaintiff's lawyers was a appropriate thing for him to say.  
9 It was good advocacy, but are plaintiff lawyers in the MDL  
10 expected to spend 300,000 or \$500,000 a case? Most of it on  
11 expert testimony and depositions? We have to go out now, every  
12 time a document comes forward, and take somebody's deposition  
13 that either worked for Merck or is working for Merck, just in  
14 order to get the document to an expert to look at. And these  
15 experts are putting their reputations on the line.

16                   I think that Your Honor has had enough  
17 experience with experts, judicially and as an attorney, that if  
18 an expert sits on that stand and Your Honor believes he's  
19 dishonest, you call the lawyers up, they're subject to  
20 cross-examination by a skilled advocate. And we have lawyers  
21 all over the country now saying, what are we going to do for  
22 specific causation? We're not a drug company. We weren't the  
23 ones that were supposed to run a CV test. Merck has got,  
24 whatever they said, a half a billion dollars, a billion  
25 dollars, to spend on lawyers and experts? What are we to do in

1 the MDL? We've got a single practitioner on Canal Street who's  
2 got a client to protect. How much money is she exposed to  
3 spend using an MDL product if she can't have a local  
4 cardiologist expert come into court and opine on causation? Or  
5 other people in the MDL?

6 Your Honor, I do not want to overstep the bounds  
7 or my welcome here this Court certainly has the power to have  
8 trials. Your Honor is a gatekeeper. You certainly have that  
9 power, and, Your Honor, as one concrete example of the  
10 imbalance that we see is learned counsel for the defendants  
11 called a Dr. Silver to testify. His qualification was he was  
12 an investigation on Arcoxia. We have been trying to get  
13 Arcoxia documents for three or four months. How do we get a  
14 cardiologist or a pathologist and how do we cross-examine when  
15 we don't have the discovery?

16 And so the issue here is: Is there a tool that  
17 safeguards the sanctity of this Court without -- and at the  
18 same time doesn't automatically exclude -- I shouldn't use the  
19 word "automatically" because a lot of consideration has been  
20 given to Your Honor -- that doesn't exclude a cardiologist or a  
21 pathologist from testifying based on the fact that they  
22 don't -- that they haven't read all the articles, et cetera,  
23 that the foundation is not what -- it's not the greatest  
24 foundation in the world. But I certainly believe that.

25

1 And I ask Your Honor, because I know that Your Honor gives this  
2 trial and every trial deep consideration. You've never been --  
3 you don't shoot from the hip. You study. You know more than  
4 the lawyers in the case. I'm not saying that as a it just  
5 happens to be true. And so what I ask and what I say to  
6 Your Honor, I think that this matter is so serious in terms of  
7 the MDL, that it's pivotal. And I expect Mr. Beck to do his  
8 usual good job, but what I would ask is that Your Honor spend  
9 some quiet -- some quiet moments away from the fray, before  
10 Your Honor rules on these issues, to take one more look at it.

11 **THE COURT:** Thank you, Mr. Herman.

12 **THE WITNESS:** Be reasonably brief, Mr. Beck. I think  
13 I understand the issue.

14 **MR. BECK:** Yes, I'm going to be very brief. I'm  
15 going to very briefly address the impact on Merck -- changed  
16 and the claims of prejudice by plaintiff. And Mr. Ismail will  
17 also be brief and he can address the merits as well as any  
18 Shakespeare quotes that pertain to our side of this dispute  
19 since I am not well-versed.

20 **THE COURT:** You say you're an English major.

21 **MR. BECK:** Yeah, but it was American English. Judge,  
22 I want to just talk about the practicalities of this trial  
23 since that's what I'm trying. We had Daubert rulings before  
24 the trial as to Dr. Baldwin. We had a Daubert ruling before  
25 the December trial. We had a ruling during the trial. So it

1 would have come as no surprise to the plaintiffs that  
2 Dr. Baldwin was not going to be permitted to testify on this.

3           The MDL people weighed in. There was a motion  
4 to reconsider. And there is nothing really new there. With  
5 Dr. Graham, it was -- he was kind of just a mirror image of  
6 Dr. Baldwin, and again, the Daubert ruling was made before  
7 trial.

8           Mr. Meunier asked, "Well, how about if you  
9 reserve it?" I said, "I need to know before we start the  
10 trial. Your Honor said, "No, this is my ruling." And here is  
11 my concern from my point of view, Your Honor: I stood up,  
12 based on the Court's ruling, and said they are not going to  
13 have a medical Dr. Come in here and say that Vioxx caused  
14 Mr. Irvin's death. And now they are trying to change the  
15 rulings, which, obviously, would be prejudicial to us.

16           On the other hand, this was not something, they  
17 make it sound like it would have been impossible to have  
18 experts to opine on specific cause. They had two experts at  
19 the last trial who gave opinions on specific cause. They had a  
20 pathologist that Your Honor found was qualified, Dr. Bloor, and  
21 he gave testimony on specific cause, and they decided they  
22 didn't want to call him this time because they've changed  
23 theories.

24           They decided that they couldn't sell the theory  
25 of no plaque rupture, and so they changed pathologists, but

1 they had one in the last case who was qualified to talk about  
2 specific cause. Similarly, they had Dr. Lucchesi, and he gave  
3 an opinion on specific cause last time, and they decided not to  
4 call him either. And I don't know why, but it may have been  
5 because of their perception of how he did in terms of trying to  
6 sell this idea of the imbalance theory. So they had two  
7 experts who gave specific cause opinions, both of whom they  
8 decided, for whatever tactical reasons, they did not want to  
9 use this time, and instead, they wanted to use someone who had  
10 been excluded last time and another person who they should have  
11 known hadn't done any kind of reasonable amount of work.

12           So, Your Honor, that's all I have to say about  
13 that. In terms of the MDL, we're trying this case now, and I  
14 think we're entitled to rulings under the rules of evidence in  
15 this case rather than because of what lawyers would like in  
16 other cases.

17           **THE COURT:** Thank you.

18           **MR. ISMAIL:** Your Honor, as we see the issue and read  
19 your prior rulings, this Court has not imposed a litmus test on  
20 the litigants as plaintiff's counsel has suggested in the  
21 consideration of Daubert in 702. This Court has never ruled  
22 that the absence of a Vioxx prescription or the absence of  
23 research experience on NSAIDs precludes an expert, but what we  
24 have with Drs. Baldwin and Graham is that they did, in fact,  
25 come to this litigation with no relevant experience, either as

1 a prescriber, particularly as to specific cause as a diagnosER  
2 of thrombotic injury, neither have been familiar with the  
3 literature, neither had been a researcher on these issues.

4 So the question then becomes: Have they,  
5 through their work in this case, elevated themselves to one who  
6 should be allowed to give an opinion to this jury? And as to  
7 both experts, Your Honor has correctly ruled three times now  
8 for Dr. Baldwin and twice now for Dr. Graham that they have not  
9 done so.

10 Dr. Baldwin, as Your Honor has observed, has  
11 spent very little time reviewing the cardiovascular literature  
12 related to Vioxx for COX-2s, and that is compounding his lack  
13 of relevant experience that he brought to this case.

14 Your Honor has obviously read both depositions where  
15 Dr. Baldwin was unable to field rather basic questions about  
16 the literature that he purports to rely upon. And it's not a  
17 question of did Merck have information that Dr. Baldwin has  
18 been unfairly shielded from.

19 He purports to base his opinion, in fact, on the  
20 peer-reviewed literature. The problem with Dr. Baldwin is he  
21 had no expertise in that literature prior to this litigation,  
22 has spent very little time learning that literature, and is  
23 unable at this point to offer anything to the Jury on specific  
24 causation.

25 And as to Dr. Graham, Your Honor has seen his

1 deposition as well. Charitably, Dr. Graham has spent maybe two  
2 or three hours familiarizing himself with the science relevant  
3 to this case. He has testified that prior to being retained by  
4 plaintiffs, he had absolutely no expertise with COX-2 inhibitor  
5 drugs. 7,000 autopsies, not a single diagnosis that would be  
6 relevant.

7           So, Your Honor, as it relates to these experts  
8 and the concerns of plaintiff's counsel, we do in the see your  
9 rulings as one that raises a impossible bar, but rather, we've  
10 had several experts clear that bar. We've just had two experts  
11 in this case who, through their own lack of experience and lack  
12 of review of the relevant materials, could not do so.

13           And with respect to the -- I think everyone in  
14 this courtroom today recognizes that motion is not one for  
15 clarification but rather for a reversal of prior rulings.  
16 Your Honor has previously ruled neither expert can attribute  
17 Vioxx to Mr. Irvin's death, and the proposed hypotheticals, in  
18 fact, seek to get that opinion to the jury. And that would be  
19 contrary to the three rulings on Dr. Baldwin, now two rulings  
20 on Dr. Graham.

21           And the problem with both experts, Your Honor,  
22 is the hypothetical doesn't -- neither expert is qualified to  
23 give the opinion even as phrased in the hypothetical.  
24 Dr. Graham's entire opinion is the attributable risk is greater  
25 than 2. Well, we heard from an expert from plaintiffs on that

1 issue who is a epidemiologist. Dr. Graham is a pathologist,  
2 brings nothing to that issue -- expertise, training, or  
3 otherwise.

4 And Dr. Baldwin, the hypothetical proposed a  
5 diagnosis that he does not do in his practice. He does not in  
6 his practice assume a risk that he's not qualified to see that  
7 is there, and without any individual opinions about the  
8 plaintiff, neither Dr. Graham, nor Dr. Baldwin, say "I've  
9 looked at Mr. Irvin's medical records and pathology and I can  
10 discern that Vioxx caused his death." Instead they retreat to  
11 saying, "Well, if it's an increased risk, then it must have  
12 caused his death." That is an opinion that is directly  
13 contrary to the rules in 703 and opinions under Daubert. Thank  
14 you.

15 **THE COURT:** Thank you very much. Let me share with  
16 you my views in this matter, and I appreciate the remarks of  
17 counsel. I always learn from learned counsel and always take  
18 the time to give them an opportunity to speak.

19 As I see the Daubert situation, FRE 702, of  
20 course, is really the redactor's attempt to codify the Daubert,  
21 Kumho, and Joiner cases and put this jurisprudence into a black  
22 letter rule as opposed to having it explained in those three  
23 cases as well as a number of other cases throughout the country  
24 in the appellate courts.

25 Basically, as I see the rule, it is that for 702

1 purposes the testimony must be helpful to the fact finder and,  
2 of course, relevant to the issues in dispute. The expert must  
3 be qualified as an expert by knowledge or skill -- and I don't  
4 put an "and," I think it's an "or" -- in terms of knowledge or  
5 skill or experience or training or education to express an  
6 opinion on the fact at issue.

7           The Court makes an attempt always, rather than  
8 exclude the entire testimony, to see whether or not an expert  
9 who is qualified can give testimony even on a issue or two as  
10 opposed to three or four issues.

11           And, of course, the last requirement is  
12 methodology. The methodology must be appropriate. It's not  
13 the job of the Court, at least in its gatekeeper role, to test  
14 the conclusion. In fact, the Supreme Court has always taken  
15 the position that conclusion is for the jury or fact finder;  
16 methodology is for the Court.

17           I read the ultimate purpose of 702, as well as  
18 the Daubert and Kuhmo and Joiner cases, is to make certain that  
19 an expert, whether basing an opinion on professional studies or  
20 personal experience or education, employs in the courtroom the  
21 same level of intellectual rigor characterized in his or her  
22 practice outside of the courtroom. That is to say, they have  
23 some experience or education or training outside of the  
24 courtroom which is relevant and helpful and they use the same  
25 rigors, the same approach, demand of themselves as well as

1 others the same requirements inside of the courtroom as they do  
2 outside of the courtroom.

3           With regard to Dr. Michael Graham, he is a  
4 pathologist, professor and also a working pathologist, brings  
5 both theory and practice, I think, to the Court -- or to his  
6 patients. He's got significance experience in pathology. He's  
7 performed over 7,000 autopsies; most of those, at least in the  
8 early days of his career, were done by himself. He's got some  
9 assistants now, but he has participated in a substantial number  
10 of autopsies.

11           And because heart disease is a major problem, at  
12 least in this country, a pathologist, by just that fact alone,  
13 accumulates a lot of experience with cardiovascular pathology.  
14 So it doesn't surprise me that he knows something about  
15 cardiovascular pathology and may not even have been trained in  
16 that particular subspecialty, but with his experience day to  
17 day out there, he has gotten a great deal of experience and  
18 knowledge in that field. He's certainly qualified, in my  
19 opinion, to testify to the cause of death, the heart attack,  
20 the cause of the heart attack, the plaque rupture. I thought  
21 it would be helpful to the Jury.

22           The issues that I see in Dr. Graham are really  
23 twofold: One is whether he's qualified to testify regarding  
24 Vioxx, and also, his methodology is appropriate. I didn't  
25 discuss it in the opinion because I didn't get that far, but

1 the methodology I tell you gives me some concern. The issue  
2 with regard to qualifications, to my mind, is whether he has  
3 education or experience or knowledge to testify that Vioxx  
4 caused, in whole or in part, Mr. Irvin's demise. This is a  
5 issue that I think is a lot different than other facts, other  
6 scenarios, if you will.

7           Let me illustrate this point by this example.  
8 Assume there are two pathologists, one who worked at Charity  
9 Hospital, when it was ongoing, in the emergency room and saw a  
10 lot, a lot of knife wounds and treated or at least examined  
11 people, did pathological work and concluded that the death was  
12 due to a knife wound. Another pathologist, equally talented,  
13 may not work at Charity, may not see any knifings in the heart  
14 or whatever, but has seen over the years some damage to the  
15 heart. Assume further that someone is brought in with a  
16 significant knife wound and the knife accompanies him, and the  
17 pathologist examines the victim, measures what they need to  
18 measure, see what they need to see, and concludes that the  
19 heart was stopped, damaged by a knife. May not have written  
20 any articles on it, may not have had any experience on it.

21           To me, both of those pathologists would be  
22 appropriate to testify in the case as an expert as to what  
23 caused the wound in the heart. Both would satisfy a Daubert  
24 analysis. The latter might be attacked under cross-examination  
25 more than the former because he didn't see any knife wounds in

1 the past, but he can deduce or conclude from what he saw and  
2 what his experience is that it was a knife wound. He would  
3 testify. His credibility and experience might be questioned,  
4 but I would let the jury weigh that and take that into  
5 consideration.

6 But the question of whether or not Vioxx  
7 participated or caused heart damage is a lot more subtle than  
8 my above example. Vioxx doesn't leave a fingerprint. There is  
9 no "Vioxx clot" which is distinguished by structure or form  
10 from any other clot. It requires some knowledge or some  
11 education or some experience with Vioxx or even COX-2  
12 inhibitors or NSAIDs or something that qualifies the witness to  
13 testify that Vioxx caused the death or MI.

14 I turn to the testimony in the deposition of  
15 Dr. Graham that was taken, and I look over first the education  
16 and experience of Dr. Graham. On page 62, Dr. Graham admits he  
17 is not an epidemiologist, he's not a cardiologist, he has no  
18 training as a pharmacologist, and he hasn't done a thorough  
19 investigation in the pathology of Vioxx.

20 "Q. And you really haven't done a thorough  
21 investigation into pharmacology?"

22 On page 27, line 24:

23 "A. I've looked at it to the extent that I need to  
24 answer questions in this particular case. I'm not a  
25 universal expert in Vioxx."

1 "Q. Nor are you an expert in pharmacology of Vioxx?

2 "A. Other than what I need in this case, no, I'm  
3 not. That's correct."

4 I also look at his knowledge of clinical trials,  
5 which is not essential, but would be helpful for him to  
6 understand the statistical controversy in a case of this sort.

7 Page 64:

8 "Q. Would you agree that placebo-controlled clinical  
9 trials are the gold standard for determining the risks of  
10 medicine?"

11 "A. I would defer to experts who design studies to  
12 look at specific things. That's not in my area of  
13 expertise."

14 Line 15:

15 "Q. You're agreeing you're not qualified to  
16 determine the hierarchy or reliability is with respect to  
17 the clinical trial evidence that exists on Vioxx?"

18 "A. Correct. Yeah, that's not something I do. I  
19 would defer to experts on a daily basis."

20 I look to writings to see whether or not he's  
21 done any writings or has conducted any research on Vioxx or any  
22 COX-2 inhibitor. I see on page 28 of his deposition, line 22:

23 "Q. All right. So would I be correct, sir, that you  
24 have never published any article on the specifics of  
25 cardiac pathology that deals with Mr. Irwin's death.

1 Correct?"

2 "A. Not the specifics, that's correct."

3 "Q. And indeed, you've never written an article that  
4 deals with the mechanism of sudden cardiac death from  
5 plaque rupture, correct?"

6 "A. Not specifically, no."

7 "Q. Have you ever written an article that dealt with  
8 atherosclerotic or sudden cardiac death?"

9 "A. No."

10 I look to whether or not he's conducted any  
11 research on any of the types of drugs involved.

12 "Q. Now, you've never done any research on the class  
13 of medicines known as NSAIDs, correct?"

14 "A. I have not.

15 "Q. And obviously, that includes no research ever  
16 done on COX-2 inhibitors?"

17 "A. That's correct.

18 "Q. Have you ever prescribed Vioxx or Celebrex?"

19 This fellow is a pathologist. I don't think he  
20 can help the people that he examines from the standpoint of  
21 freedom of pain. Generally, they're dead. So it doesn't  
22 surprise me. But he doesn't have any experience. I simply  
23 note that.

24 Experience before he was retained, as I said,  
25 was considerable. Over 7,000 autopsies he's been associated

1 with. He's never opined that a COX-2 inhibitor drug was the  
2 cause of death. I think counsel makes a valid point. This is  
3 rather new. It's only, what, ten years old now or thereabouts?  
4 So it's somewhat new. It's not today or yesterday, but it's  
5 somewhat new.

6 But, in any event, he hadn't had any personal  
7 experience with ever diagnosing or mentioning that that was a  
8 cause. Page 36:

9 "Q. Have you ever, in any of the 7,000 autopsies  
10 you've performed, ever come to the conclusion, whether you  
11 were asked or not, that Vioxx or any other COX-2  
12 contributed to the cause of death?"

13 "A. I have not."

14 Question about what is his experience in his  
15 day-to-day practice, page 39:

16 "Q. Is it fair to say that you never considered the  
17 cardiac safety of Vioxx until you were contacted by  
18 plaintiff's counsel?"

19 "A. ...it wasn't something that I dealt with on a  
20 daily basis."

21 On page 51:

22 "Q. So prior to being retained as plaintiff's  
23 expert, Vioxx, to your knowledge, was not relevant to  
24 anything you were doing, right?"

25 "A. It was nothing that I was focused on. It wasn't

1 on my radar screen on individual case management."

2 I look at his readings before he was retained by  
3 counsel, readings about Vioxx, page 50:

4 "Q. And prior to being retained in this case, you  
5 were just a casual reader to the extent Vioxx literature  
6 appeared in journals you happened to be reading at the  
7 time, right?"

8 "A. Yes."

9 Review of the medical literature after he was  
10 retained indicates he reviewed articles, but the articles that  
11 he reviewed were only articles he was given by plaintiff  
12 counsel, and I'm not quite sure he reviewed all of those.

13 "Q. I mean, so do you recall what part of this list  
14 you put together and what part was put together by  
15 others?"

16 It's on page 38:

17 "A. I mean, as far as the list goes, I think most of  
18 the Vioxx articles on the list were listed by the law  
19 firm" -- meaning the law firm that retained him. "Some of  
20 that overlapped with articles that I had already had, but  
21 I -- you know, I didn't change that. Most of the cardiac  
22 pathology sudden death articles, I added."

23 What did he do with the articles? He said that  
24 he flipped through them. On page 35, he says:

25 "Q. Other than perhaps flipping through

1 Vioxx-related articles in the *New England Journal* prior to  
2 being contacted by the plaintiff counsel, had you done any  
3 review of cardiovascular safety on the drug?"

4 "A. No."

5 I also note the time that he spent on reviewing  
6 the articles that he was given on page 38:

7 "Q. So, really, you've got eight or nine hours in  
8 total that possibly could be connected to your review of  
9 the cardiovascular safety of Vioxx?"

10 "A. Yes."

11 The extent of his knowledge about the articles  
12 concerned me a bit when he's asked on page 66:

13 "Q. Other than VIGOR, can you name any clinical  
14 trials of Vioxx?"

15 "A. Well, I mean, there was APPROVe, there was  
16 VICTOR, there was VIM, there was ADVANTAGE."

17 "Q. What's the third one you said? VIM?"

18 "A. VIM."

19 "Q. Never heard of VIM."

20 "A. I think it was called VIM. It was a, I think,  
21 prostate cancer prevention study."

22 "Q. VIP?"

23 "A. Oh, VIP, I'm sorry. You're right. Yeah."

24 "Q. You said APPROVe, VICTOR, VIP, ADVANTAGE. Any  
25 others?"

1 "A. Not specifically Vioxx, but it was class. I  
2 think that was Celebrex."

3 "Q. Right. Anything else?"

4 "A. There was a bunch with numbers. I don't know  
5 that they were ever published, but there was a number of  
6 studies, apparently, that were done that were number  
7 studies. I mean, they had, like, a code number on them."

8 I try to discern whether he has some knowledge  
9 about the issues that are present. One of the significant  
10 theories of plaintiff's case is that Vioxx decreased or  
11 inhibited prostacyclin and increased thromboxane; and while  
12 that theory is questioned, it's a rather visible theory and a  
13 significant one and explained by counsel to the Jury on  
14 occasions. Page 108:

15 "Q. Do you have an opinion what degree of  
16 prostacyclin inhibition in the vascular system is needed  
17 in order to increase the risk of cardiac events?"

18 "A. No."

19 "Q. Do you have any opinion to what degree Vioxx  
20 inhibits prostacyclin production in the vascular system?"

21 "A. No."

22 Page 94:

23 "Q. And more specifically, your opinion regarding  
24 the fact that -- your opinion that Vioxx reduces  
25 prostacyclin in production in the vascular system is

1 something you reached in the last two or three weeks?"

2 "A. Yeah. Last month or so, sure. Yeah."

3 I'm concerned about his knowledge or familiarity  
4 about the risks, that he understands the risks. Page 97:

5 "Q. Do you believe the risk changes over duration of  
6 use?"

7 "A. There is some data that the longer you use it,  
8 the risk does go up to some period, and then long-term  
9 use, it seems to stabilize."

10 "Q. Do you recall what that data comes from?"

11 "A. No, I don't off the top of my head. I mean,  
12 there were some studies, and part of it may have been  
13 Solomon that looked at, like, less than 30 days and then  
14 longer. There was one that looked at less than 16 -- or  
15 six months or longer. Then, as I recall it, there was  
16 another study that showed, basically, after you get to a  
17 certain point, you couldn't demonstrate the risk anymore."

18 He also reviewed other expert reports, which is  
19 significant and helpful, because 703 allows that and instructs  
20 the experts to do that. Question on page 73:

21 "Q. I noticed that you didn't review any of Merck's  
22 expert reports other than Dr. Wheeler; is that correct?"

23 "A. I wasn't given any. Nobody gave them to me to  
24 review."

25 "Q. They only gave you Dr. Ray on the question of

1 epidemiology?"

2 "A. There was another one by, I think, somebody from  
3 University of Michigan."

4 "Q. Dr. Lucchesi?"

5 "A. Yes."

6 "Q. Yeah, he's another plaintiff expert."

7 "A. Okay. I saw that. That's the only ones I saw.  
8 I did not see defense reports other than Dr. Wheeler's or  
9 anything."

10 "Q. So the only reports that you considered on the  
11 question of the relative risk of Vioxx for cardiovascular  
12 events are the ones provided by plaintiff experts, not  
13 Merck experts, right?"

14 "A. That -- as far as expert reports, that's  
15 correct. That's all that was given to me to review."

16 I look at it in its totality, and I am concerned  
17 that he has enough experience, enough education, or enough  
18 hands-on or knowledge or even whether he's been exposed to  
19 enough or even understands what he has been given. I also am  
20 concerned a bit about his methodology. On Page 51, he's asked:

21 "Q. Right. But that -- so if we take your sentence  
22 seriously, you would be opining that, individually, anyone  
23 who is taking Vioxx, who had a heart attack, more likely  
24 than not Vioxx contributed to the heart attack?"

25 "A. If you take them one at a time, that would be

1 correct."

2 Again, on page 61, line 4, he's asked:

3 "Q. So just so we understand your methodology for  
4 giving a specific cause opinion, the methodology you  
5 applied here suggests that, on an individual basis, you  
6 would say anyone who temporally had a heart attack while  
7 on Vioxx, more likely than not, Vioxx was a contributing  
8 cause. Correct?"

9 "A. Assuming that we're talking about individuals  
10 having heart attacks based on coronary artery disease,  
11 yeah. If you pulled an individual patient and presented  
12 it to me, I think that would be the probability, yes."

13 "Q. And that's the method you applied?"

14 "A. Yes."

15 That methodology, if you're taking the drug and  
16 you have a heart disease -- heart problem, the drug caused it.  
17 That's a methodology that I don't think passes through the  
18 gates of 702. He was further questioned on the methodology on  
19 page 109:

20 "Q. Now, earlier you agreed that it would be your  
21 expectation that not everyone who temporally had a heart  
22 attack while on Vioxx necessarily had their heart attack  
23 caused by Vioxx. Do you recall saying that?"

24 "A. Yes."

25 "Q. How do you distinguish between those people who

1 had a cardiac event that you believe was caused by Vioxx  
2 and those whom do not?"

3 "A. Again, it's probability. It's -- you're looking  
4 at statistically. If there is a more or -- more than two  
5 times incidence that any individual patient would most  
6 likely be in the group, that it was related to Vioxx.  
7 It's really a statistical probability. There is nothing  
8 in the pathology that you can point to and say this is a  
9 Vioxx thrombus."

10 "Q. All right. Let's talk about that last answer.  
11 When you say there is nothing in the pathology that you  
12 can point to and say this is a Vioxx thrombus, does that  
13 mean that there is nothing that identifies a blood clot in  
14 a coronary artery as being caused by Vioxx specifically on  
15 a pathological review?"

16 "A. That would be correct."

17 Then question on 110:

18 "Q. Does that mean, sir, that you cannot distinguish  
19 in the group of folks who had heart attacks while taking  
20 Vioxx those who had heart attacks from Vioxx and those who  
21 did not?"

22 "A. You can do them in big populations  
23 statistically. But if you're asking about this individual  
24 patient, again, you're dealing with probabilities. You  
25 can't point to the thrombus and say this is a Vioxx

1 thrombus versus a non-Vioxx thrombus."

2 I don't say that every pathologist has the same  
3 problems that this doctor does. In fact, I didn't feel that  
4 way. I looked at the two pathologists that were submitted or  
5 questioned or attacked, or objected to last time, and I felt  
6 that they were qualified to testify.

7 Dr. Lucchesi, he wasn't a treating physician,  
8 but he had a lot of credentials and was a doctor, an M.D. I  
9 felt he was qualified to testify.

10 So I don't paint with a broad brush in this  
11 situation. I'm not saying that you need to be a pathologist,  
12 that you need to have diagnosed people or that you need to have  
13 prescribed or have some experience, but a bit of some of those  
14 things are necessary.

15 I don't feel that this doctor demonstrated to me  
16 that he had any of them, and I kept looking for more to see  
17 whether or not he could get through the gate. And every time I  
18 looked a little further, it seemed more problematic.

19 So I do take these things seriously, and I don't  
20 just willy-nilly shoot from the hip. I felt that this doctor  
21 might be qualified to testify on other areas but not the  
22 specific causation, and I really have already dealt with the  
23 other doctor on several occasions and I won't change that.

24 So I understand the motion. I appreciate  
25 counsel's enthusiasm in bringing it, but I do deny the motion.

1           **MR. BIRCHFIELD:** Your Honor, may I ask a question?

2           **THE COURT:** Sure.

3           **MR. BIRCHFIELD:** I just need to know this for trial  
4 purposes because if the Court is telling us now that  
5 Dr. Lucchesi can give a specific causation opinion --

6           **THE COURT:** I did last time.

7           **MR. BIRCHFIELD:** Your Honor, I'll go back and reread  
8 your Daubert opinion, but it was my understanding that you had  
9 excluded him --

10           **THE COURT:** I thought he testified last time. I know  
11 we had two doctors testify. I think Bloor and Lucchesi. That  
12 was my notes. That's the notes that I made. I thought both of  
13 them, both Lucchesi and Bloor, testified that Vioxx  
14 specifically caused Irvin's death.

15           **MR. BIRCHFIELD:** Dr. Bloor did, that is correct. And  
16 Your Honor, if that's the case, then we'll see if we can get  
17 Dr. Lucchesi here.

18           **MR. BECK:** Your Honor, I have a written agreement  
19 with Mr. Birchfield that Dr. Lucchesi is not going to testify  
20 in this trial, and we entered that agreement after the Daubert  
21 rulings were made and before the trial started. And I gave my  
22 opening statement based on the agreement that I had in writing  
23 with Mr. Birchfield that he was not going to call Dr. Lucchesi.

24           **THE COURT:** Look, that's another issue that I'm not  
25 going to deal with at this time. I'll listen to it, but

1 you-all talk about it and see if you need my intervention on  
2 that.

3 **MR. BECK:** Your Honor, I have one last point.

4 **THE COURT:** Yeah. The question was asked by  
5 Mr. Beasley, I think, at the time, the question on the  
6 transcript, 220, line 17:

7 "Q. Now, the final question: Do you have an opinion  
8 as to whether Vioxx, based on what you've told us, caused  
9 or substantially contributed to cause the heart attack  
10 that resulted in the death of Dicky Irvin?"

11 "A. Based on reasonable medical probability, I think  
12 it's highly likely that Vioxx contributed to Mr. Irvin's  
13 demise."

14 Same way with Dr. Bloor. On Page 314 of the  
15 transcript, line 18:

16 "Q. Doctor, based upon your review of the medical  
17 records and the autopsy report, have you come to a  
18 conclusion as to whether or not Vioxx caused or  
19 contributed to cause Dicky Irvin's nonattached clot?"

20 "A. I think, as I stated earlier, it's my opinion  
21 that Vioxx played a contributing role in the formation of  
22 the thrombus."

23 And he goes on to relate it to the death. So I  
24 think both of these folks gave specific answers to those  
25 questions. I've dealt with them and that's -- there are just

1 some witnesses that just -- not because of their degree, but  
2 because of the whole picture, have problems and I know -- I  
3 practiced in the Fifth Circuit and I know how they are. There  
4 is no sense in plugging error into a record to have to redo  
5 something again.

6 **MR. BECK:** Your Honor, on a separate matter, just a  
7 housekeeping thing and a heads-up for the Court. This has to  
8 do with Dr. Topol. Just to alert the court that today in  
9 New Jersey, I'm told, Mr. Lanier announced that Dr. Topol is  
10 leaving the Cleveland Clinic; that Mr. Lanier is his personal  
11 lawyer in his negotiations over separating from the Cleveland  
12 clinic and that Mr. Lanier is hoping to secure his testimony in  
13 future cases. So in case you thought your life was getting  
14 less complicated, Your Honor, we've got those things looming.  
15 And I haven't figured out what they mean for Dr. Topol, but I  
16 wanted everybody to know the same thing that I know.

17 **THE COURT:** I appreciate it. Okay, folks. Thank you  
18 very much.

19 **MR. HERMAN:** Your Honor, on behalf of MDL, we  
20 appreciate the opportunity to be before you. We know that you  
21 never shoot from the hip. It's obvious that the details that  
22 you've given in support of your consistent rulings are going to  
23 be very instructive, and we appreciate it.

24 **THE COURT:** Thank you very much. We'll stand in  
25 recess.

