

NO. 10-0006

In the Supreme Court of Texas

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

REPLY TO RESPONSE TO PETITION FOR REVIEW

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ISSUES PRESENTED

1. Sufficiency of evidence

After a month long trial, the jury found Merck guilty of marketing defect, design defect and negligence for causing the death of Bob Ernst. Most of the testimony at trial concerned whether Vioxx was a cause of Mr. Ernst's death. Testimony was presented through renowned medical experts, documents and cross-examination. On appeal, the court of appeals disregarded all of that evidence and held that Mrs. Ernst presented no evidence that Vioxx was a cause of Bob Ernst's death. Specifically, the court of appeals failed to consider evidence presented, created a new standard for review of differential diagnosis evidence, disregarded evidence that favored the judgment, and resolved conflicting evidence against the judgment.

- Did the court of appeals improperly apply the standard for no evidence review by disregarding evidence favorable to the judgment and resolving conflicts in the evidence and inferences against the judgment?
- Did the court of appeals erroneously create an improper standard for review of differential diagnosis evidence, by disregarding evidence of exclusion of risk factors?
- Are the jury findings supported by legally sufficient evidence of specific causation?

2. Constitutional rights (unbriefed)

- Did the court of appeals, by disregarding evidence in the record contrary to the standard of review, and by substituting itself for the jury, violate Mrs. Ernst's rights under the Texas and United States Constitution to procedural due process and to the right to trial by jury?

STATEMENT OF JURISDICTION

Petitioner invoked the Court's jurisdiction because the court of appeals held differently from a prior decision of another court of appeals or of this Court, specifically *City of Keller v. Wilson*, 168 S.W.3d 802, 823 (Tex. 2005) (holding that where there are conflicts in the evidence, the court of appeals cannot disregard evidence and cannot substitute its opinion for that of the jury).¹ Petitioner also invoked this Court's jurisdiction because the proper application of the standard of review for no evidence is a recurring issue of substantial importance to Texas jurisprudence. TEX. GOV'T CODE § 22.001.

When appellate courts disregard evidence and vacate jury verdicts, without a reasonable explanation, the public loses faith in the justice system. *City of Keller*, 168 S.W.3d at 827; *In re Columbia Medical Center of Las Colinas, Subsidiary, L.P.*, 290 S.W.3d 204, 213 (Tex. 2009). The present case, which is nationally known, provides the Court with an important vehicle to clarify the standards of appellate review, not just for this case, but in all cases that involve evidence of medical causation.

In this regard, Merck cites a litany of cases in which this Court has reviewed expert opinion evidence in other contexts. That list only confirms how important this Court considers those issues. This case presents the Court with an important opportunity to provide guidance to courts and litigants on this recurring issue.

¹ Although Merck says that Petitioner did not show conflicts with other cases, the petition is filled with dozens of citations to opinions from both courts of appeals and this Court which conflict with the opinion of the court of appeals below.

TO THE HONORABLE JUSTICES OF THE SUPREME COURT OF TEXAS:

INTRODUCTION

Merck’s response demonstrates why this case is important. Throughout its response, Merck contrasts the testimony presented by Ernst’s experts with the testimony presented by Merck’s experts, and Merck attempts to convince the Court that Merck’s point of view is correct. However, in review of a judgment based on a jury verdict, the Court must “consider the evidence in the light most favorable to the verdict, and indulge every inference that would support it.” *City of Keller v. Wilson*, 168 S.W.3d 802, 822 (Tex.2005). And, if reasonable and fair-minded people could differ on their conclusions, neither this Court, nor the court of appeals, is free to substitute its opinion for that of the jury. *Id.*

When, as here, an appellate court disregards large chunks of evidence, and resolves conflicts in the evidence contrary to the verdict, the integrity of the civil justice system is at issue. *Id.* at 827 (“[A]n appellate court that begins by disregarding one party’s evidence may strike many citizens as extending something less than justice for all.”). This case presents the Court with a rich record on which to clarify the proper standard of no evidence review of medical causation.

ARGUMENT

I. Merck’s “no clot on autopsy” argument does not eradicate all competent evidence of causation

According to Merck, the failure to find a clot on autopsy “defeats Plaintiff’s claim.” This is a little like a killer saying that because you didn’t find a bullet, there is no evidence that the victim died of a gunshot wound.

To eradicate all competent evidence of causation, as developed through over a month of testimony, Merck attempts to rely on various theories based on facts that are not supported on the record. When all the evidence is considered, Merck's theories are seen to be without substance. The resolution of the conflicts in the evidence was for the jury, not the court of appeals. Because clarification of the proper standard of review of medical causation is important to the jurisprudence of Texas, this Court should grant this petition for review.

A. The “no clot found on autopsy” theory is not dispositive

Merck's leading refrain, that wafts through every argument, is that there is no evidence of causation because no clot was found in the autopsy. There is no scientific support for that sort of “magic bullet” theory. Not a single scientific article or scientist, other than Merck's experts, has ever taken the position that one is unable to diagnose an ischemic event that causes a sudden cardiac death if one does not find a clot during the autopsy. In fact, the overwhelming evidence on this record was that, for a variety of reasons, clots that cause ischemic events are usually not found on autopsy.

Although Merck now takes the position that a clot must be found on autopsy to diagnose a sudden cardiac death caused by ischemia, that is not the position taken by the coroner who performed the autopsy. In fact, when asked directly why she did not find a clot on autopsy, the coroner, Dr. Araneta, testified that the purpose of the autopsy is not to find clots or do a detailed dissection of the heart, but to rule out foul play (33 RR 84, 147). Dr. Weiner also explained to the jury the distinction between research studies, which make detailed findings, versus the autopsy, which tries to rule out foul play (22 RR 65). As a result, Dr. Araneta testified that clots are rarely found on autopsy (33 RR 88). Dr. Araneta's

testimony could not be clearer, but its message was apparently lost on Merck: “Like I said, I seldom was able to see clots where I did my own autopsies; but I just saw the end result.” (33 RR 76). “But like I told you, I see most of the time the clot is not there. But I see evidence of what the clot has done.” (33 RR 128). She testified that just because she did not see a clot on autopsy “doesn’t mean it wasn’t there.” (33 RR 147).

In its Response, Merck now argues that there is no scientific explanation about why there was no clot found on autopsy. But, Merck’s argument overlooks Dr. Araneta’s testimony that the autopsy is not designed to find clots and that clots are rarely found on autopsy. Merck’s argument also overlooks the scientific testimony that clots are often not found because: (1) the clot may be too small to be seen (36 RR 73); (2) the clot could be in a location not dissected in an autopsy (36 RR 89-90); (3) the clot could have dissolved (36 RR 85-86);² and (4) the clot could move away (26 RR 92; 36 RR 91).³

Based on that evidence, Merck cannot take the position—which it does take—that because no clot was found in the autopsy, there can be no proof of causation. As the scientific evidence revealed, the fact that no clot was found on autopsy is not dispositive of anything. No conclusion can be drawn from that fact because clots are rarely found on autopsy, for various reasons. The Court should not conclude, based on the “no clot found

² Merck continues to parrot the testimony of its expert, Dr. Pratt, who testified that the process of fibrinolysis (dissolving of clots) takes 24 to 48 hours and ends after the patient dies. Dr. Pratt admitted he had no scientific support for that opinion (52 RR 65). On the other hand, Dr. Lucchesi, who has worked with clots for over five decades, explained that the process of dissolving of clots continues after death (36 RR 85-86). The Merck Manual, which Dr. Pratt discounts, supports Dr. Lucchesi’s opinion (52 RR 66). Merck’s other expert, Dr. Wheeler, testified that the number of clots that dissolve is likely to be large (44 RR 134).

³ Dr. Pratt confirmed this movement or “reperfusion” can cause ventricular fibrillation, and confirmed that the clot can “go away.” (52 RR 69).

on autopsy” fact alone, that the rest of the evidence of causation, as presented by Ernst’s experts through weeks of testimony, was “no evidence.”

B. The “no physical evidence of myocardial infarction” theory is not dispositive

In addition to relying on the “no clot found on autopsy” theory, Merck also claims that there can be no evidence of causation because there was no physical evidence of a myocardial infarction. That argument is misleading because, as Merck later admits in its Response, when a person dies of sudden cardiac death, like Mr. Ernst, there will not be physical evidence of a myocardial infarction. *See* Merck’s Response, at 12. It is undisputed that the color changes in the heart that show a myocardial infarction do not appear for 12 to 18 hours after death, and that although one could see changes with electro microscopy after 6 hours, electro microscopy is not done on autopsy (33 RR 44-45, 60-61). “Sudden cardiac death is, by definition, not a myocardial infarction. It is what doctors term the condition when someone dies of a heart attack before their heart muscle has a chance to deteriorate. It is only when a person survives long enough for muscle deterioration that it is called myocardial infarction. That is why Merck always included “sudden cardiac death” and “myocardial infarction” in their studies as two sides of the same coin—*i.e.*, ischemic heart events (“commonly called “heart attacks.”). Thus, with a sudden death, as here, “you would not see a myocardial infarction.” (33 RR 44; *see also* 22 RR 77), and “the autopsy is not a useful way of . . . ruling in or ruling out myocardial infarction.” (22 RR 81).

But, the fact that one cannot see physical signs of an MI in an autopsy does not mean that a sudden cardiac death did not occur. Merck’s expert, Dr. Wheeler, admitted that Bob

Ernst presented the “classic textbook complication” of a myocardial infarction (44 RR 138). Dr. Wheeler explained that myocardial infarctions are “often associated with thrombus formation on coronary arteries” and are responsible for numerous sudden deaths, like Bob Ernst’s death (44 RR 133-34). Dr. Wheeler admitted that Ernst died from sudden cardiac death caused by ventricular fibrillation (44 RR 101-102). And, Dr. Wheeler agreed that “although acute MI is often the underlying precipitant of ventricular fibrillation in cardiac arrest, 50 percent of victims have no evidence of MI.” (44 RR 103-04).

Further, the coroner, Dr. Araneta, testified, in reasonable medical probability, that Mr. Ernst suffered “an acute ischemic event,” and that the acute ischemic event “would be an MI.” (33 RR 145). In its Response, Merck says that Dr. Araneta changed her opinion from the autopsy. Of course, Dr. Araneta denied that she changed her opinion and testified that she was only explaining her opinion (33 RR 64). But, even if there were inconsistencies in her testimony, or in the testimony of other experts, the resolution of those inconsistencies was for the jury, not the court of appeals.

C. The “arrhythmias can occur from other causes” theory is without merit

Another theory that Merck espouses in its response is that arrhythmias can occur from other causes and, therefore, Merck says, the fact that Ernst died of an arrhythmia cannot be considered in the causation analysis. In that argument, Merck conveniently ignores the testimony at trial of Dr. Lucchesi, a world renowned expert on arrhythmia, who has written some 480 peer-reviewed papers, and who performed a differential diagnosis of the causes of Bob Ernst’s arrhythmia (36 RR 87-90, 106-110). In his analysis, Dr. Lucchesi considered and ruled out the “other causes” of arrhythmia, such as genetic defects, earlier myocardial

infarctions, hypertrophied heart, electrocution, valvular defects, coronary artery disease, and spontaneous arrhythmia, and reached the conclusion that the most likely cause was ischemia caused by Vioxx (*Id.*).

Further, on two separate occasions, Merck's expert, Dr. Wheeler, walked through this same differential diagnosis, and conceded that none of the "other causes" of arrhythmia, as listed in the Merck Manual and a textbook, were present, and he concluded that the only likely cause was myocardial infarction (44 RR 98-117, 131-34; 45 RR 80-85).⁴

The only way that Merck and the court of appeals could ignore Dr. Lucchesi's and Dr. Wheeler's testimony would be to conclude that differential diagnosis is not a valid methodology to determine medical causation—a conclusion that would be contrary to well settled law. *See Praytor v. Ford Motor Co.*, 97 S.W.3d 237, 244-245 (Tex. App.—Houston [14th Dist.] 2002, no pet.) ("Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated."); *see also Merrell Dow Pharms. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997) (holding that to raise a fact issue on causation, one should exclude other causes).

Moreover, Merck cannot condemn that methodology because Merck's own experts validated that methodology. Dr. Wheeler stated that he "always" uses differential diagnosis to come up with the "most likely" cause of a medical problem (44 RR 131).

⁴ Dr. Wheeler tried to explain this conclusion away by saying that the Merck Manual, and even a textbook that he used to teach his students, is wrong (44 RR 109; 45 RR 67, 71).

Thus, Merck's position that there is no evidence of causation because arrhythmias can be caused by other causes finds no support in the record. The court of appeals improperly disregarded the testimony of Dr. Lucchesi and Dr. Wheeler on the "other causes" of arrhythmia and incorrectly ruled that there was no evidence to support the jury verdict.

II. The court of appeals did not analyze every question raised by the Petitioner

In its Response, Merck states that the court of appeals analyzed every question raised by the Petitioner. That is incorrect. In fact, the reason that the Petitioner has filed this petition for review is that the court of appeals (by a 3 - 3 vote) denied the motion for rehearing en banc that pointed out the court of appeals' errors. The issues that are being raised in this petition for review are expressly based on errors of the court of appeals that were not resolved by the court of appeals and need to be resolved by this Court.

III. The court of appeals created an unworkable standard for differential diagnosis

Another reason for the Court to review this case is to outline the parameters and use of differential diagnosis as proof of medical causation. As pointed out in the petition for review, the court of appeals created a brand new analysis of differential diagnosis methodology—an analysis that is not supported by the record, by any medical literature, or by the case law. The court of appeals held that in differential diagnosis, one does not attempt to rule out risk factors, such as the risk factors of heart attack. *Merck v. Ernst*, 296 S.W.3d 81, 99 (Tex. App.—Houston [14th Dist] 2009, pet. filed).

In its Response, Merck says that the court of appeals did not hold that all risk factors could not be considered. However, Merck's position is belied by the language of the court of appeals' opinion itself. *See Merck*, 296 S.W.3d at 99 ("This diagnostic process does not

contemplate the consideration of risk factors; it is a consideration of symptoms and potential causes.”). In other words, contrary to the medical authority presented at trial, and contrary to the case authority (presented in the petition for review), the court of appeals embarked on its own unique species of differential diagnosis that does not consider risk factors.

It is important for this Court to grant review in order to explain the parameters of differential diagnosis and the use of differential diagnosis in civil litigation to prove the most likely cause of a medical problem.

IV. The court of appeals disregarded evidence favorable to the judgment

Perhaps the most objectionable part of the court of appeals’ opinion is its wholesale disregard of the testimony presented by Ernst’s experts concerning causation and resolution of conflicts in the evidence against the verdict. In every instance, the court of appeals erred in choosing Merck’s expert’s opinions over Ernst’s expert’s opinions. When the medical experts are highly qualified with extensive experience, and base their opinions on objective data, as here, it is the province of the jury to determine the value of their conflicting expert testimony. *Brandt v. Surber*, 194 S.W.3d 108, 132-133 (Tex. App.—Corpus Christi 2006, pet. denied). In the present case, the court of appeals reviewed the evidence and substituted its judgment for the jury’s judgment, in contravention of the proper standard of review. *See City of Keller*, 168 S.W.3d at 822; *Jackson v. Axelrad*, 221 S.W.3d 650, 653 (Tex. 2007).

CONCLUSION

The petition for review should be granted.

Respectfully submitted,

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