

NO. 10-0006

IN THE TEXAS SUPREME COURT

**CAROL A. ERNST, INDIVIDUALLY AND AS REPRESENTATIVE OF
THE ESTATE OF ROBERT CHARLES ERNST**

Petitioner,

V.

MERCK & CO., INC.

Respondent

ON REVIEW FROM THE FOURTEENTH COURT OF APPEALS, HOUSTON, TEXAS
No. 14-06-00835-CV

MERCK & CO., INC.'S RESPONSE TO PETITION FOR REVIEW

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ORAL ARGUMENT REQUESTED

IDENTITY OF PARTIES

Respondent is Merck Sharp & Dohme Corp., formerly known as Merck & Co.,
Inc.

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STATEMENT OF THE CASE

Nature of the Case: Plaintiff and Petitioner Carol Ernst brought a personal injury and wrongful death suit against Defendant and Respondent Merck & Co., Inc. now known as Merck, Sharp & Dohme Corp. (“Merck”) for the death of her husband Robert Ernst. 1 CR 2-24. Plaintiff alleged that the prescription drug Vioxx® – which Mr. Ernst purportedly took for several months before he died – caused his death. *Id.* Plaintiff asserted various causes of action contending that Merck failed to warn about an alleged cardiac risk associated with Vioxx and that Vioxx was defectively designed. *Id.*

Merck appealed from a \$26,100,000 trial judgment in favor of Plaintiff based on a claim of injury from the prescription drug Vioxx. 42 CR 7516-17. The Court of Appeals reversed and rendered judgment for Merck. *Merck & Co. v. Ernst*, 296 S.W.3d 81 (Tex. App.–Houston [14th Dist.] 2009, pet. filed).

Course of Proceedings in Trial Court: Plaintiff filed her original petition on May 24, 2002. 1 CR 2. The case was tried to a jury. 36 CR 6787-97. On August 19, 2005, after a four-week trial, the jury returned a verdict in the total amount of \$253,450,000, including compensatory and exemplary damages. *Id.*

Plaintiff waited until April 19, 2006, to submit a judgment to the trial court. 36 CR 6798. The hearing on the entry of judgment took place on June 15, 2006. 1 R 1 (the reporter’s record for this hearing was labeled 1 R 1, even though the trial transcript also contains a volume 1).

On June 23, 2006, after reducing the punitive damages award to \$1,650,000 pursuant to TEX. CIV. PRAC. & REM. CODE § 41.008, the trial court entered judgment in Plaintiff’s favor in the amount of \$26,100,000. 42 CR 7516-17.

Merck filed a Motion for New Trial and in the Alternative Motion for Suggestion of Remittitur on July 21, 2006, which the trial court denied on September 5, 2006. 42 CR 7518-71, 7621. Merck filed a timely notice of appeal on September 19, 2006. 42 CR 7621.

Trial Court: The trial court is the 23rd Judicial District Court of Brazoria County, Texas, the Honorable Ben Hardin, presiding.

**Court of Appeals’
Disposition** The Court of Appeals reversed and rendered a take nothing judgment, finding legally insufficient evidence of specific causation. Specifically, the Court held that there was no factual and scientific basis for Plaintiff’s experts’ opinions on specific causation. *Merck & Co. v. Ernst*, No. 14-06-00835-CV, 2008 WL 2201769, *5-7 (Tex. App.–Houston [14th Dist.] May 29, 2008). Plaintiff filed a Motion for Rehearing. In response, the Court issued another opinion, again reversing and rendering the judgment for the same reason – lack of legally sufficient evidence of specific causation. In this substitute opinion, the Court again held that there was no factual and scientific support for Plaintiff’s experts’ opinions. *Merck & Co. v. Ernst*, 296 S.W.3d 81, 96-100 (Tex. App.–Houston [14th Dist.] 2009, pet. filed).

Plaintiff filed a Motion for Rehearing En Banc on September 3, 2009. The Court did not request a response to the Motion from Merck. On November 19, 2009, the Court denied the Motion 3-3, with two justices abstaining and one vacant seat. On December 7, after another justice had been appointed to fill the vacant seat on the Fourteenth Court, Plaintiff filed a Motion to Reconsider Motion for Rehearing arguing that the Motion should be considered by the full Court. The newly constituted Court denied this Motion on December 21, 2009.

ISSUES RESTATED AND PRESENTED

1. *Restated issue raised by the Petition.* Plaintiff alleged that a blood clot triggered by Vioxx caused Mr. Ernst's death, but all of Plaintiff's experts agreed that there was no evidence of a clot, offering only unscientifically based theories on how such a clot might have vanished without a trace. Given the complete failure of evidence of causation, did the Court of Appeals correctly render judgment because there is no legally sufficient scientific evidence that Vioxx caused Mr. Ernst's death?¹

2. (Unbriefed) Putting aside Plaintiff's failure to prove that Mr. Ernst suffered a cardiovascular event triggered by a blood clot, did the Court of Appeals err in not rendering judgment for Merck on legal insufficiency grounds because Plaintiff failed to produce reliable scientific evidence, as required by *Merrell Dow Pharms. v. Havner*, 953 S.W.2d 706 (Tex. 1997), that Vioxx doubled the risk of such events for Mr. Ernst?² Did the trial court err in allowing these speculative theories to be presented to the jury, despite Plaintiff's failure to prove they were scientifically reliable?³

¹ In the unlikely event that the case is remanded to the Court of Appeals, Merck preserves the issues it raised in the Court of Appeals: In the alternative, is Merck entitled to a new trial because there is no factually sufficient scientific evidence that Vioxx caused Mr. Ernst's death? Did the trial court err in allowing these speculative theories to be presented to the jury, despite Plaintiff's failure to prove they were scientifically reliable?

² In the unlikely event that the case is remanded to the Court of Appeals, Merck preserves the issue it raised in the Court of Appeals on factual sufficiency: Alternatively, is Merck entitled to a new trial because there is no factually sufficient evidence that Vioxx doubled Mr. Ernst's risk of such events?

³ The Court of Appeals held that Plaintiff proved general causation with probative evidence. *Ernst*, 296 S.W.3d at 96 n.7.

ADDITIONAL ISSUES PRESENTED

Pursuant to TEX. R. APP. P. 53.3(c)(2), (3) and 53.4, and to preserve the right to raise issues not considered by the Court of Appeals in the unlikely event that this Court grants review, Merck asserts the following issues:

1. (Unbriefed) In this case in which the cause of Mr. Ernst's death was the central issue, Plaintiff was allowed to call an undesignated expert witness – the coroner – in the middle of trial to offer a new and different opinion on the cause of death. Was Merck denied a fair trial and entitled to a new trial because the trial court improperly permitted Plaintiff to designate and call this previously undisclosed expert witness three weeks into trial?

2. Is Merck entitled to judgment or a new trial because Plaintiff failed to prove each liability finding?

(a) (Unbriefed) Is Merck entitled to judgment on Plaintiff's design defect claim because: (1) Texas law should not recognize "design defect" claims for prescription drugs and (2) Plaintiff in any event failed to present any legally sufficient evidence of a safer alternative design?⁴

(b) (Unbriefed) It is undisputed that no one, including Mr. Ernst's treating physician, knew of his advanced atherosclerosis which was later found on autopsy. Is Merck entitled to judgment on Plaintiff's failure to warn claim because there is no legally

⁴ In the unlikely event that the case is remanded to the Court of Appeals, Merck preserves the issue it raised in the Court of Appeals on factual sufficiency: Alternatively, is Merck entitled to a new trial because there is no factually sufficient evidence of a safer alternative design?

sufficient evidence that a different or stronger warning about cardiovascular risks would have made any difference to the treating physician's prescribing decision?⁵

(c) (Unbriefed) Absent a claim of negligent manufacture, which Plaintiff does not make here, the only arguable duties owed by a pharmaceutical company are to properly design and market its medicines. Is Merck entitled to judgment or a new trial because the design and marketing claims fail?

3. (Unbriefed) Is Merck entitled to a new trial because of instructional error? The trial court refused to instruct the jury on the "but for" component of producing cause. After the trial, this Court again stated that the proper definition of producing cause requires that the action be a "substantial factor" in causing an injury. *Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 45-46 (Tex. 2007). Is Merck entitled to a new trial because the trial court improperly refused to instruct the jury on the proper definition of producing cause as stated by this Court?

4. (Unbriefed) Is Merck entitled to a new trial because of trial court evidentiary errors?

The trial court admitted irrelevant prejudicial and inflammatory evidence, including (1) speculative and unreliable calculations of the alleged number of deaths on Vioxx, (2) FDA warning letters about alleged misconduct in marketing other drugs, and (3) mar-

⁵ In the unlikely event that the case is remanded to the Court of Appeals, Merck preserves the issue it raised in the Court of Appeals on factual sufficiency: Alternatively, is Merck entitled to a new trial because there is no factually sufficient evidence that a different or stronger warning about cardiovascular risks would have made any difference to the treating physician's prescribing decision?

keting materials having no nexus to Plaintiff's prescribing physician. Was Merck denied a fair trial and entitled to a new trial because the jury was prejudicially influenced, and its verdict irretrievably tainted, by erroneously admitted evidence?

5. Is Merck entitled to judgment, remittitur or new trial because of Plaintiff's failure to prove damages?

(a) (Unbriefed) Compensatory damages awards must be supported by the evidence in the case and not excessive in comparison to other awards. Should the jury's award of over \$24 million in mostly non-pecuniary damages be overturned because it was excessive and unsupported by the evidence? Alternatively, should the jury's compensatory award be remitted?

(b) (Unbriefed) Should the jury's finding of malice be overturned because there was no legally sufficient evidence to support that finding?⁶

(c) (Unbriefed) Should the jury's award of punitive damages be overturned because the trial court erroneously refused to instruct the jury that it could not award punitive damages for conduct that had no nexus to Plaintiff's claim or for harm to other parties, and allowed the jury to consider punishment on that basis?

⁶ In the unlikely event that the case is remanded to the Court of Appeals, Merck preserves the issue it raised in the Court of Appeals on factual sufficiency: Should the jury's finding of malice be overturned because there was no factually sufficient evidence to support that finding?

CONDITIONAL ISSUES PRESENTED⁷

1. (Unbriefed) The uncapped amount of punitive damages awarded by the jury was legally unsupported. Is there legally sufficient evidence to support the jury's finding that \$229 million is the sum of money that should be assessed against Merck and awarded to Plaintiff as exemplary damages for the death of Mr. Ernst?⁸

2. (Unbriefed) The uncapped amount of punitive damages awarded by the jury was grossly excessive. Would a judgment awarding the full amount of the jury's exorbitant \$229 million exemplary damages assessment violate Merck's rights under the Texas and United States constitutions?

STATEMENT OF JURISDICTION

Plaintiff has not shown that this Court has jurisdiction. The claimed basis of jurisdiction is that the Court of Appeals held differently from another court of appeals or this Court. Petition ("P") viii; TEX. GOV'T CODE § 22.001(a)(2). But nowhere in either the Statement of Jurisdiction or in the Argument does Plaintiff cite any Texas court of appeals decision that resolved any legal issue differently from *Ernst*. Plaintiff cites three unpublished out-of-state cases (two of which are state trial court opinions) discussing dif-

⁷ As it did below, Merck assigns the following conditional issues on a precautionary basis because Plaintiff filed a notice of cross-appeal and briefed in the Court of Appeals a challenge to the constitutionality of TEX. CIV. PRAC. & REM. CODE § 41.008, which capped Plaintiff's judgment for exemplary damages in this case. Plaintiff then argued that there was sufficient evidence to support the amount of uncapped punitive damages.

⁸ In the unlikely event that the case is remanded to the Court of Appeals, Merck preserves the issue it raised in the Court of Appeals on factual sufficiency: Is there factually sufficient evidence to support the jury's finding that \$229 million is the sum of money that should be assessed against Merck and awarded to Plaintiff as exemplary damages for the death of Mr. Ernst?

ferential diagnosis, which she claims hold differently from the opinion here. P 12. But those cases do not in any way conflict with the decision here (*see* 8-10, below), and even if they did, this Court’s jurisdiction does not extend to resolving conflicts with out-of-state opinions, particularly trial court opinions.

Plaintiff also cites this Court’s opinion in *City of Keller v. Wilson*, 168 S.W.3d 802 (Tex. 2005), but only to argue that the Court of Appeals did not properly apply that case, not that the Court established a contrary rule of law. *See, e.g.*, P 1, 14. Plaintiff argues that this case could be used to “clarify *City of Keller*,” but does not state what points in *City of Keller* need clarification or how a grant of review here could be used to clarify them. P 1. There was no departure from *City of Keller* here. This was a straightforward case in which no factual or scientific evidence supported Plaintiff’s expert opinions on a critical and dispositive issue: whether the decedent’s sudden cardiac death was triggered by a blood clot so as to implicate Vioxx – an alleged pro-clotting agent – as a potentially contributing factor. As discussed below, a thorough autopsy found no evidence that a clot had triggered the death in this case. The Court of Appeals’ review of the legal sufficiency of Plaintiff’s experts’ opinions in the face of this physical evidence faithfully followed the *City of Keller* standards and applied them to the letter.

Likewise, Plaintiff has not shown that this case presents a legal issue of “such importance to the jurisprudence of the state” that this Court should correct a perceived error. TEX. GOV’T CODE § 22.001(a)(6); P viii. The only cited “importance” of the case is that the original jury verdict was notoriously large. P 1. But neither the size nor the notoriety of a verdict is a proxy for “importance” within the meaning of the Government Code.

Moreover, the large verdict here resulted from multiple trial court errors (*see* vii-xi, above), including the allowance of legally insufficient specific causation opinions which lack factual or scientific support.

This Court has spoken several times in recent years on legal sufficiency issues particular to expert opinions. *See, e.g., Whirlpool Corp. v. Camacho*, 298 S.W.3d 631, 637 (Tex. 2009) (expert’s opinion can be unreliable and thus no evidence “if it is based on assumed facts that vary from the actual facts”); *City of San Antonio v. Pollock*, 284 S.W.3d 809, 818-19 (Tex. 2009). Each of these cases raised and resolved a question of more general applicability, warranting review. *See, e.g., Whirlpool*, 298 S.W.3d at 636, 638-39 (court of appeals had limited its review of expert testimony to admissibility and failed to conduct a proper legal sufficiency review); *City of San Antonio*, 284 S.W.3d at 816-17 (defendant’s failure to object to an expert’s opinion did not preclude legal sufficiency review). There is no such question here and no reason for this Court to return yet again to the ground well covered by *City of Keller* and its progeny. The Court of Appeals’ straightforward application of settled legal principles implicates no important question of Texas law requiring review.

SUMMARY OF ARGUMENT

Texas law requires expert opinions to have a valid factual and scientific basis. Otherwise, the opinions are not evidence that can support a judgment. Applying that unremarkable principle, the Court of Appeals found that such a basis was lacking here.

As the Court explained and the record shows without dispute, Plaintiff's experts' causation opinions were all predicated on the same theory: that Vioxx increases the risk of thrombotic cardiac events by increasing the likelihood of blood clots in the coronary arteries. Plaintiff's experts' opinions depended, therefore, on the assumption that Mr. Ernst died from a cardiac event triggered by such a clot. The critical issue on appeal was whether there was legally sufficient evidence supporting that assumption. The Court carefully outlined the undisputed evidence – including most notably the physical evidence from Mr. Ernst's autopsy – and properly concluded that there was no direct or indirect evidence of a clot. *Merck & Co. v. Ernst*, 296 S.W.3d 81 (Tex. App.–Houston [14th Dist.] 2009, pet. filed). The Court could have ended its analysis there, because without such evidence the experts' opinions could not support the judgment. But the Court went on to analyze Plaintiff's theories that a fatal clot had formed but then disappeared, finding them to be equally lacking in scientific or factual support. *Id.* at 96-97.

As is plain from the face of the Court of Appeals' opinion, Plaintiff's charges that the Court "corrupted" the standard of review and failed to provide a "reasonably specific explanation" for its decision (P 1) are unsustainable. That Court correctly stated and applied the legal sufficiency standard of review established by this Court's opinions and meticulously explained why Plaintiff's experts' opinions fell short of Texas standards.

And the mere fact that the verdict made headlines five years ago (P1) is no reason to find the case important to Texas jurisprudence or otherwise worthy of review.

Indeed, nothing about this case warrants this Court's intervention. As the remainder of this response will show, the Court of Appeals' disposition of the case did not implicate any novel or controversial legal principle, but instead turned on a highly case specific and record intensive review of whether there was legally sufficient evidence, direct or indirect, that Mr. Ernst died from a clot-triggered event.⁹ That the analysis of this question is necessarily technical is not a reason for this Court to invite full briefing on the merits. The Court of Appeals has twice analyzed the question, and its exhaustive substitute opinion issued after Plaintiff's first rehearing motion addresses every question Plaintiff now raised in this Court. As the Court of Appeals correctly recognized when it denied Plaintiff's second rehearing petition, another fifty pages of briefing will not produce what Plaintiff has never had – evidence of a clot. Plaintiff's petition should be denied.

ARGUMENT

I. Plaintiff Failed to Prove Causation Because She Failed to Show That Mr. Ernst Had a Thrombotic Cardiovascular Event

Much of the factual and scientific evidence in this case was undisputed. All agreed that to show even a theoretical causal link to Vioxx, Plaintiff had to show that Mr.

⁹ In this regard, Merck notes that Plaintiff does not raise the question of whether the epidemiologic evidence is sufficient to show that Vioxx is generally capable of causing thrombotic cardiovascular events, *i.e.*, the lead issue on which this Court granted review in *Merck & Co., Inc. v. Garza*, No. 09-0073. The Court of Appeals here accepted Plaintiff's premise that there was legally sufficient evidence that Vioxx can increase the risk of thrombotic cardiovascular events, *see Ernst*, 296 S.W.3d at 96 n.7, and confined its opinion to whether there was legally sufficient evidence of specific causation, *i.e.*, whether Mr. Ernst in fact died from such an event.

Ernst died from a *thrombotic* cardiovascular event, *i.e.*, a myocardial infarction or sudden cardiac death triggered by a “thrombus” (blood clot).¹⁰ *Ernst*, 296 S.W.3d at 90-91 (noting that Plaintiff’s causation theory was based on an association between Vioxx and thrombotic cardiovascular events).¹¹ Indeed, the trial court excluded, as scientifically unsupported and unreliable, all evidence or argument that Vioxx could cause sudden cardiac death *other* than by a thrombotic mechanism. *Id.* at 90-91; 4 R 75-78; 34 R 11-15. Plaintiff did not challenge this ruling. Thus, without factual evidence that Mr. Ernst’s death was triggered by a blood clot, Plaintiff could not prove a causal link to Vioxx.

A. There Was No Direct or Circumstantial Evidence That Mr. Ernst Had a Myocardial Infarction or a Clot

Plaintiff had no competent evidence that Mr. Ernst died from a clot-triggered event. The experts agreed with the autopsy finding that Mr. Ernst died of an arrhythmia (*i.e.*, an irregular heart rhythm causing a loss of blood to the brain, 43 R 50). 22 R 110; 31 R 82; 33 R 144-45; 36 R 99; 44 R 64-65; 51 R 105-06. And all agreed that no studies link Vioxx to increased risk of arrhythmias. 22 R 108-09; 36 R 128; 44 R 65; 51 R 119.

The experts also agreed – and medical literature confirmed – that fatal arrhythmias can occur *without* thrombotic causes. 22 R 73; 33 R 41-42; 36 R 146; 44 R 64-65; 51 R 82, 88-90. They further agreed that fatal arrhythmias are associated with atherosclerosis,

¹⁰ Myocardial infarction refers to death of heart tissue that occurs when a blockage in a coronary artery cuts off the flow of blood. 51 R 68. All experts agreed that the usual cause of a myocardial infarction is a blood clot formed in response to a rupture or fissure of atherosclerotic plaque in the inner lining of the artery. 22 R 63-65; 33 R 83-84; 51 R 73-74; *Ernst*, 296 S.W.3d at 90.

¹¹ Specifically, Plaintiff’s experts opined that Vioxx increases the risk of blood clots in the coronary arteries by inhibiting production of the anti-clotting agent prostacyclin. *Ernst*, 296 S.W.3d at 85, 90-91; 30 R 23-24; 36 R 59-60, 66-67, 71-72.

which Mr. Ernst indisputably had. 22 R 90-91; 36 R 135-37; 44 R 8, 10-11, 64-65; 51 R 88-89; DX 480; 33 R 55-57, 79.¹² The autopsy established that Mr. Ernst had longstanding undiagnosed atherosclerosis occluding his major coronary arteries by as much as 75%. Consistent with this recognized association, the autopsy concluded that Mr. Ernst died of a “[c]ardiac arr[h]ythmia secondary to coronary atherosclerosis.” DX 480 at 1.

Most importantly, the experts agreed – or had to concede – that there was *no* clinical or pathological evidence that Mr. Ernst had a myocardial infarction or clot. There was no clinical evidence because Mr. Ernst was found unresponsive and was never revived. 38 R 24-26; 40 R 64-70. He exhibited none of the common clinical symptoms of myocardial infarction such as chest or arm pain, and diagnostic tests for myocardial infarction such as 12-lead EKGs or blood enzymes were not performed. 22 R 73-82; 43 R 40-43; 44 R 56-57; 45 R 8-9; 51 R 104-05, 108-11, 114; *Ernst*, 296 S.W.2d at 92.

There was no pathological evidence because the autopsy found no damaged heart tissue and no clot – the kind of evidence the experts agreed would be required to confirm a myocardial infarction pathologically. *Ernst*, 296 S.W.3d at 90; 22 R 81-82, 84-85, 87, 94; 33 RR 59-63, 68, 77-80, 83-84; 36 R 134, 146; 43 R 43-45. But all generally agreed, and the coroner confirmed, that the autopsy had been performed both carefully and thoroughly. 33 R 72-76, 125-26; 54 R 124; 43 R 63-65; 44 R 30-31. The autopsy report stated, and the experts agreed, that “the myocardium showed no evidence of recent or

¹² Plaintiff’s expert Dr. Lucchesi acknowledged that atherosclerosis of the left anterior descending artery (which Mr. Ernst had) is especially so associated. 36 R 142-43; *Ernst*, 296 S.W.3d at 91, 96.

remote infarction.” *Ernst*, 296 S.W.3d at 92; 22 R 84-85; 33 R 83; 36 R 134; 44 R 8-9. And neither the coroner nor any other expert found any evidence of a clot on either gross or microscopic examination of the coronary arteries. *Ernst*, 296 S.W.3d at 90; 22 R 87; 30 R 80-81; 33 R 60-62, 83-84, 146-47; 36 R 144-46; 44 R 8.

Indeed, the pathological evidence showed that there never *was* a clot. *Ernst*, 296 S.W.3d at 90, 92. Merck’s expert Dr. Thomas Wheeler, head of pathology at Baylor, explained without contradiction that ruptured or fissured atherosclerotic plaques are the precursor to clot formation. 43 R 21-22, 44-45; 44 R 115-16. Plaintiff’s experts, including the coroner, agreed with Dr. Wheeler that Mr. Ernst’s plaques showed no evidence of rupture or fissure. 22 R 93-94; 33 R 83-84; 44 R 8; 45 R 41-43; 54 R 120. His plaques were intact and highly calcified, so much so that the coroner had to soak his arteries in acid in order to section them without breaking her knife. 33 R 70-72; 44 R 21-27, 37-38.

B. Without Direct or Circumstantial Evidence of a Myocardial Infarction or a Clot, Plaintiff Had No Evidence of Causation

The absence of either direct evidence (a clot or dead tissue) or circumstantial evidence (plaque rupture) of a myocardial infarction or clot defeats Plaintiff’s claim. As the Court of Appeals correctly observed, where a claim is “supported by only meager circumstantial evidence, the evidence does not rise above a scintilla [and thus is legally insufficient] if jurors would have to guess whether a vital fact exists.” *Ernst*, 296 S.W.3d at 97 (citing *City of Keller*, 168 S.W.3d at 813). Without direct or circumstantial evidence of a myocardial infarction or a clot, the jurors here could only “guess” whether Mr. Ernst had a thrombotic event – the “vital fact” in issue. Put differently, the parties invited the

jury to draw two opposing inferences: (1) that Mr. Ernst had no clot and hence no myocardial infarction or other thrombotic event (Merck's view) or (2) that Mr. Ernst had a thrombotic event triggered by a clot (Plaintiff's view). But because no direct or circumstantial evidence supported the latter, the inferences were *not* equal and only the first was legally permissible. *City of Keller*, 168 S.W.3d at 813. And even if the inferences were deemed equal (which they are not), *City of Keller* would still preclude a finding of causation: “[w]hen the circumstances are equally consistent with either of two facts, neither fact may be inferred.” *Ernst*, 296 S.W.3d at 97 (citing *City of Keller*, 168 S.W.3d at 813). Since the jury would have to “guess” at the “vital fact” in issue, the causation evidence would still legally fail. Thus, under *City of Keller*, the Court of Appeals did not need to go further and consider the speculative opinions of why the clot was not found. *See* 12-15, below. Nonetheless, the Court did examine those theories and found them without factual or scientific basis. *Id.*; *Ernst*, 296 S.W.3d at 97-98.

II. Plaintiff Has Not Shown That the Court Ignored any Legally Sufficient Evidence That Mr. Ernst Died of a Thrombotic Event

A. Unsupported Speculation by Plaintiff's Experts is Not Causation Evidence

Plaintiff's claimed evidence of causation (P 6-10) merely repeats her experts' qualifications and opinions. But each of these opinions assumed, contrary to the evidence from the autopsy, that Mr. Ernst's death was triggered by a blood clot. 21 R 71-74; 30 R 21-25 (Egilman); 22 R 66-67, 108-09 (Weiner); 33 R 58-62, 144-45 (Araneta); 54 R 151-52 (Lucchesi). As the Court of Appeals correctly recognized, absent reliable evidence supporting that underlying assumption, the opinions had no evidentiary value.

Ernst, 296 S.W.3d at 97 (citing cases). And that remains true even if, as Plaintiff contends, the experts were qualified. *E.g.*, P 4 (noting Dr. Egilman’s certification); P 7 (citing Dr. Lucchesi’s résumé). The law requires reliability in addition to qualifications. *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 711 (Tex. 1997).

Equally non-probative are Plaintiff’s citations to general statements by experts for both sides that Mr. Ernst likely died of an arrhythmia caused by “ischemia.” P 7. “Ischemia” is a medical term for inadequate blood flow to the heart – *i.e.*, insufficient coronary artery blood flow to meet the demands of the heart muscle. 22 R 54-55; 43 R 38-39; 44 R 140-41; 45 R 67-69; 46 R 41; 51 R 15; *Ernst*, 296 S.W.3d at 96. Experts for both sides testified that an ischemic episode may or may not involve a clot-triggered blockage. 21 R 70-71; 22 R 44-45; 33 R 80-82; 45 R 19; 46 R 35; 51 R 15, 19, 21, 33, 77-79. The medical literature, which Plaintiff’s experts were not free to ignore, *see Havner*, 953 S.W.2d at 725-26, likewise confirms that “ischemic” arrhythmias need *not* have thrombotic causes. 22 R 73; 33 R 41-42; 36 R 146; 43 R 34-35, 51-52; 44 R 64-65; 45 R 67-69, 85; 46 R 41, 44; 51 R 15, 77-78, 82, 88-90. Thus, the cited opinions of Drs. Egilman, Weiner, and Araneta are no evidence of specific causation. P 6-9.¹³

Likewise, Dr. Lucchesi’s opinion that Mr. Ernst died of “sudden cardiac death” is no evidence of myocardial infarction. P 7. Plaintiff’s expert Dr. Weiner explained that

¹³ Plaintiff speculates, without citation to the record, that a fatal clot which occluded only part of an artery might be more difficult to find on autopsy. P 7. But none of Plaintiff’s experts so testified, and the Court of Appeals properly rejected Dr. Lucchesi’s alternative speculation that Mr. Ernst’s death might have been caused by non-occlusive “micro-clots.” *See Ernst*, 296 S.W.3d at 92-93 (noting, first, that Dr. Lucchesi’s cited medical literature did not support his speculation that microemboli could cause sudden cardiac death, and second, that Dr. Lucchesi admitted that the autopsy uncovered no evidence of microemboli). *See further discussion at 14-15, below.*

sudden cardiac death is a general term which can include both fatal arrhythmias (which can have non-thrombotic causes, *see* 3, above) and fatal myocardial infarctions. 22 R 59, 61, 73. Dr. Weiner testified that sudden cardiac death means simply no prior symptoms, death within six hours of onset of symptoms, and cause of death being cardiac-related. 22 R 61. Merck witnesses Drs. Wheeler and Santanello agreed that this very general term can include sudden death from a myocardial infarction, 27 R 35; 18 R 36-39, but those opinions are likewise no evidence that Ernst had a clot-caused death.¹⁴ Thus, saying that Mr. Ernst suffered “sudden cardiac death” is no more probative of causation than the statement that he had an “ischemic event.” *Ernst*, 296 S.W.2d at 91.

Plaintiff’s assertion that Merck’s expert Dr. Wheeler opined that Mr. Ernst had a “heart attack” (an often-used lay term for myocardial infarction) is similarly non-probative and in any event without record support. P 9. Dr. Wheeler consistently opined that Mr. Ernst did not have a thrombotic event of any type, including a “heart attack,” and the record does not support Plaintiff’s contrary assertion. *E.g.*, 45 R 8-9; 46 R 28 (Dr. Wheeler’s opinion that Mr. Ernst did not have a heart attack or thrombotic event).

B. Differential Diagnosis Cannot Substitute for Facts and Valid Science

The Court of Appeals did not, as Plaintiff argues, “create[] a new and unworkable standard of review for differential diagnosis.” P 10. As the Court recognized, differential diagnosis is a medical methodology by which an expert may, in an appropriate case, establish causation by first “ruling in” the potential alternative causes and then “ruling

¹⁴ Dr. Santanello agreed only that Merck studied the general category of sudden cardiac death which all experts agree can include both thrombotic and non-thrombotic events. P 9; 27 R 35.

out” the ones that are inconsistent with the facts and circumstances. *Ernst*, 296 S.W.3d at 98. But like any other expert opinion offered in Texas courts, an opinion based on differential diagnosis must be based on proven facts and reliable science or else it is no evidence. *See, e.g., Praytor v. Ford Motor Co.*, 97 S.W.3d 237, 245 (Tex. App.–Houston [14th Dist.] 2002, no pet.) (differential diagnosis not based on science or the medical facts of the particular case “does not present reliable evidence of causation”). The Court of Appeals properly applied that standard here.

First, the Court correctly rejected Plaintiff’s argument that all causes other than Vioxx could be ruled out because Mr. Ernst had no “risk factors for heart attacks” other than his age. P 11. Mr. Ernst’s autopsy demonstrated that despite his relative lack of observable risk factors when alive, he had severe atherosclerosis in his coronary arteries, a disease that develops over many years and is highly associated with fatal arrhythmias. *See* 3-4, above. The Court did not hold that risk factors are never relevant to a differential diagnosis, but only that their absence could not reasonably support a causation opinion in this case because Mr. Ernst died and his autopsy revealed that he did, in fact, have severe underlying coronary artery disease. *Ernst*, 296 S.W.3d at 99. The out-of-state cases cited by Plaintiff, P 12, which consider the use of differential diagnosis to assess causation of injury or disease in living persons, are inapposite.

Second, Plaintiff’s experts did not and could not “rule out” coronary artery disease as the cause of Mr. Ernst’s fatal arrhythmia. As already discussed, all of them admitted that coronary artery disease is highly associated with fatal arrhythmias, which can occur without thrombotic causes. And contrary to Plaintiff’s argument, Dr. Lucchesi did not

“rule out” coronary artery disease as the cause of Mr. Ernst’s death, but merely noted that his atherosclerosis was asymptomatic. As the Court of Appeals correctly noted, this meant only that Mr. Ernst could exercise without symptoms such as fatigue, shortness of breath and chest pain, but did not rule out that he died from an ischemic episode related to his underlying coronary disease. *Ernst*, 296 S.W.3d at 99 (noting that Dr. Lucchesi stated that coronary artery disease was the underlying cause of Mr. Ernst’s death); *see* 38 R 88, 99. Indeed, Mr. Ernst’s autopsy revealed areas of fibrosis (old scarring) in his heart tissue, indicating he not only had undiagnosed atherosclerosis, but also had experienced past episodes of unrecognized ischemia. 33 R 80-81; 43 R 62-63; 51 R 90.¹⁵

Finally, a valid differential diagnosis must have a reliable scientific basis for “ruling in” the alleged causal agent. *Coastal Tankships, U.S.A. v. Anderson*, 87 S.W.3d 591, 608 (Tex. App.–Houston [1st Dist.] 2002, pet. denied). Here, as already discussed, to implicate Vioxx, Plaintiff needed to show that Mr. Ernst died from a clot-triggered event. But as detailed above, the autopsy found no evidence of a clot, no evidence of ruptured or fissured plaque from which a clot might have formed, and no evidence of recently infarcted heart tissue suggesting that a clot had been present. *See* 4-5 above. Taking the autopsy results into account, any reasoned differential diagnosis would rule *out* a clot-

¹⁵ Notably, two of the three out-of-state cases cited by Plaintiff similarly found the proffered differential diagnoses insufficient to support a scientifically reliable causation opinion. *See Zandi v. Wyeth*, No. A08-1455, 2009 WL 2151141, *6-7 (Minn. Ct. App. July 21, 2009) (differential diagnosis held inadmissible to demonstrate cause of plaintiff’s breast cancer); *Scaife v. AstraZeneca*, No. 06-C-04-218 SER, 2009 WL 1610571, *16-18 (Del. Super.Ct. Mar. 27, 2009) (differential diagnosis held inadmissible to demonstrate cause of plaintiff’s diabetes). The third case noted in passing the plaintiffs’ position that their experts had conducted reliable differential diagnoses, but made no ruling on the point. *In re PPA*, 2003 WL 22417238, *20 (N.J. Super. Law Div. July 21, 2003) (ruling limited to sufficiency of general causation evidence).

triggered event.¹⁶ For all of these reasons, the Court of Appeals correctly concluded that the purported differential diagnosis in this case was no evidence of causation.

C. The Court of Appeals Did Not Disregard Evidence Favorable to the Verdict or Resolve Conflicts Against the Judgment

Contrary to Plaintiff's assertion, expert "evidence" favorable to the verdict must be disregarded in a sufficiency review if the opinions lack valid factual support. *City of Keller*, 168 S.W.3d at 813. The Court of Appeals' opinion took that rule into account. Plaintiff has not shown that the Court improperly disregarded any evidence pertinent to its decision. P13. The claim that the Court ignored Dr. Egilman's testimony is flat wrong, as the Court specifically reviewed and discussed his opinions. *Ernst*, 296 S.W.3d at 96 (noting that Dr. Egilman's opinion assumed the existence of a clot, contrary to the evidence). The claims (without record citations) that the Court misstated the evidence about the Vigor trial, other clinical trials, the withdrawal of Vioxx, and Merck's standard operating procedures are not only wrong but irrelevant. Those matters have no bearing on the issue of specific causation or, more precisely, whether there was scientifically reliable proof that Mr. Ernst died from a clot-triggered event, which was properly the Court's sole focus. And as discussed above, the Court was correct in concluding that Dr. Lucchesi did not rule out atherosclerosis as a cause of Mr. Ernst's arrhythmia.

¹⁶ Plaintiff's assertion that Merck's expert Dr. Wheeler concluded from a differential diagnosis that Mr. Ernst had a myocardial infarction, P 12, is wrong. Dr. Wheeler opined at length that Mr. Ernst did not have a myocardial infarction or other thrombotic event. 44 R 108. Plaintiff questioned Dr. Wheeler using an inapplicable section of the Merck Manual – a quick reference book. 45 R 10-11 (questioning from the section on cardiac and respiratory arrest and cardiopulmonary resuscitation). Dr. Wheeler confirmed that the applicable section of the Merck Manual on ventricular arrhythmias identified non-thrombotic causes of arrhythmias. 45 R 11-16.

Plaintiff next claims the Court misstated that Dr. Araneta’s trial opinion – formed five years after her careful and thorough autopsy found no evidence of either a myocardial infarction or a clot – was contrary to her report. P 13; 33 R 28, 136-38. Her autopsy report concluded that the cause of death was “[c]ardiac arr[h]ythmia secondary to coronary atherosclerosis.” DX 480 at 1; 33 R 40. It is beyond dispute that she changed that conclusion at trial by speculating that he died of a myocardial infarction while admitting that she found no evidence of one. 33 R 44-45, 64,144-47.

Finally, Plaintiff claims (again without record cites) that the Court ignored that clots are “typically” not found on autopsy and that Mr. Ernst’s death occurred too fast for signs of a myocardial infarction to develop. P 13. But the opinion specifically discusses these issues. *Ernst*, 296 S.W.3d at 98. Because of the time needed before death for a clot to naturally dissolve and for heart tissue to show damage, it was not disputed that if death from a thrombotic cause occurs within one hour (as here), an autopsy *will not* detect damaged heart tissue but *will* usually detect a clot. 44 R 57-62. If the person lives for six hours, then evidence of *both* clots and damaged tissue can be observed. If death occurs after 24 hours, then the autopsy may detect *only* damaged tissue. *Id.*; 33 R 61, 67-68; 22 R 67, 77, 81. Here, Mr. Ernst died within one hour, but the autopsy found no clot or even a precursor of a clot. 41 R 69-70; 33 R 50, 53; *see* 4-5 above.

D. The Court Correctly Rejected as No Evidence Plaintiff’s Speculation That a Clot “Could Have” Existed and “Could Have” Disappeared

Plaintiff lastly argues that the Court of Appeals should have accepted her theories that a fatal clot could have disappeared. P 14-15. The Court properly rejected Plaintiff’s

serial speculations, concluding that her “experts’ speculation that a clot ‘could have’ existed, but ‘could have’ dissolved, been dislodged, or fragmented gives rise to nothing more than conjecture.” *Ernst*, 296 S.W.3d at 97. And in so doing, the Court applied settled principles of evidentiary sufficiency review. *Schlumberger Well Surveying Corp. v. Nortex Oil & Gas Corp.*, 435 S.W.2d 854, 858 (Tex. 1968); *Entex v. Gonzalez*, 94 S.W.3d 1, 8 (Tex. App.–Houston [14th Dist.] 2002, pet. denied) (“a vital fact may not be established by piling inference upon inference. Therefore, facts from which an inference may properly be drawn must be established by direct evidence, not by other inferences.”).

The dissolved clot theory. The Court correctly rejected Plaintiff’s speculation that a clot could have dissolved naturally prior to the autopsy. *Ernst*, 296 S.W.3d at 97. All experts agreed that a clot can dissolve through fibrinolysis (the body’s natural process to dissolve clots). 22 R 67-68; 33 R 138; 36 R 85; 44 R 41-42. But none opined that fibrinolysis could dissolve a clot quickly enough to prevent its detection in the case of Mr. Ernst, who died within an hour after losing consciousness. 54 RR 55, 85-89 (discussing process of fibrinolysis but giving no time frame). Indeed, Plaintiff’s experts agreed with Dr. Pratt’s uncontradicted opinion that fibrinolysis typically takes 24 to 48 hours, and that even clot-busting drugs designed to accelerate that process (which were not used here) take more than an hour.¹⁷ 36 R 85 (Dr. Lucchesi agreeing that fibrinolysis works “very

¹⁷ Dr. Pratt had extensive experience with fibrinolysis and clot-busting drugs through his work on the clinical trials of those drugs and his regular use of them as director of the Coronary Care Unit at Methodist Hospital. 51 RR 32-41, 12. That some clots may naturally dissolve in 24 hours is consistent with all the expert’s opinions, but is no evidence that the clot in this case naturally dissolved within one hour. P 14-15. Likewise, Dr. Wheeler’s general statement that many clots naturally dissolve, P 15, says nothing about what happened in this case. 44 R 134.

slowly in comparison to giving a clot buster”); 51 R 117-18; 54 R 85, 89, 115; 22 R 88-89. And Dr. Araneta agreed with Dr. Wheeler that fibrinolysis stops at death, so that a clot present at death would be found on autopsy. 44 R 40-43; 45 R 65-66; 33 R 134-35.

In the face of this uniform testimony, Plaintiff cites Dr. Lucchesi’s comment that all blood in the body clots at death, after which the post-mortem clotting starts to dissolve. But this is no evidence that a pre-mortem clot would have dissolved before the autopsy. P 15; 36 R 85-86. As Dr. Araneta explained, pathologists can easily discern pre-mortem clots in the coronary arteries from the post-mortem clotting of the entire body. 33 R 64-65, 133-34. And Dr. Wheeler testified without contradiction that refrigeration (which was done here) prevents clots from dissolving after death. 44 R 42-43. Dr. Lucchesi’s statement considered neither the fact of refrigeration nor the difference between pre-mortem and post-mortem clots. It also fails to explain why the autopsy detected no evidence of a clot precursor, such as ruptured or fissured plaque. *See* 5 above. The Court thus properly held Plaintiff’s argument that an event-triggering clot could have dissolved before the autopsy to be both unsupported and conjectural. *Ernst*, 296 S.W.3d at 97.

The “too small clot” theory. As noted above, Dr. Lucchesi also speculated that Mr. Ernst’s alleged triggering event might not have been an occlusive clot of the kind typically associated with myocardial infarctions, but instead a microscopic clot that either dissolved or was too small to be found. *Ernst*, 296 S.W.3d at 97. But the only science Dr. Lucchesi could cite for this theory was an article concluding that “[t]he causal involvement of microemboli in death from malignant arrhythmias and/or cardiac failure remains unclear.” 54 RR 57-59, 93, 117-18. Dr. Lucchesi further admitted that there was

no physical evidence of a micro-clot, 54 R 119, a conclusion that Dr. Wheeler confirmed from review of the autopsy slides. *Ernst*, 296 S.W.3d at 93-94; 44 R 51-54; 45 R 42-43. And while the article Dr. Lucchesi cited did not discuss how long it would take for a micro-clot to dissolve, it confirmed that those clots, like larger clots, originate with plaque ruptures. PX 2022 at 279, 282. Here, as already discussed, the experts agreed there was no evidence that Mr. Ernst had a plaque rupture. *See* 5, above.¹⁸

CONCLUSION AND PRAYER FOR RELIEF

The Court of Appeals applied a textbook legal insufficiency analysis, parsing through the speculative opinions offered by Plaintiff’s experts in concluding that she had offered legally insufficient evidence of causation. And the Court did so not once but twice – first, on Merck’s initial appeal and again after Plaintiff’s first motion for rehearing. Plaintiff has suggested no valid reason why she should now receive a third bite at the apple in this Court. Plaintiff’s petition for review should be denied.

¹⁸ At trial, Drs. Lucchesi and Araneta posited yet another speculative explanation for the absence of a clot – that a clot could have been dislodged or disintegrated by the CPR performed on Mr. Ernst by the paramedics. The Court of Appeals properly rejected this theory as scientifically and factually unsupported based on Drs. Araneta’s and Lucchesi’s own testimony. 35 R 97 (Dr. Lucchesi agreed no published literature or case reports “[i]n any recorded human history at any point in any language” supported the CPR theory); 54 R 82 (Dr. Lucchesi admitted that his opinion that a clot would move was speculative: “So, one *possibility* is let us say we have what we’re calling a clot right over here... And it’s *possible*, then, for the clot to move backwards and to back up; or it’s *possible* that this is a very small mass of platelets that have moved down into one of these fine vessels to obstruct them”); 33 R 135-38 (Dr. Araneta agreed that the CPR theory was no more than “my guess” and “a possibility”); *see generally Ernst*, 296 S.W.3d at 96-98.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 14, 2010, a copy of the Response to Petition for Review was served in compliance with Texas Rules of Appellate Procedure upon the following, by Federal Express.

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