No. 09-0073

In the Supreme Court of Texas

Merck & Co., Inc.,

Petitioner,

v.

Felicia Garza, et al.,

Respondents.

RESPONSE TO PETITION FOR REVIEW OF FELICIA GARZA, ET AL.

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Statement of the Case

Nature of the case	Product liability action brought by the family of Leonel Garza against Merck & Co., Inc., the makers of Vioxx.
Trial court	229th District Court, Starr County, Hon. Alex Gabert
Jury verdict	The jury found marketing and design defects in Vioxx were a producing cause of Mr. Garza's death, CR 83-84, and awarded actual damages to his widow and three adult children. CR 85-88. The jury found that the damages resulted from the gross neglect of Merck, CR 89, and assessed $25 million in exemplary damages. CR 90.
Trial court disposition	Judgment rendered on jury verdict for actual damages; exemplary damages reduced to $750,000. CR 94-100.
Court of Appeals	Fourth Court of Appeals, panel consisting of justices Stone, Speedlin, and Marion (author)
Court of Appeals disposition	Reversed and remanded because a juror failed to volunteer past financial relationship with Mrs. Garza. Found legally sufficient evidence of general causation, specific causation, and marketing defect. Found legally insufficient evidence of design defect.
Court of Appeals opinion	*Merck & Co. v. Garza*, No. 04-07-00234-CV, 2008 WL 5169577 (Tex. App.—San Antonio 2008, pet. filed)

Issues Presented

1. **General causation**: Does the record contain legally sufficient evidence that Vioxx can cause fatal heart attacks ?

2. **Specific causation:** Does the record contain legally sufficient evidence that Vioxx was a producing cause of Mr. Garza's fatal heart attack?

Statement of Facts

In the 1990s, Merck developed Vioxx, a pain relief medicine. RR 3:160-61. Vioxx was phenomenally successful, generating annual sales of $2.5 billion dollars. RR 5:91-93. But there were concerns about Vioxx from the beginning, because it creates an imbalance in the body by permitting formation of enzymes that cause clots, but suppressing the enzymes that break up clots, RR 3: 194, 199; 10:52-57, 59, 66-67, 69, 75; 11:56-58. By September 2004, so much information about its cardiovascular risks had become public that Merck decided to withdraw its best-selling drug from the market. RR6:96; 7:9; 8:103 9:42-43. But Merck had known that Vioxx caused an increased risk of fatal heart attacks long before the drug was withdrawn, and long before Leonel Garza's fatal heart attack.

Merck's statement of facts focuses on Leonel Garza's history of cardiac complications. PFR at 1-3. That history is significant precisely because a patient with a history of heart problems is the "last person in the world" who should have been taking Vioxx. RR10:76-77; 13:41; 19:50. If Merck had promptly and adequately warned doctors about the risks of Vioxx, it would not have been prescribed for Mr. Garza. RR 19:51; 11:34. Accordingly, we will address Mr. Garza's health before taking Vioxx, rounding out the full picture presented to the jury. We also will discuss Merck's conduct that allowed a man in his condition to be exposed to this deadly drug.

Mr. Garza's health

Although Mr. Garza had a history of heart problems, when he started taking Vioxx he was on "optimum medical management." RR 11:107, 26:91-92. He was taking aspirin, RR 26:91, which reduces cardiac risk by 20-25%, RR 23:33, and cholesterol medicine, RR 26:91, which reduces cardiac risk by 30-40%. RR 23:33. As a result, his former hypertension was under control, and his "bad cholesterol was way down." RR 11:87; 13:55; 23:143; 25:53-54. Although Mr. Garza smoked, he had cut back from two packs a day to two-to-three cigarettes per day. RR 22:48, 50. He lived an "active" life. RR 11:111. He often went dancing, walked everywhere, worked on his ranch and in his gardens, went hunting, and did the driving on out-of-town trips. RR:17:44, 47; 18:30; 21:53, 22:53-54.

The only thing that changed about this stable picture is that Mr. Garza began taking Vioxx. Several weeks later, he died of a heart attack caused by two "fresh occlusions," or recently developed blood clots that were not present when he began taking Vioxx. RR 10:60; 12:59; 13:96; 23:130; 25:67-68. The fact that he developed two clots in two different arteries simultaneously was "very, very unlikely," because usually you find only one clot. RR 11:109-10; 25:67. The **only** explanation for this rare occurrence was that he started taking Vioxx. "Then you have a causative effect. You have something that has been shown to cause clots, and now you could explain this— this simultaneous event of two vessels being blocked . . . at the same time." RR 11:110; *see also* RR 11:109; 12:59. Based on this scientifically explainable sequence of cause and effect, Dr. Simonini—an expert witness whose qualifications and methodology are not challenged—testified based on reasonable medical probability that Vioxx caused Mr. Garza's death. RR 11:109-11; 12:59; 13:95-96.

Merck's conduct

As early as 1997—two years before Vioxx received FDA approval—Merck scientists designing a clinical trial suspected that Vioxx could cause heart problems. One confessed that "the possibility of increased CV [cardiovascular] events is of great concern." PX2; RR 3:177. The same scientist even proposed a method of obscuring the dangerous truth: "What about the idea of excluding high risk CV patients from this study? . . . This may decrease the CV rate so that a difference between the two groups would not be evident." PX2; RR 3:179. This suggestion was approved, so that Merck's studies on Vioxx excluded high risk CV patients. RR 3:180-81; 16:77-80. Nevertheless, Merck's clinical trials still revealed substantial increases in adverse cardiovascular events in healthy patients. RR 3:44; 6:23, 25; 9:44, 60-61; 15:64-65, 97; 28:57-58. When Merck's outside physician consultants urged it to test Vioxx on people with atherosclerosis, Merck refused. RR 3:205-14; PX 10.

Merck scientists were under pressure to ignore red flags about Vioxx. In 1998, Dr. Scolnick, president of Merck Research Laboratories, RR 6:75, advised employees responsible for seeking regulatory approval from the FDA that Vioxx was "essential to the financial success of the Firm," and "Vioxx's success was necessary to preserve Merck and Merck Research Labs." RR 15: 22-23. Merck was in a race with a drug company developing Celebrex, a similar drug to Vioxx. RR 4:17; 15:135-37. It was estimated that the drug that failed to make it to market first would lose approximately $611 million. RR 4:26.

In March 2000, the preliminary results of Merck's VIGOR study showed that patients taking Vioxx were five times more likely to experience an adverse cardiovascular event than

patients using another drug. RR 6:23-25. Merck's Dr. Scolnick told his colleagues that he was "in minor agony" over the results. RR 15:35-36. He admitted that the adverse cardiovascular data was "clearly there," RR 5:19, 15:24, and that the result was caused by the drug, "as we worried it was." RR 15: 24, 26,147.

Scolnick admitted that Merck could not exclude the possibility that the result was due to the harmful effects of Vioxx until a cardiovascular-outcomes trial was done. RR 15:35-36. Scolnick described a CV outcomes study as "the only ESSENTIAL study!" RR 6:86 (emphasis in original), and explained that "essential means just that, essential, not preferred, not useful, not helpful, essential." RR 6:87. Nevertheless, Merck did not order a cardiovascular-outcomes study in 2000 after receiving the VIGOR results, nor did it schedule a cardiovascular-outcomes study during 2001, the year that Mr. Garza died of the cardiovascular outcome for which Merck should have tested. RR 3:213, 6:87; 15:26, 36-37. When Merck finally got around to doing its one and only cardiovascular-outcomes study in 2004, the results were so alarming that Merck withdrew Vioxx from the market immediately after the results became public. RR 6:96, 8:103, 9:42-43.

A month after receiving the VIGOR test results, Merck disseminated a "CV card" to its sales force to provide information for talking to its doctor customers. RR 5:40-41;15:80. The card did not contain the mortality data from the VIGOR trial, RR 15:89-91, and Merck directed its salesmen not to tell physicians about the VIGOR study. RR 5:41-43.

In October 2000, a Merck employee prepared a "Cardiovascular Meta-Analysis," which combined and analyzed all of the cardiovascular data about Vioxx that Merck had acquired up

to that point. *See* PX 279; RR 15:61-62. It revealed that the relative risk that Vioxx would cause a myocardial infarction (heart attack) compared other pain relievers, to a 95% confidence interval, was 2.02%—a doubling of the risk. *See* RR:62-65; PX 279. Yet just three months later, when Merck was providing information to the FDA about Vioxx, Merck did not mention anything about the analysis. RR 15:66-68. Scolnick admitted that drug companies should never selectively report data to the FDA. RR 15:68-69.

Merck wrote an article about the results of the VIGOR trial that was published in the New England Journal of Medicine (NEJM) in November 2000. The NEJM later discovered that Merck had altered data within days of its submission by deleting three heart attacks from the statistics. RR 18:68-80, 84-88. If the accurate facts had been reported, the relative risk factor for Vioxx would have been 20 percent higher. RR 18:89-90.

Other Merck studies in 2001 showed a statistically significant increase in cardiovascular deaths in patients on Vioxx. RR 15:72-76, 81; PX 283. Merck did not timely disclose these studies to the FDA, RR 15:79, and did not tell physicians at all. RR 15:79-80.

When the FDA insisted that Merck provide stronger warnings about the cardiovascular risks of Vioxx, Merck refused, RR15:57, instead entering into a label negotiation process that delayed the inclusion of any information about the VIGOR study for two years, RR 6:66-68. Merck estimated that an appropriate warning would cost Merck $229 million. RR6:83. On another occasion, Merck projected that a failure to "neutralize" safety concerns about Vioxx could cause losses of $500 million. RR 5:91-92. Meanwhile, Vioxx still was being prescribed

for and taken by unsuspecting patients like Mr. Garza, who began taking Vioxx a year after the VIGOR results became known to Merck, but not disclosed.

Summary of Argument

This case is not about whether Merck will be required to pay the actual and punitive damages found by the jury. The judgment based on the jury findings already has been reversed and remanded for new trial by the court of appeals because of a juror's failure to volunteer that he previously borrowed money from Mrs. Garza. The Garza family is not appealing that disposition by the court of appeals. So if this petition is denied, the case still will go back to the trial court for a new trial, as Merck requested.

However, not satisfied with a reversal and remand, Merck now seeks reversal and rendition. To get there, it twists this Court's precedent to attempt to create a jurisprudentially important question. Merck criticizes the court of appeals for failing to apply to clinical trials the standards articulated in *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997). But *Havner* expressly limited its reach to epidemiological studies, and with good reason: epidemiological studies are considered inherently unreliable, while clinical trials are so reliable they are referred to as the "gold standard" of scientific proof. *Havner* recognized and incorporated this basic distinction, and the court of appeals merely applied *Havner* as written. Merck ignores the limiting language in *Havner* and makes the novel and extraordinary assertion that clinical trials and epidemiological studies are the same. PFR at 12. This bald assertion lacks any support, and is controverted by *Havner* itself, the very scientific treatise relied on by Merck, and Merck's own testimony at trial. The court of appeals engaged in a

routine application of this Court's precedent, and Merck provides no valid reason to disturb that decision.

Merck's second point is a garden-variety legal sufficiency assertion that can only succeed if substantial expert testimony and scientific evidence are ignored. Although Mr. Garza had a history of heart disease, expert testimony, bolstered by medical records and a substantial body of scientific testing and literature, explained why the precipitating event for his heart attack was his beginning to take Vioxx, and not his stable cardiac condition.

Argument

I. The court of appeals analysis of general causation is entirely consistent with this Court's requirements for the reliability of scientific proof articulated in *Havner*.

A. The court of appeals opinion correctly acknowledged that *Havner's* guidelines for epidemiological studies do not apply to the more reliable clinical trials relied on by the Garzas.

The San Antonio court of appeals correctly read *Havner* to articulate standards that apply to inherently unreliable epidemiological studies, **not** to controlled studies such as the clinical trials in this case. *See Merck & Co. v. Garza*, No. 04-07-00234-CV, 2008 WL 5169577, *2 (Tex. App.—San Antonio 2008, pet. filed).

Merck attempts to obscure the distinction between epidemiological studies and clinical trials by pretending it does not exist. PFR at 12. But sweeping both under the broad umbrella of "epidemiological evidence" ignores significant differences in reliability that are recognized by *Havner*, the scientific treatise that Merck cites, and the testimony of Merck's own corporate representative.

In *Havner*, this Court began by distinguishing direct, controlled scientific experiments (clinical trials) and observational studies of existing populations (epidemiological studies).

> In some cases, **controlled scientific experiments** can be carried out to determine if a substance is capable of causing a particular injury or condition, and there will be **objective criteria by which it can be determined with reasonable certainty that a particular individual's injury was caused by exposure to a given substance**. However, in many toxic tort cases, direct experimentation cannot be done and there will no reliable evidence of specific causation. **In the absence of direct, scientifically reliable proof of causation, claimants may attempt to** demonstrate that exposure to the substance at issue increases the risk of their particular injury. . . . The Havners **rely** to a considerable extent **on epidemiological studies** for proof of general causation. Accordingly, we consider the use of epidemiological studies and the 'more likely than not' burden of proof.

Havner, 714-15 (emphasis added). The discussion that follows—the part of the opinion upon which Merck relies—applies only to epidemiological studies, not to "controlled scientific experiments" such as clinical trials.[1]

The only authority Merck cites in its attempt to lump together clinical trials and epidemiological studies is a chapter on epidemiology in a reference manual on scientific evidence. *See* PFR at 12 (citing Michael D. Green et al., *Reference Guide on Epidemiology*, in Federal Judicial Center, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (2d. ed. 2000)). Yet even that chapter acknowledges the distinction between clinical trials and epidemiological studies that the Garzas make, but which Merck ignores:

> **To determine whether an agent is related to the risk of developing a certain disease or an adverse health outcome we might ideally want to**

[1] In the discussion that follows, the Court notes that even the Havners' own witnesses, as well as commentators in this area "uniformly acknowledge" that epidemiological studies cannot reliably establish causation. *Hanver*, 953 S.W.2d at 715.

> **conduct** an experimental study in which the subjects would be randomly assigned to one of two groups: one exposed to the agent of interest and the other not exposed. After a period of time, the study participants in both groups would be evaluated for development of the disease. This type of study, called **a randomized trial, clinical trial, or true experiment**, is **considered the gold standard for determining the relationship of an agent to a disease or health outcome**. Such a study design is often used to evaluate new drugs or medical treatments and is the **best way to ensure that any** observed difference between the two groups in **outcome is likely the result of exposure to the drug** or medical treatment.

Id. at 338 (emphasis added). This optimal form of proof is exactly what the Garzas offered at trial. Because clinical trials are not always available for ethical reasons, researchers sometimes are forced to rely on less reliable testing, like epidemiological studies:

> When an agent's effects are suspected to be harmful, we cannot knowingly expose people to the agent. Instead of the investigator controlling who is exposed to the agent and who is not, most **epidemiological studies are observational** — that is, they 'observe' a group of individuals who have been exposed to an agent of interest, such as cigarette smoking or an industrial chemical, and compare them with another group of individuals who have not been so exposed. . . . **In contrast to clinical studies, in which potential risk factors can be controlled, epidemiological investigations** generally focus on individuals living in the community for whom characteristics other than the one of interest . . . . may contribute to the risk of the disease in question. . . . [T]hese characteristics **cannot be controlled directly by the investigator** . . . .

Id. at 339 (emphasis added). Thus, the treatise relied on by Merck does not lump clinical trials and epidemiologic studies together; it carefully analyzes their differences, and explains why one is considerably more reliable than the other.

At trial, Merck's corporate representative was the head of its Department of Epidemiology. RR 3:135. She could not have been more clear about the distinction between epidemiological studies and clinical trials. She admitted that Merck's studies of Vioxx—the

ones that the Garzas now rely upon—were "not epidemiological data," but were "clinical trials" which are "different from an epidemiological study." RR 3:236. More specifically, she conceded that clinical trials are "much more powerful than an epidemiological study," RR 3:237, and are "the gold standard for epidemiologists." RR 4:71.

Thus, there is agreement among the *Havner* opinion, the scientific treatise cited by Merck, and Merck's own epidemiologist that clinical trials and epidemiological studies are light years apart, and the difference is that clinical trials are considerably more reliable. Merck's assertion that they are the same, and its assertion that the court of appeals read *Havner* wrong, are simply wrong.

B. Even if the *Havner* guidelines for epidemiological studies applied to the clinical trials in this case, the court of appeals correctly applied this Court's "totality of the evidence" test articulated in *Havner*.

As explained in the previous sections, the *Havner* guidelines applicable to epidemiological studies do not apply to the clinical trials in this case. But even if they did, the court of appeals opinion is entirely consistent with the "totality of the evidence" standard articulated in *Havner*.

1. The *Havner* opinion expressly rejected a bright-line approach to scientific reliability, instead instructing courts to apply a "totality of the evidence" standard.

Merck incorrectly asserts that *Havner* establishes a bright-line test that this evidence cannot be reliable unless there are two statistically significant studies that show more than a doubling of the risk. Again, the court of appeals opinion reads *Havner* correctly, and Merck

invites this Court to deviate from existing precedent.

> In *Havner*, this Court went out of its way to avoid a bright-line rule:
>
> > We do not hold, however, that a relative risk of 2.0 is a litmus test. . . . Other factors must be considered. . . . There may in fact be no causal relationship even if the relative risk is high. . . . Likewise, even if a particular study reports a low relative risk, there may in fact be a causal relationship. The strong consensus among epidemiologists is that conclusions about causation should not be drawn, if at all, until a number of considerations have been considered.
>
> *Havner*, 953 S.W.2d at 718.
>
> > [T]here are a number of reasons why reliance on a relative risk of 2.0 as a bright-line boundary would not be in accordance with sound scientific methodology in some cases. Careful exploration and explication of what is reliable scientific methodology in a given context is necessary.
>
> *Id.* at 719. Finally, this Court articulated the reliability analysis that courts should follow in lieu of a bright-line test:
>
> > In sum, we emphasize that courts must make a determination of reliability from all the evidence. Courts should allow a party, plaintiff or defendant, to present the best available evidence, assuming it passes muster under *Robinson*, and only then should a court determine from a totality of the evidence, considering all factors affecting the reliability of particular studies, whether there is legally sufficient evidence to support a judgment.
>
> *Id.* at 720. The court of appeals reading of *Havner* as **not** articulating a bright-line test[2] is absolutely faithful to this Court's opinion in the *Havner*, and does not require correction.

2. The court of appeals opinion correctly concluded that the totality of the evidence establishes that the evidence supporting general causation was reliable.

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[2] The court of appeals correctly concluded that *Havner* does not establish "a bright-line test for causation." *Merck*, 2008 WL 5169577, *2.

Merck asserts that the court of appeals erred in applying the "totality of the evidence" test because the opinion only mentions Dr. Topol, and he allegedly relied on unreliable supporting evidence. *See* PFR at 11-14. The opinion does mention the testimony of Dr. Topol, a renowned cardiologist who was not retained by either side but subpoenaed for deposition testimony that was presented at trial. He relied on the results of four randomized clinical trials—all designed and conducted by Merck—each of which excluded persons with high-risk factors for cardiac disease, and were designed to test for other associations, but produced a significant increase in adverse cardiac events among persons taking Vioxx. RR 16:77-88. He testified that these trials demonstrated "that the risk of Vioxx for heart attacks can occur at any time after the initiation of the medicine." *Id.* at 88. In addition to those clinical trials, Dr. Topol also stated that he relied on four peer-reviewed studies published in highly respected medical journals, *The Lancet* and *Circulation*. RR 16:89-90.

Even though the court of appeals could have supported its finding of legal sufficiency solely on the testimony of Dr. Topol, the opinion never states that its review was limited to his testimony. Instead, it states, "After reviewing the evidence and considering the appropriate standard of review for a legal sufficiency challenge, we conclude the plaintiffs carried their burden of presenting legally sufficient evidence to support a finding of general causation." *Merck*, 2008 WL 5169577, *3. The evidence reviewed included not only Dr. Topol, but the Garza's other expert on causation, Dr. Simonini. *See* RR 11:84-85, 115-16. It included the VIGOR clinical trial, the Protocol 090 trial, the Juni meta-analysis, the Protocol 010 study, the ADVANTAGE clinical trial, the Solomon case control study, the VICTOR clinical trial, the

APPROVE clinical trial, the Ingenix observational study, and Dr. Graham's observational study. *See* Brief of Appellees Felicia Garza, et al., at 8-17. In short, there was abundant evidence that Vioxx causes adverse cardiac events.

The court of appeals opinion represents the application of well-established standards to a body of evidence that support the jury verdict. In the absence of any issues of jurisprudential significance, the petition should be denied.

II. The court of appeals correctly found legally sufficient evidence excluding other plausible causes with reasonable certainty.

The court of appeals opinion provides a reasoned basis for its conclusion that "the plaintiffs carried their burden of presenting legally sufficient evidence to support a finding of specific causation." *Merck*, 2008 WL 5169577 at *4. Merck's challenge to this finding focuses exclusively on Dr. Simonini's testimony about simultaneous clot formation. Dr. Simonini noted that medical tests showed no evidence of clots three weeks before Mr. Garza's death. RR 12:59; 13:96. After taking Vioxx he quickly developed not one, but two clots simultaneously, which was "very rare." RR 11:109-10; 25:67. Those clots were identified on autopsy as the cause of Mr. Garza's death. RR 12:59; 23:130; 25:67-68.

The fact that there were two clots rather than one bolstered Dr. Simonini's opinion, but was not essential to it. Even if there had been only one fatal clot, there still would be evidence from Dr. Simonini that:

- Drugs like Vioxx create an imbalance in the body by permitting formation of enzymes that cause clots, but suppressing the enzymes that break up clots, RR 3:194, 199; 10:52-57, 59, 66-67, 69, 75; 11:57-58;

- The formation of clots is a common cause of heart attacks, RR 10:60;

- Mr. Garza died because of a heart attack caused by recent clotting, RR 10:60;

- People with a history of heart disease like Mr. Garza are particularly at risk for clotting and heart attacks after taking Vioxx, RR 10:75-78; 11:55-56; 13:41;

- Numerous tests have shown that Vioxx can cause serious adverse cardiac events soon after a patient begins taking it, RR 10:122; 11:27-28,39, 47, 56-57;

- Mr. Garza's cardiac tests three weeks before his death showing he was at low risk, followed by his fatal heart attack caused by clotting, is consistent with Vioxx's tendency to cause clotting, RR 11:109-10; and

- Vioxx was a producing cause of Mr. Garza's heart attack, RR 13:95-96.

In short, whether there was one clot or two clots was not essential to Dr. Simonini's analysis.

Merck asserts that Dr. Simonini "provided no scientific connection between exposure to Vioxx for less than twenty-five days and the formation of clots." PFR at 15. Yet Dr. Simonini cited numerous studies that support this connection:

- In the VIGOR clinical trial conducted by Merck, differences between the Vioxx group and the control group began appearing in the first month, RR 10:122;

- The Protocol 010 study showed a heart attack in the Vioxx group within 7 days, RR 11:39;

- The Solomon study showed heart attacks "throughout, no matter how long they were exposed to Vioxx . . . [it] wasn't something that happened late," RR 11:47;

- The Juni meta-analysis concluded that it "didn't matter how long they were on it. Even a short duration was able to demonstrate the effect," RR 11:56; and

- The VICTOR clinical trial showed curves separating from the very beginning, "it's almost immediate," RR 11:66-68.

Thus, Dr. Simonini did provide scientific evidence demonstrating that the connection between Vioxx and heart attacks could be demonstrated almost immediately.

The court of appeals conclusion that there was legally sufficient evidence of specific causation by ruling out other plausible causes has ample support in the record. In the absence of any issues of jurisprudential importance, the petition should be denied.

Prayer for Relief

Respondents Felicia Garza, et al., respectfully request that the petition for review be denied, and that they be granted all other relief to which they may be entitled.

Respectfully submitted,

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