

No. 09-04-00344-CV

**In The
Ninth Court of Appeals
Beaumont, Texas**

**WYETH,
*Appellant,***

v.

**JERRY COFFEY, INDIVIDUALLY AND AS REPRESENTATIVE OF THE ESTATE OF CYNTHIA
CAPPEL, DECEASED AND AS NEXT FRIEND OF RACHEL COFFEY, SARAH COFFEY AND
JENNIFER COFFEY, MINORS,
*Appellees.***

On Appeal from the 172nd Judicial District Court of
Jefferson County, Texas
Trial Court Cause No. E-167334

REPLY BRIEF FOR APPELLANT

Lawrence L. Germer
State Bar No. 07824000
GERMER GERTZ, LLP
550 Fannin
Beaumont, Texas 77701
(409) 650-6700
(409) 835-2115 (fax)

Marie Yeates
State Bar No. 22150700
VINSON & ELKINS L.L.P.
1001 Fannin Street, Suite 2300
Houston, Texas 77002
(713) 758-2222
(713) 615-5544 (fax)

Claudia Wilson Frost
State Bar No. 21671300
J. Brett Busby
State Bar No. 24031778
Jeremy J. Gaston
State Bar No. 24012685
MAYER, BROWN, ROWE & MAW LLP
700 Louisiana Street, Suite 3600
Houston, Texas 77002-2730
(713) 221-1651
(713) 224-6410 (fax)

ATTORNEYS FOR APPELLANT

Oral Argument Requested

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The reporter's record is cited "__RR__," where the first blank refers to the volume number and the second blank refers to the page number.

Plaintiffs' exhibits, which are contained in volumes 29-43 of the Reporter's Record, are cited "PX__," where the blank refers to the exhibit number.

Defendant's exhibits, which are contained in volumes 44-50 of the Reporter's Record, are cited "DX__," where the blank refers to the exhibit number.

Court exhibits, which are contained in volumes 51-55 of the Reporter's Record, are cited "CX__," where the blank refers to the exhibit number. Court exhibits are documents admitted into evidence but not sent back to the jury room during deliberations.

Offers of proof are cited "__OP__," where the first blank refers to the volume of the Reporter's Record and the second blank refers to the page number.

The appendix to Wyeth's opening brief is cited as "__AP__," where the first blank refers to the appendix tab number and the second refers to the page number of the item.

TO THE HONORABLE NINTH COURT OF APPEALS:

INTRODUCTION

On the key arguments raised by Wyeth, Plaintiffs' silence is deafening. Although their brief tracks Wyeth's outline of the issues, the substantive gaps in Plaintiffs' responses are remarkable. Plaintiffs simply ignore many of Wyeth's legal arguments and fail to cite applicable precedent on others. Wyeth's un rebutted arguments require reversal.

Plaintiffs' silence is telling in other respects. They evidently are embarrassed by the unprecedented size of the jury's verdict – over a billion dollars for a wrongful-death claim – because they mention it only once, in passing, on page 42 of their brief. And although the sheer size of the verdict is compelling evidence by itself that the trial was massively tainted, many other facts also reflect a runaway verdict that was the product of a one-sided trial where, time and again, the trial court gave Plaintiffs free rein while tying Wyeth's hands when it tried to defend itself:

- Plaintiffs were permitted to present Mr. Coffey's speculation that his wife never would have taken any drug that warned of potentially fatal risks. Yet Wyeth was barred from rebutting this claim by showing that Mrs. Coffey took other diet drugs with labels that warned of potentially fatal PPH risks after being expressly told of those risks by her doctors.
- Plaintiffs were permitted to rely on an epidemiological study that computed the PPH risks of diet drugs as a group (not drug by drug) as evidence that Pondimin caused her PPH. Yet Wyeth was barred from telling the jury that the drugs the same study associated with PPH included not only Pondimin, but also Tenuate, which Mrs. Coffey used as much as Pondimin and closer in time to developing PPH.
- Plaintiffs' paid witnesses were allowed to opine as "experts" regarding Wyeth's supposed "intent" to violate FDA regulations. The trial court then compounded its error of admitting such "expertise" by barring Wyeth from rebutting it with the testimony of a former FDA official who would have testified to Wyeth's regulatory compliance.
- Although Mrs. Coffey did not suffer from any heart valve abnormalities, the jury heard as much about heart-valve injuries as it did about PPH. In addition, although Mrs. Coffey did not take Redux, another Wyeth diet drug, the jury heard as much about Redux as it did about Pondimin.
- The trial court gave Plaintiffs' spoliation instruction, thereby directing a verdict in

favor of busting the punitive damages cap, even though the evidence supported no finding of spoliation, let alone spoliation of the kind of documents specified in the Penal Code section on which Plaintiffs relied.

- The court’s spoliation instruction also destroyed Wyeth’s credibility on other matters by telling the jury which party to believe. Then, when Wyeth tried to defend itself, Plaintiffs’ counsel simply said, “[i]f you don’t want to trust me the lawyer [about what the truth is], would you please trust Judge Floyd, the judge,” and he reiterated the court’s erroneous instructions regarding document destruction. 26RR213-14; *id.* at 214 (Plaintiffs’ counsel: “Judge Floyd says, bunk. They deliberately destroyed them.”).

Such errors, among others, sharply tilted the proceedings against Wyeth, irretrievably harmed its credibility, and deprived it of a fair trial.

Plaintiffs tacitly acknowledge the tainted nature of the proceedings below by now painstakingly distancing themselves from what they claimed at trial was the “very heart of [their] case,” 2RR87: Wyeth’s alleged deception of the FDA. Plaintiffs want to forget that theory because the Supreme Court held it is preempted by federal law. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001). Plaintiffs cannot hide from this fatal flaw by relegating all discussion of *Buckman* to a footnote. *See* Plaintiffs Br. 41 n.26.

Plaintiffs otherwise strive to curry sympathy and smear Wyeth by exploiting the improperly one-sided record below. In doing so, Plaintiffs mimic their trial strategy of using irrelevant facts and prejudicial themes to inflame the decision-maker and obtain a runaway result that cannot be justified under the law. While that strategy, uncontrolled by the trial court, was “effective” before the jury, its reprise here just proves Wyeth’s point: the one-sided show below simply bore no resemblance to a fair trial.

In this reply, Wyeth focuses on those issues where Plaintiffs’ brief confirms, by silence or otherwise, that Wyeth is entitled to the relief it seeks. Wyeth also will address those areas where Plaintiffs’ brief confuses otherwise clear issues, as well as recent legal developments that buttress its position on preemption. And although numerous issues

require a new trial or substantial remittitur, Wyeth first will address those that support rendition of judgment in its favor.

I. Plaintiffs Failed to Prove that Pondimin Caused Mrs. Coffey’s PPH.

A. Plaintiffs do not have two studies meeting *Havner’s* requirements.

Plaintiffs (at 14) do not dispute that, to raise a fact issue on causation, *Havner*¹ required them to provide two or more epidemiological studies showing (at a 95% confidence level) that people exposed to Pondimin experienced a more-than-doubling of the background risk of developing PPH. While the two studies on which Plaintiffs relied (SNAPH and the IPPHS) may be useful for other purposes, they simply do not meet *Havner’s* foundational causation requirements because neither concluded that exposure to Pondimin alone was associated with a more-than-doubled incidence of PPH.² Indeed, Plaintiffs’ PPH-and-causation expert conceded on cross-examination that the IPPHS did *not* show that exposure to Pondimin by itself was associated with any statistically significant increased risk of PPH.³ Wyeth Br. 27 (citing 9RR108-09). Plaintiffs ignore this concession, but it defeats their entire case. It means the IPPHS cannot be used to raise a fact issue on causation and, in turn, that Plaintiffs cannot satisfy *Havner’s* multiple-studies requirement. Wyeth Br. 22.

As to SNAPH, the problem is not merely that it failed to use a “pristine” control group, as even Plaintiffs concede (at 15), but that, unlike the IPPHS, SNAPH was not designed to compare people who had PPH with healthy people. SNAPH measured the frequency of Pondimin use in various types of patients who had pulmonary hypertension.

¹ *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997).

² In an effort to escape their burden of proof on causation, Plaintiffs state (at 13) that, “At trial, Wyeth agreed that Pondimin caused PPH.” But as previously explained (Wyeth Br. 22 n.7), while Wyeth did not dispute at trial that Pondimin, like some other diet drugs, may cause PPH in *some* people under *some* circumstances, Wyeth never conceded that exposure to Pondimin “more than doubles” the risk of PPH in the general population; that Pondimin more-probably-than-not was the cause of Mrs. Coffey’s PPH; or that Plaintiffs’ causation evidence and methodology otherwise were reliable. It thus remained Plaintiffs’ burden to prove these essential elements.

³ Plaintiffs insinuate (at 5-6) that Wyeth hired Dr. Faich to write a medical journal editorial to blunt the effects of the IPPHS, but Dr. Faich was not hired by Wyeth to write the editorial. 17RR98-99, 101.

In other words, *all* individuals in SNAPH had pulmonary hypertension. In contrast, a case-control study “identifies individuals with a disease and a suitable control group of people *without* the disease.” *Havner*, 953 S.W.2d at 721 (emphasis added). Plaintiffs cite no law, reasoning, or expert evidence to support the notion that a study like SNAPH could satisfy *Havner*’s causation requirements. Indeed, the silence of Plaintiffs’ experts regarding SNAPH is particularly telling. None of them testified that SNAPH was a properly controlled epidemiological study from which to infer causation under *Havner*.⁴

B. Mrs. Coffey was not similar to the subjects of the studies. Mrs. Coffey also was not similar to the IPPHS and SNAPH test subjects, as *Havner* requires, in two crucial respects: duration of drug exposure and timing of disease onset. Wyeth Br. 23-25.

1. Exposure. Plaintiffs proclaim (at 16) that Mrs. Coffey met SNAPH’s six-month duration requirement, citing Dr. Coulter’s testimony that Mrs. Coffey told her she had taken Pondimin for six months. 14RR76. This contradicts Mrs. Coffey’s prescription records (three months’ use, 8RR147-48; 9RR25), her husband’s testimony that she did not even finish those prescriptions (CXZ, Ex. 1 at 94), and her own statements to Dr. Frost (five months’ use, 9RR25). It also contradicts what Plaintiffs’ counsel told the trial court in obtaining a ruling in limine: they argued that Mrs. Coffey had no reason to lie when she told Dr. Frost “that she took the drug five months.” 2RR38. The court then ruled that Wyeth could not contest what Mrs. Coffey said. 2RR41.⁵

Dr. Coulter’s testimony also conflicts with her earlier testimony, where she said Mrs.

⁴ Plaintiffs claim (at 14) that SNAPH reported a “more than doubled” relative risk with 95% confidence as required by *Havner*, 953 S.W.2d at 724. This is wrong for two reasons. First, SNAPH did not report any “relative risk”; it reported an “odds ratio,” which “often overstates the relative risk.” *Id.* at 721. Second, the 95% confidence interval for the reported odds ratio had a low end of 1.7. See CXZ, Ex. 4 at 872. Because the confidence interval dipped below 2, it does not show that any relative risk “more than doubled” with 95% confidence.

⁵ Plaintiffs (at 16) cite “expert” testimony that there was no evidence in Mrs. Coffey’s medical records that she did not get *more* prescriptions. But such rank speculation does not satisfy Plaintiffs’ burden of proof: an absence of evidence is not affirmative proof of the opposite fact (especially here, where Mrs. Coffey’s medical records are missing because she took them from storage and they were never seen again). Wyeth Br. 8.

Coffey told her she had taken “diet drugs” for six months. 14RR58. But Mrs. Coffey took other diet drugs besides Pondimin and did not tell Dr. Coulter about them. Wyeth Br. 2, 23 n.6. Dr. Coulter’s change in testimony (equating “diet drugs” with “Pondimin”) is thus a speculative jump that contradicts all other evidence. Thus, her testimony is not even a scintilla of evidence that Mrs. Coffey used *Pondimin* for six months and is legally insufficient to show causation. At a minimum, it is factually insufficient and requires a new trial.

2. Disease Onset. According to Dr. Frost (Plaintiffs’ PPH expert and Mrs. Coffey’s treating physician), Mrs. Coffey’s PPH symptoms did not arise until December 2001, roughly *four-and-a-half years* after she last took Pondimin. Wyeth Br. 24. Yet neither SNAPH nor the IPPHS found any statistically significant evidence of association, let alone causation, except for test subjects whose PPH symptoms arose within *six months* or *one year* after their last diet drug exposure. Wyeth Br. 24. Because Plaintiffs’ own expert places Mrs. Coffey *several years* outside these time limits, SNAPH and the IPPHS simply do not apply to her. Plaintiffs thus lack legally or factually sufficient evidence on the key issue of specific causation: whether Mrs. Coffey’s PPH was caused by Pondimin.

Plaintiffs claim (at 19) that Mrs. Coffey, who had been morbidly obese for many years, sometimes had “shortness of breath” before December 2001. But no evidence places her onset of symptoms within a year after her last exposure to Pondimin in 1997, as IPPHS requires. Moreover, Mrs. Coffey told Dr. Frost (to whom Plaintiffs say Mrs. Coffey had no incentive to lie) that her shortness of breath came on during her pregnancy in December 2001 and never resolved. 2RR38. In any case, whether she had ever had shortness of breath before December 2001 is not the question. Instead, the question is when shortness of breath was a medical symptom of PPH. On that front, Dr. Frost’s is the only evidence as

to when Mrs. Coffey's medical symptoms of PPH began.

Plaintiffs otherwise claim (at 17) that neither the IPPHS nor SNAPH “stands for the proposition that there is no statistically significant risk to patients once they pass the six month or one year mark.” But this begs the question. The issue is not whether the studies say there is no risk after six months or a year of drug use. The issue is whether the studies find a statistically-significant and more-than-doubled risk after such time periods. Because neither IPPHS nor SNAPH make such a finding, Plaintiffs failed to carry their burden of proving that Mrs. Coffey's PPH, the symptoms of which arose significantly more than a year after her last Pondimin exposure, was in fact caused by her use of the drug.⁶

Consequently, Plaintiffs' primary causation expert – an author of the IPPHS – had to concede that the IPPHS (i) *failed* to show a cause and effect relationship for people like Mrs. Coffey and (ii) was statistical evidence *against* any association between diet drug use and PPH for people whose PPH symptoms developed more than a year after last use. Wyeth Br. 24 (citing 9RR122; 13RR145, 149, 151-53). Plaintiffs have no response to these concessions, either of which requires reversal of the judgment. Without any admissible evidence of specific causation, the judgment cannot stand.

Finally, based on materials outside the IPPHS and SNAPH, Plaintiffs claim (at 18) that the time period between Mrs. Coffey's Pondimin use and PPH diagnosis was consistent with that experienced by others in the IPPHS. But as Plaintiffs acknowledge (at 17), a party cannot “reinterpret study data” to change a study's actual conclusions, and the IPPHS and SNAPH expressed their conclusions in terms of the onset of PPH symptoms, not timing of PPH diagnosis. *Havner*, 953 S.W.2d at 720 (holding that an expert cannot

⁶ Plaintiffs' reliance on another court's statement that “the IPPHS did not conclude that there is no risk beyond twelve (12) months of the last use,” is misplaced. *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 694 (W.D.N.C. 2003). *Smith* was not decided under Texas law. As discussed above, whether IPPHS or SNAPH concluded that there is *no* risk of PPH beyond six months or one year is not the relevant question under Texas law.

pick and choose data or reanalyze data in a scientifically unreliable manner).

Plaintiffs also rely (at 18) on documents that purportedly show longer latencies for individuals who were *not* test subjects in the IPPHS or SNAPH. Reliance on such materials is invalid. *Havner* requires a plaintiff to be similar to the test subjects in the studies at issue because those are the only persons for whom any statistically significant results have been calculated. 953 S.W.2d at 720 (“A claimant must show that he or she is similar to those in the studies.”). Consequently, Plaintiffs’ extrinsic materials and reanalyses must be disregarded in assessing the legal and factual sufficiency of Plaintiffs’ causation evidence.

Because plaintiffs failed to show that Mrs. Coffey was similar to the test subjects in SNAPH and the IPPHS, the results of those studies are irrelevant and inadmissible with respect to the specific causation issue presented here: whether Mrs. Coffey’s PPH was caused by Pondimin. Accordingly, judgment should be entered for Wyeth, or, at a minimum, a new trial granted.

C. Plaintiffs failed to rule out other plausible causes of Mrs. Coffey’s PPH.

Plaintiffs claim (at 21) that Tenuate is not a plausible cause of Mrs. Coffey’s PPH because “there is no scientific evidence, anywhere, that links Tenuate to PPH.” But the very type of “scientific evidence” Plaintiffs relied upon at trial proves their claim is simply wrong. Tenuate was one of the drugs studied in the IPPHS. Tenuate also was linked to PPH in several reports in the scientific literature. Moreover, Mrs. Coffey used Tenuate at least as much as she used Pondimin and her Tenuate use occurred much closer in time to the onset of her PPH symptoms. Wyeth Br. 25.

To be sure, because the IPPHS studied diet drugs – including Tenuate – as a group, Wyeth maintains that the IPPHS does not satisfy *Havner*’s requirements for proving that

any particular diet drug in the study probably caused a particular case of PPH. But Plaintiffs cannot have it both ways. If this Court were to assume that the IPPHS permits an inference that Pondimin causes PPH, then Tenuate becomes an equally plausible cause that Plaintiffs had to exclude. The diet drug users in the IPPHS included both Tenuate and Pondimin users, and the IPPHS made no distinctions between those users in its statistical conclusions. Wyeth Br. 25-26 (citing 9RR108-09; 18OP159).

As to the reports in the literature that Tenuate users developed PPH, Plaintiffs' PPH-and-causation expert testified that those reports raised a concern of a causal relationship between Tenuate and PPH. *Id.* Indeed, Plaintiffs' primary causation expert stated that such reports may be used to elevate a drug into a "plausible cause" of PPH even if no epidemiological data exists. *Id.* Plaintiffs make no response to these concessions.

While Wyeth believes that anecdotal case reports do not suffice to provide the necessary epidemiological evidence of causation, Plaintiffs rely on such reports for that very purpose with respect to Pondimin. *See supra* Part I.B. Even though such reports would also implicate Tenuate as an alternate cause of Mrs. Coffey's illness, Plaintiffs contend that such reports cannot be used for that purpose. *See infra* Part V.A. But again, Plaintiffs cannot have it both ways.

In sum, because Plaintiffs' experts failed to rule out Tenuate as a plausible cause of Mrs. Coffey's disease, their methodology was unreliable and their causation evidence is legally insufficient. At a minimum, it is factually insufficient and requires a new trial.

D. Improper and one-sided "expert" testimony cannot create "causation." Because Plaintiffs' medical studies could not raise a fact issue on causation under *Havner*, Plaintiffs hired experts willing to ignore those requirements, recast the studies' conclusions, and testify on matters outside of them. The trial court should have seen through this gambit

and dismissed Plaintiffs' claims at the pre-trial *Havner* hearing. 3RR6-32. Instead, the court let Plaintiffs' claims proceed and gave their experts free rein in front of the jury over Wyeth's objections. 7RR108-13; 9RR4-5; 11RR17-20; 13RR4-7; 14RR5-13. The court thus abandoned its duty to keep unreliable expert testimony out of the courtroom and allowed Plaintiffs' causation "experts" to mislead the jury. Wyeth Br. 26-28.

The court further exacerbated the unfairness of the trial by precluding Wyeth from responding to these "expert" characterizations of the studies, thus preventing the jury from getting the full picture and learning three undeniable facts: (i) according to the IPPHS and other reports, Tenuate users had developed PPH; (ii) the IPPHS reported no greater statistical association between PPH and Pondimin than between PPH and Tenuate; and (iii) Mrs. Coffey used Tenuate much closer in time to the onset of her PPH. Wyeth Br. 25. The trial court's willingness to allow the jury to hear only Plaintiffs' legally and factually insufficient evidence of causation contributed to the one-sided proceedings that, at a minimum, demand a new trial.

II. The Liability Findings Cannot Support the Judgment.

A. Plaintiffs' liability theories are preempted by federal law. Plaintiffs fail to respond to Wyeth's argument that their claims for design defect, marketing defect and negligence are preempted under *Buckman*. Instead, Plaintiffs suggest in passing in a footnote (41 n.26) that *Buckman* is inapplicable because Plaintiffs did not plead a fraud-on-the-FDA cause of action. But Plaintiffs cannot escape the fact that in their counsel's own words, Wyeth's alleged deception of the FDA was the "very heart of [their] case." 2RR87.

1. Alleged Fraud on the FDA. Before trial, Wyeth moved to exclude any evidence that Wyeth allegedly misled the FDA. In opposition, Plaintiffs' counsel said,

"I agree It would be improper for Wyeth to put a warning different than what the FDA says. Therefore, *we're faced with the only option, and that is*

to show to the jury how they have got to that point, by misleading the FDA and deceiving the FDA about what the product was, what the number of adverse reactions were. . . .”

“And because the FDA regs are what they are, we’re left with no other choice but to do it that way. *We have to show that they have exercised deception in convincing the FDA to let it on the market. Otherwise, hey, the FDA approved it. Case closed.*” 2RR87-88 (emphases added).

The trial court denied Wyeth’s motion and, true to their word, Plaintiffs made Wyeth’s alleged deception of the FDA the “heart” of their case. 2RR87. Plaintiffs’ counsel began by introducing this unquestionably preempted liability theory in his opening statement:

“Wyeth and its lawyers are here not to apologize; they’re here to beat this family and to deny them any justice and any compensation. And how do they plan to accomplish that unjust result? By using the same tactics – and the evidence will show you what those tactics were – using the same tactics that Wyeth used year after year to manipulate and deceive the FDA [into] letting them continue to sell a known dangerous drug.” 7RR13-14.

Then, throughout trial and over Wyeth’s objections, numerous witnesses for Plaintiffs featured Wyeth’s alleged deception of the FDA. Dr. Moye characterized Wyeth’s reports to the FDA as “staggering falsehoods,” 15RR194, and asserted that “thousands of people” had been hurt because of Wyeth’s alleged failure to submit information to the FDA, 15RR210-11. Fueling the fire, and consistent with the one-sided nature of the case the jury heard, Dr. Moye was permitted to take Wyeth’s statements from an FDA transcript out of context and portray them as deceptive while Wyeth was precluded from introducing other portions of the same transcript to explain those statements. 12RR97-102. Likewise, Wyeth’s expert, Dr. Lowe, was prohibited from testifying that Wyeth acted honestly and responsibly in reporting information to the FDA, that there was no manipulation of the FDA, and that Wyeth did not withhold data or provide flawed information to the FDA. 26RR93-94.

The court then impermissibly vouched for Plaintiffs’ FDA-deception claim and irreparably damaged Wyeth’s credibility by instructing the jury that Wyeth had destroyed

relevant documents that should have gone to the FDA. *See infra* Part V.A.

Finally, throughout closing, Plaintiffs' counsel made the most of this FDA mantra, exhorting the jury that this case was about

“how [Wyeth] manipulated the FDA into allowing them to sell this drug until the body count got too big by September of '97, [and] the FDA met with them and required it to be taken off the market” 26RR118.

And that the case was about

“how [Wyeth] manipulated the FDA for at least two years – you read the memos – maybe longer than two years – into not requiring them to put the best warning possible, which is the black box warning . . . so that there is no chance for any lack of knowledge or misunderstanding.” *Id.*

“Did they lie to the FDA? Sure, they did. Sure, they did.” 26RR145.

“They also did something else. The court has now – will give you . . . an instruction, and that instruction is going to read like this: . . . The Court has instructed you that the deliberate alterations of the CDSSS records by Wyeth is spoliation or destruction of evidence relevant to this case.” 26RR147.

“And they destroyed evidence because they didn't want the FDA to have it and they didn't want the people to have it. . . . And they got caught. And now it's time. Now it's time.” 26RR148.

“And not only did they destroy some files, they removed some stuff out of the files. They concealed – how did they conceal it? They didn't tell anybody about it until the FDA come [*sic*] in on September the 10th and started looking around. . . .” 26RR150.

“[W]hat Wyeth was saying is not true, that they were concealing information from the FDA, that they were hiding the ball on this.” 26RR153.

Plaintiffs' suggestion that their case was *not* about alleged fraud on the FDA is simply preposterous.

Nor does the fact that Plaintiffs did not plead a formal “fraud-on-the-FDA” claim render *Buckman* inapplicable. Plaintiffs' message was clear: had Wyeth not lied, destroyed evidence, and deceived the government (according to Plaintiffs' one-sided version), Pondimin never would have been on the market or never would have been sold without a

black box warning. In either case, Plaintiffs contended that but for Wyeth's alleged fraud on the FDA, Mrs. Coffey would not have died. Similarly, the *Buckman* plaintiffs claimed that "but for" the defendant's alleged misrepresentations to the FDA in obtaining approval to market a medical device, they would not have been injured by the device. 531 U.S. at 344. *Buckman's* holding that this type of claim is preempted applies equally here.

Because Plaintiffs' fundamental theory of liability was preempted by federal law, the judgment should be reversed. At a minimum, because it is impossible to determine the extent to which the jury was motivated by Plaintiffs' preempted theories, a new trial must be granted. *See Crown Life Ins. Co. v. Casteel*, 22 S.W.3d 378, 389 (Tex. 2000) (requiring new trial where commingling of invalid liability theory with other liability theories precluded meaningful appellate review).

2. General Conflict Preemption. Plaintiffs' liability theories are also preempted because they undermine federal objectives. Specifically, they second-guess the FDA's determinations that Pondimin's benefits outweighed its risks, that it was safe and effective for its intended use, and that its PPH warnings were adequate. *Buckman*, 531 U.S. at 348; *see* Wyeth Br. 29-31, 36-39.

The cases Plaintiffs cite (at 23, 29) in response to Wyeth's preemption arguments do not save any of their claims. All but one case pre-dated *Buckman*. Their recent case did not include any claim of FDA deception, did not consider *Buckman*, and addressed a *different* question of conflict preemption. *See Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876 (E.D. Tex. 2005). In *Cartwright*, the question was whether Texas failure-to-warn law conflicted with FDA regulations that "merely set minimum standards with which manufacturers must comply," not regulations that "*expressly* . . . prohibit a manufacturer from add[ing to] or strengthen[ing] a contraindication, warning, precaution, or adverse

reaction.” *Id.* at 882 (internal quotation marks omitted). In contrast, the warning advocated by Plaintiffs here was a “black box,” and FDA regulations *do* prohibit a manufacturer from giving that kind of warning without FDA approval. *See infra* Part II.C.1.

In addition, when the *Cartwright* court wrestled with the “difficult and very close” preemption question before it, 369 F. Supp. 2d at 881, it did not have the benefit of the guidance contained in an FDA rule issued in January 2006, which explains the preemptive effect of FDA approval and reiterates the FDA’s view that such approval precludes all state tort suits like this one. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, Final Rule, 71 FED. REG. 3922 (Jan. 24, 2006). The FDA’s preamble to this rule states that FDA drug labeling requirements are not a “floor” of minimum safety standards that manufacturers may supplement at will, thus rejecting the very premise of *Cartwright*:

“[The] FDA interprets the [Food Drug & Cosmetics Act] to establish ***both a ‘floor’ and a ‘ceiling,’*** such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.” 71 FED. REG. at 3935.

The FDA also reiterated that state tort suits asserting the inadequacy of FDA-approved prescription drug labeling “encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of FDA.” *Id.* These lawsuits necessarily conflict with the FDA’s interpretation of its own regulations and “frustrate the agency’s implementation of its statutory mandate.” *Id.* at 3934. Thus, it is the FDA’s unambiguous position that “under

existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.” *Id.* Because the FDA’s position makes clear that Plaintiffs’ liability claims in this case are precisely the type of “second-guessing” preempted by federal law, *id.*, the judgment should be reversed and a take-nothing judgment rendered for Wyeth.

B. The jury’s design-defect finding fails as a matter of law. Alternatively, Wyeth is at least entitled to a new trial because the jury’s finding that Pondimin was defectively designed fails in two respects.

1. No Defective Design Tort. “Texas law and [the RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965)]” do not “allow plaintiffs to sue for defective *design* of prescription drugs.” *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (emphasis added). Instead, “[d]efendants can only be held strictly liable” for defective *manufacturing* or *marketing* of prescription drugs—that is, “if the drug was not properly prepared or marketed or accompanied by proper warnings.” *Id.*⁷

Plaintiffs have not found a single case holding that Texas recognizes a design-defect cause of action for prescription drugs.⁸ Moreover, they have no response to the common-sense reasons why “many courts” have followed the Restatement’s Comment k and refused to allow such claims.⁹ As the Texas Supreme Court recognized in *Crocker v. Winthrop*

⁷ *Hackett* does not suggest, as Plaintiffs contend (at 22-23), that design defect claims can be maintained if a plaintiff also proves a marketing defect claim for complete failure to warn. Rather, it holds that defendants in cases involving prescription drugs can “*only* be held strictly liable” on a marketing or manufacturing defect theory, not a design defect theory. *Hackett*, 246 F. Supp. 2d at 595 (emphasis added). Based on this holding, the *Hackett* court granted partial summary judgment to defendants on the plaintiff’s design defect claim. It did not dismiss the plaintiff’s claim that defendants failed to warn his prescribing physician. *Id.* at 594.

⁸ See *Havner*, 953 S.W.2d at 708-09 (plaintiffs sued for negligence, defective design, and defective marketing, but appellate courts considered only causation, not addressing design defect); *Am. Cyanamid Co. v. Frankson*, 732 S.W.2d 648, 651, 656 (Tex. App.—Corpus Christi 1987, writ ref’d n.r.e.) (plaintiff sued for negligence and defective marketing and design, but appellate court considered only negligence and inadequate warning claims); *Madden v. Wyeth*, No. 3-03-CV-0167-BD, 2005 WL 2278081 (N.D. Tex. Sept. 14, 2005) (involving *non*-prescription drug ibuprofen).

⁹ *Hackett*, 246 F. Supp. 2d at 595 (citing cases); RESTATEMENT (SECOND) § 402A cmt. k. Plaintiffs’ cited case (at 23 n.14) merely observes that Virginia has taken a different approach. *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1114-15 (4th Cir. 1988).

Laboratories, 514 S.W.2d 429, 432 (Tex. 1974), prescription drugs “cannot be made perfectly safe to all users” and thus might be considered “defectively designed” under a traditional test. These drugs obviously have benefits for certain people, however, and their risks can be limited by giving proper, FDA-approved warnings to prescribing physicians. Thus, instead of permitting suits for defective design, courts only allow plaintiffs to sue for defective marketing of prescription drugs that have not been “made reasonably safe by being marketed with adequate warning[s].” *Id.* at 433. Accordingly, the jury’s finding that the prescription drug Pondimin was defectively designed cannot support the judgment.

2. *Failure to Submit All Elements.* If the Court holds that Texas does recognize a design-defect cause of action for prescription drugs, the jury must at least be properly charged on whatever elements are required. In states that recognize such causes of action under § 6(c) of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998), a plaintiff must prove that the drug’s foreseeable risks are sufficiently great in relation to its benefits that reasonable health-care providers would not prescribe it for *any* class of patients. *Wyeth Br. 31.* Alternatively, a plaintiff at least must prove a safer alternative design, as Texas courts minimally require in design-defect cases not involving prescription drugs. *Wyeth Br. 32; see also PJC § 71.4B (2003).* Over *Wyeth’s* objection, the court submitted the design-defect theory but refused to instruct about either of these requirements. *Wyeth Br. 32 (citing CR2615-20).*¹⁰

Plaintiffs do not dispute these requirements. Instead, they argue (at 24 n.15) that additional instructions were not necessary because both elements were supported by the evidence. This is not the law. Even if there were factually sufficient evidence of these two

¹⁰ *Wyeth* proffered evidence from two of Mrs. Coffey’s treating physicians that they prescribed other similar diet drugs for her, because her obesity made the risk of PPH the lesser of two evils, but the court erroneously excluded this evidence. *Wyeth Br. 80.*

elements, which Wyeth disputes (*see* Wyeth Br. 31-32), those elements cannot be deemed found in Plaintiffs' favor because Wyeth objected to their omission from the charge. Wyeth Br. 32; TEX. R. CIV. P. 279; *State Dep't of Highways & Pub. Transp. v. Payne*, 838 S.W.2d 235, 241 (Tex. 1992); *Winfield v. Renfro*, 821 S.W.2d 640, 657 (Tex. App.—Houston [1st Dist.] 1991, writ denied). Because the jury's design defect finding did not include these essential elements, that finding cannot support the judgment against Wyeth. *Id.*¹¹

The failure of Plaintiffs' design-defect claim means that Wyeth is entitled to a new trial. Because the trial court submitted only one set of damages questions for all three of Plaintiffs' claims, it is impossible to tell whether the jury based the damage awards in whole or part on its legally flawed finding of defective design. Accordingly, Wyeth is entitled to a new trial on all issues. Wyeth Br. 39; *see also Romero v. KPH Consolidation, Inc.*, 166 S.W.3d 212, 225-28, 230-31 (Tex. 2005) (new trial required when no evidence supported one of two claims jury considered in apportioning and awarding damages).

C. The jury's marketing-defect finding fails as a matter of law.

1. Availability of Adequate, FDA-Approved Warnings. Plaintiffs have no solution to the fatal flaw in their marketing defect claim: by the time Dr. Tyrell wrote Mrs. Coffey's third prescription (the one that would have put her in the "3 months or more" usage category found significant by the IPPHS), the supplemented 1997 PHYSICIANS' DESK REFERENCE and revised Pondimin label were out, and both contained what is *still* the most comprehensive information on the risks of PPH associated with Pondimin. Wyeth Br. 34.

That Wyeth did not send Dr. Tyrell his own personal "Dear Doctor" letter does not show that Dr. Tyrell was not adequately warned. Plaintiffs Br. at 25. There is no legal requirement that, to warn a "learned intermediary," a pharmaceutical company must send a

¹¹ *See also Clayton W. Williams, Jr., Inc. v. Olivo*, 952 S.W.2d 523, 529 (Tex. 1997); *Diamond Shamrock Ref. & Mktg. Co. v. Mendez*, 844 S.W.2d 198, 200 (Tex. 1992); *Physicians & Surgeons Gen. Hosp. v. Koblizek*, 752 S.W.2d 657, 660 (Tex. App.—Corpus Christi 1988, writ denied).

personal letter when the relevant warning is already in the current PHYSICIANS' DESK REFERENCE *and* drug label; Plaintiffs cite no authority for such a notion.

Indeed, it is precisely because a personal letter is not required to warn a learned intermediary that the trial court's repeated instruction about Dr. Tyrell's not having received one from Wyeth was so pernicious. *See infra* Part V.B.2. Implicit in that instruction was the assumption that Dr. Tyrell was not warned at all because he may not have received a personal letter. But the PHYSICIAN'S DESK REFERENCE is the principal source "learned" physicians consult for this purpose. Wyeth Br. 33.¹²

The gravamen of Plaintiffs' argument (at 8, 26-28) is that the PPH warning at the time of Dr. Tyrrell's third prescription was inadequate because it was not in a "black box." But only the FDA can determine whether a black-box warning is appropriate. 44 FED. REG. 37,434, 37,448 (June 26, 1979).¹³ Thus, the very warning Plaintiffs say was required was a warning that federal law prevented Wyeth from giving.

Indeed, the FDA recently restated and reinforced its position that federal law bars efforts by litigants to second-guess its judgment regarding the labeling of prescription drugs. The FDA's rule makes plain that the "determination whether labeling revisions are necessary is, in the end, *squarely and solely FDA's* under the act." 71 FED. REG. at 3934 (emphasis added). And here, despite critics' requests that the FDA require a black-box

¹² Further ensuring a one-sided presentation of evidence, the court permitted Plaintiffs to argue that Wyeth salesmen misled physicians, focusing on an internal sales memorandum about Redux. Plaintiffs Br. 9 (citing PX1319). Yet when Wyeth tried to call the memo's author to explain it to the jury, the court sustained Plaintiffs' objection to his testimony. 21RR73-75. Then, during closing, the court denied Wyeth's motion to strike after Plaintiffs' counsel argued as follows: "Instead [of putting a black box warning on Redux and Pondimin], they sent their sales force out into your community . . . to come in there and sing the song – which the memos have said we've got to get out there and start singing . . . if we're going to sell this Redux This is all benefit and no risk. That's what the witness testified to. . . . If that didn't happen, why didn't they bring the sales representative in here to say it didn't happen that way? Huh?" 26RR118-19.

¹³ The FDA recently reiterated that federal law preempts *all* state-law warnings claims based on a drug maker's alleged failure to "emphasize" information that nonetheless appears on the label. *See* 71 FED. REG. 3922, 3935-36 (Jan. 24, 2006). Thus, claims based on the absence of a black box warning (which Plaintiffs assert (at 8, 26-28) for the third prescription), and claims based on the listing of an adverse event in the "precautions" rather than "warnings" section (which Plaintiffs assert (at 7, 27) for the first two prescriptions) are preempted.

warning for Pondimin, the FDA approved the nature and placement of the Pondimin PPH warnings Wyeth provided and did not require a black-box warning. Wyeth Br. 29-30 & nn.11-12, 36-37 & n.16. Plaintiffs' contrary claims are precisely the type of "second-guessing" the FDA has condemned; thus, they are preempted as a matter of law.

Unable to respond to these arguments, which defeat their marketing defect claim, Plaintiffs try to confuse the issue by asserting (at 28) that it is "presumed" that if an "adequate" warning had been given, it would have been heeded. Plaintiffs cite no authority for the proposition that such a presumption is available in a pharmaceutical duty-to-warn case. This is not surprising because the duty to warn in such a case runs to the physician – the learned intermediary – not the direct consumer. Wyeth Br. 33. Nor would such a presumption make sense in prescription drug cases because the fact that a drug warning is "heeded" does not necessarily mean the drug is not taken: it just means the risks and benefits are considered and may still counsel in favor of using the drug.

Moreover, even if such a presumption existed, it is irrelevant here. The relevant Pondimin warning – the one before the third prescription – was adequate with respect to the potential risk of PPH because it contained what is still the most up to date information regarding those risks. Furthermore, any presumption was rebutted by evidence Wyeth proffered, but was barred from introducing: that Mrs. Coffey was warned of the fatal risk of PPH associated with diet drug use and yet chose to take such drugs anyway. Wyeth Br. 80.

Plaintiffs simply failed to meet their burden of proving that the warning was inadequate and that a different warning would have changed Dr. Tyrell's decision to prescribe Pondimin to Mrs. Coffey. Wyeth Br. 32-36.

2. No Duty to Warn About Irrelevant Risks. Plaintiffs claim (at 26) that Wyeth waived the argument that failure to warn Mrs. Coffey of the risk of valvular heart disease is

not actionable. That is false. Before, during, and after trial, Wyeth explained to the court that evidence regarding valvular heart disease – which Mrs. Coffey did not have – was irrelevant and unfairly prejudicial.¹⁴ The issue, presented in Wyeth’s opening brief (at 34-35), is thus squarely before this Court and should be resolved in Wyeth’s favor as a matter of Texas law. To decide whether warnings are adequate, the relevant consideration is whether those warnings sufficiently informed the prescribing doctor of the risk of the particular condition or disease that allegedly caused the plaintiff’s injury or death.¹⁵ That the Third Circuit in *dicta* suggested that such evidence may sometimes be admissible (*see* Plaintiffs Br. 26) does not change the fact that in this case, evidence of an alleged failure to warn Mrs. Coffey or her doctor about valvular heart disease, which she did not have, should never have been admitted. Such evidence was irrelevant to show the existence of a marketing defect that could be a producing cause of PPH and was unfairly prejudicial.

D. The negligence finding fails because it includes flawed theories. Plaintiffs’ negligence claim cannot support the judgment because it is functionally identical to their flawed design and marketing defect claims. They try to avoid this conclusion by listing several “areas” of allegedly negligent conduct (at 29-30), but those are simply part of the obligation to design and market products safely. *E.g.*, *Wood v. Phillips Petroleum Co.*, 119 S.W.3d 870, 873 (Tex. App.—Houston [14th Dist.] 2003, pet. denied) (duty to warn includes duty to “test and inspect” product and to “research” dangers involved in its use); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) (discussing when “seller or other distributor” is liable for defective design or marketing). Accordingly, a

¹⁴ 2RR66-74, 79-81 (before). 7RR108, 116-18; 10RR35-36, 45, 49, 51-53, 58-60, 138-39, 146, 150-51, 156, 159, 161, 164, 175-79, 185; 11RR25-27; 21RR48, 52, 56, 60-61; CXZ; *id.* at 35 & n.21 (during). CR3302-03 & n.6 (after).

¹⁵ *See* *Burton v. Am. Home Prods. Corp. (In re Norplant Contraceptive Prods. Liab. Litig.)*, 955 F. Supp. 700 (E.D. Tex. 1997), *aff’d*, 165 F.3d 374 (5th Cir. 1999). Consistently, in informed-consent cases, Texas courts reject the notion that an undisclosed risk is relevant when it is not the risk that caused a plaintiff’s injury. *E.g.*, *Greene v. Thiet*, 846 S.W.2d 26, *as modified*, 1993 Tex. App. LEXIS 551, *8 (Tex. App.—San Antonio Jan. 13, 1993, writ denied); *Jones v. Papp*, 782 S.W.2d 236, 241 (Tex. App.—Houston [14th Dist.] 1989, writ denied).

separate negligence claim should never have been submitted, and the jury's negligence finding fails along with its findings of design and marketing defects. Wyeth Br. 37-38.

Moreover, Plaintiffs' claim that this is the only ground on which Wyeth attacks the negligence claim is simply wrong. Even if the broad-form negligence finding is not based solely on theories of design and marketing, it is based at least *in part* on those theories. Wyeth Br. 38-39. Plaintiffs concede as much (at 29), noting that some conduct involved in their negligence claim was "design and marketing." Because Plaintiffs' theories of negligent design and marketing are based on the same alleged product defects as their strict-liability design and marketing claims, they fail for the same reasons.¹⁶

Despite Wyeth's objection (CR2585), the trial court submitted a broad-form negligence charge that included these invalid theories of negligent design and marketing. Because it is impossible to tell whether the jury answered the negligence question "yes" and awarded damages based on one or more of these invalid theories, Wyeth is at least entitled to a new trial. Wyeth Br. 38-39.

All three of Plaintiffs' liability theories are preempted and fail on the merits. Accordingly, this Court should reverse and render judgment in Wyeth's favor. Alternatively, if the Court determines that even one of Plaintiffs' liability theories is preempted or fails on the merits, Wyeth is entitled to a new trial.

III. The Jury Awarded Unproven and Unrecoverable Actual Damages.

A. There is insufficient evidence of compensatory damages beyond \$1.5 million. At trial, there was no legally or factually sufficient evidence of economic damages beyond \$1.5 million. Wyeth Br. 39-40. Indeed, in closing, Plaintiffs' counsel stipulated

¹⁶ Wyeth Br. 37; *see Toshiba Int'l Corp. v. Henry*, 152 S.W.3d 774, 785 (Tex. App.—Texarkana 2004, no pet.) ("Before a negligence theory can be utilized in a products liability case, there must be proof of a defect in the product. Because there is no defect for which Toshiba is responsible, it necessarily follows that the negligence theory cannot be upheld."); *Wood*, 119 S.W.3d at 873 n.6 ("[L]iability for failure to warn is imposed (like negligence liability) only for a failure to exercise reasonable care in discovering, and warning of, a danger.").

that “[t]he pecuniary loss with the death is \$1.5 million.” *Id.* at 40 (quoting 26RR227). Yet the jury awarded \$26,723,000 in “pecuniary” damages. Plaintiffs only response (at 31) is that a jury “can form its own opinion from other evidence and by use of its own experience and common knowledge.” But the fact that a jury need not leave “experience and common knowledge” at the door does not negate the more fundamental principle that jury findings must be supported by evidence. Plaintiffs cite no evidence to support the difference between the \$1.5 million in economic damages shown and the \$26.7 million awarded.

B. The jury charge improperly failed to segregate damage elements.

Plaintiffs admit (at 31) that “issues such as loss of advice, counsel, maintenance and support often defy mathematical calculation.” This proves Wyeth’s point that the definition of “pecuniary loss” in the jury charge commingled economic and non-economic elements. Plaintiffs maintain (at 32) that this was permissible because that definition of “pecuniary loss” was in accordance with the Pattern Jury Charge and *Moore v. Lillebo*, 722 S.W.2d 683, 687 (Tex. 1986). But after *Moore*, the Legislature changed the law by requiring that non-economic damages beyond \$750,000 be ignored when applying the punitive damages cap, thus making the distinction between economic and non-economic damages of substantive importance. TEX. CIV. PRAC. & REM. CODE ANN. (“CPRC”) § 41.008(b) (Vernon Supp. 2004-2005). As previously explained, this entitled Wyeth to a separate jury determination of economic damages, which the trial court (over Wyeth’s objection) improperly refused by commingling economic and non-economic damages in the charge. Wyeth Br. 54. Plaintiffs’ reliance on *Moore* is thus misplaced. This may indicate that the PJC is outdated, but any other view would prevent this Court from reviewing the jury’s non-economic damages awards or applying the punitive damages cap. *See Harris County v. Smith*, 96 S.W.3d 230, 232-34 (Tex. 2002); *Casteel*, 22 S.W.3d at 387-89.

C. There is insufficient evidence supporting the non-economic damages award. With respect to the jury’s award of \$86.63 million in other non-economic damages, Plaintiffs make no attempt to detail the record evidence that could ever support such a massive award. Rather, Plaintiffs baldly claim (at 32) that the jury’s verdict must be upheld because such damages are presumed in a wrongful death case, again citing *Moore*. Decided in 1986, *Moore* held that proof of a family relationship in a wrongful death case constitutes some evidence of the existence of compensable mental anguish, even if such anguish is not shown by a physical manifestation. 722 S.W.2d at 686. But ten years later, the Texas Supreme Court raised the standard, holding that “[n]ot only must there be evidence of the existence of compensable mental anguish, there must also be some evidence to justify the *amount* awarded.” *Saenz v. Fid. & Guar. Ins. Underwriters*, 925 S.W.2d 607, 614 (Tex. 1996) (emphasis added). Plaintiffs’ rhetorically ask (at 33), “[W]hat evidence could a survivor offer to support the ‘amount’ of mental anguish that she suffered for the loss of her mother?” That could be said about any case involving mental anguish. Plaintiffs’ question reflects their criticism of *Saenz*, but provides no basis for ignoring it.¹⁷ For these reasons, a new trial or substantial remittitur is required. *See* CR3434-35, 3437-42, 3460-67 (collecting Texas cases supporting remittitur).

D. Alternatively, the non-economic damages award is unconstitutional. If Plaintiffs somehow are right that a jury has unfettered discretion to award non-economic damages (1) in any amount it pleases, (2) unsupported by actual evidence, and (3) commingled with economic damages over objection, it just proves Wyeth’s point three

¹⁷ Plaintiffs claim (at 33) this Court cannot look to other cases for guidance, which contradicts this Court’s precedent. *See* Wyeth Br. 42 (citing *Moses v. Adams*, 428 S.W.2d 131, 134 (Tex. Civ. App.—Beaumont 1968, writ ref’d n.r.e.)). Plaintiffs also misstate (at 33 n.23) the record concerning the Coffeys’ marriage, claiming that the only relevant inquiry is whether Mr. Coffey was a surviving spouse because the Coffeys had a common-law marriage since 1990. But at trial, Plaintiffs presented no evidence that the Coffeys had a common-law marriage. The duration of their legal marriage thus bears on damages issues, and the trial court erred in excluding relevant evidence, such as the fact that they did not marry until May 2002, one month prior to suit. Wyeth Br. 42-43.

times over that the jury's non-economic damages awards were unconstitutional because they are incapable of meaningful appellate review. Wyeth Br. 43-44.

E. Wrongful death beneficiaries cannot recover pre-death damages.

Because death extinguishes common-law claims for damages, damages relating to the death are permitted only if allowed by statute. Wyeth Br. 44. For surviving family members, the wrongful death statute permits recovery only of damages “resulting from the death,” CPRC § 71.010(a) (Vernon 1997). This precludes third parties, including family members, from recovering for pre-death damages such as *their* emotional distress.

In response, Plaintiffs note (at 35) that the statute initially provides that “[a]n action for actual damages arising from an injury that causes an individual’s death may be brought if liability exists under this section.” *Id.* § 71.002(a). That is correct, but the statute then limits what the jury may award: “The jury may award damages in an amount proportionate to the injury *resulting from the death.*” *Id.* § 71.010(a) (emphasis added). Thus, wrongful death beneficiaries cannot recover damages for losses incurred *before* the decedent’s death, because those damages did not *result* from it. Plaintiffs’ argument may show that the more specific provision is more restrictive than the more general provision, but a fundamental principle of statutory construction is that the more specific provision controls. *See City of Arlington v. Whitaker*, 977 S.W.2d 742, 746 (Tex. App. – Fort Worth 1998, pet. denied).

IV. The Exemplary Damages Award Must Be Vacated or Massively Reduced.

A. The evidence does not support the malice finding under Question 4.

1. Objective Prong. The jury’s \$900 million exemplary damages award must be vacated because the purported evidence of the objective prong of malice is legally and factually insufficient. To recover exemplary damages, Plaintiffs had to prove by clear and convincing evidence that taking Pondimin involved “an extreme degree of risk” of

developing PPH, considering (i) “the probability and” (ii) the “magnitude of the potential harm to others.” 3AP2959; Wyeth Br. 45-46. Because this objective requirement is “a function of **both** the magnitude and the probability of the potential injury,” *Universal Servs. Co. v. Ung*, 904 S.W.2d 638, 641 (Tex. 1995) (emphasis added), “a remote possibility of serious injury” is **not** sufficient to meet it. *Qwest Int’l Commc’ns, Inc. v. AT&T Corp.*, 167 S.W.3d 324, 327 (Tex. 2005) (per curiam); *Transp. Ins. Co. v. Moriel*, 879 S.W.2d 10, 22 (Tex. 1994).

Plaintiffs’ brief (at 36) focuses only on the **magnitude** of the potential harm from PPH, arguing that a person who contracts the disease has a 100% chance of death or serious injury. Yet the same can be said of the decedent in *Ung*, who had a 100% chance of serious injury or death when struck by a trailer. 904 S.W.2d at 639. Indeed, “[i]n every . . . gross negligence case, some injury has allegedly occurred. But the magnitude of the injury may be entirely disproportionate to the riskiness of the behavior.” *Moriel*, 879 S.W.2d at 23 (emphasis added). Thus, even though the magnitude of harm in *Ung* was death, the Texas Supreme Court found no evidence of the objective prong of malice because the **probability** of harm was so low. 904 S.W.2d at 641. Here, Plaintiffs’ own experts conceded that the same is true of PPH, for even among diet drug users, the risk of developing it is less than 1/100th of one percent. Wyeth Br. 46. Plaintiffs have no response to *Ung* or this evidence. Accordingly, this Court should hold that Wyeth’s conduct in selling Pondimin did not, as a matter of law, create the extreme probability of risk required to show malice.

2. Subjective Prong. The trial court erroneously permitted Plaintiffs’ “expert” witnesses to testify about Wyeth’s subjective mental state and to speculate about whether it supported an award of exemplary damages. These opinions were the witnesses’ personal views of disputed facts taken from documents hand-picked by Plaintiffs’ counsel. The court

erred in admitting such evidence because it was not based on scientific, technical, or other specialized knowledge and because it was not founded upon any methodology – let alone one that was reliable and scientific. TEX. R. EVID. 702; Wyeth Br. 48-51. Plaintiffs’ claims (at 37-38) that malice may be proven by circumstantial evidence and that an expert may testify whether a proven set of facts meets the legal standard for malice are beside the point. At issue is whether an “expert” may be used to prove a corporation’s mental state by serving as a fact witness on disputed issues where he possesses neither personal knowledge nor expertise in “inferring malice” from non-personal sources of information. Allowing such proof disregards all requirements for expert testimony. Nor do Plaintiffs deny the obvious harm caused when the trial court let Plaintiffs’ “expert” testify about Wyeth’s state of mind and sponsor Plaintiffs’ disputed version of facts, but precluded Wyeth from offering rebuttal expert testimony from its own witness. 22RR81-82. This one-sided and unreliable method of litigating Wyeth’s subjective intent requires a new trial.

B. The Legislature’s cap on exemplary damages applies. Even if Plaintiffs had offered legally and factually sufficient evidence of malice, the exemplary damages awarded may not exceed the statutory cap.

1. Wrong Kind of “Writing.” Plaintiffs tried to lift the cap by contending that Wyeth committed a felony under TEXAS PENAL CODE § 32.47 (Vernon 2003) by fraudulently destroying a particular kind of writing. But the only types of writings whose destruction can be a felony under section § 32.47 are wills, codicils, deeds, mortgages, and other documents whose destruction would impair a property interest. Wyeth Br. at 58-60. This follows from the *ejusdem generis* canon of statutory construction, to which Plaintiffs have no response. Because Amy Myers’ overwriting did not involve such a writing, it was not a felony under § 32.47 and cannot trigger the cap-busting statute as a matter of law.

2. Failure to Obtain Findings on Intent and Causation. To invoke this cap exception, Plaintiffs had to prove that Wyeth “knowingly or intentionally” committed the felonious conduct, which the statute defines (in part) as destroying or altering a specified writing “*with intent to defraud or harm another.*” *Id.* (emphasis added). Plaintiffs also had to show that their “cause of action” and “recovery of exemplary damages” were “*based on*” the felonious conduct – *i.e.*, that the conduct caused their damages. CPRC § 41.008(c) (emphasis added). But both of these required elements were omitted from the charge, despite Wyeth’s objection, and neither is supported by the evidence. Wyeth Br. 55-58.

Plaintiffs respond (at 40) that they submitted the question as recommended by the Pattern Jury Charge Committee, but that is patently false. PJC § 110.37 (2003) asks the jury whether the defendant altered the writing at issue “with intent to defraud or harm another.” Further, the PJC comment observes that the question should be submitted only when “the harm to the plaintiff *resulted from* [the] conduct described as a felony.” (Emphasis added); *see* Wyeth Br. 45, 52-53, 55. These are precisely the elements that Plaintiffs failed to prove and that the court failed to include in the charge. As a result, the jury’s answer to Question 5 cannot support an award of exemplary damages in excess of \$2.29 million, a figure Plaintiffs otherwise do not dispute. Wyeth Br. 55-58.

Plaintiffs also argue (at 40) that including the words “knowingly or intentionally” in the charge was enough to meet the intent requirement. Plaintiffs misunderstand the difference between specific and general intent, however. The offense at issue here is *fraudulent* destruction of a writing, which requires that the defendant act not only with general intent to destroy a writing or knowledge that he is doing so, but also with a specific “intent to defraud or harm another.” *In re E.P.*, No. 03-04-00352-CV, 2006 WL 263582, at *1 (Tex. App.—Austin Feb. 2, 2006, no pet. h.). “This specific intent is a material fact in

the description of the offense that must be specifically alleged . . . and is not incorporated . . . by the allegations of the general culpable mental states of knowingly and intentionally.” *Ryan v. State*, 708 S.W.2d 577, 578 (Tex. App.—Houston [1st Dist.] 1986, pet. ref’d).¹⁸ Accordingly, to lift the cap, Plaintiffs had to prove and obtain a finding that Wyeth destroyed or altered documents “with intent to defraud or harm another.” Because they failed to do so, this Court should reform the judgment and apply the cap.

3. Failure to Segregate Exemplary Damages Based on Other Conduct. Over Wyeth’s objection, Plaintiffs failed to obtain a jury finding that segregated exemplary damages based on overwriting from those based on other allegedly malicious conduct. *Wyeth Br. 65-66* (citing CR2638-39). Plaintiffs’ response proves this was fundamental charge error, for they steadfastly claim (at 43) that the jury’s award of exemplary damages was based not only on overwriting, but also on other allegedly malicious conduct. None of the other alleged conduct fits any exception to the punitive damages cap, however. Thus, even if the jury’s answer to Question 5 could uncap exemplary damages “based on” Ms. Myers’ overwriting, the cap still would apply to all exemplary damages “based on” other allegedly malicious conduct. Because Plaintiffs’ failed to obtain the necessary jury finding segregating these amounts, the cap cannot be applied properly and a new trial is required. *Casteel*, 22 S.W.3d at 389.

C. Exemplary damages for Wyeth’s dealings with the FDA are preempted. Having no response to Wyeth’s preemption argument, Plaintiffs boldly claim (at 41) that Wyeth “cites no cases” to support it. But Plaintiffs know that is false, for in a footnote they cite *Buckman*, which makes plain that the comprehensive federal scheme of drug

¹⁸ See also, e.g., TEX. CODE CRIM. PROC. ANN. art. 21.05 (Vernon 1989); *Victory v. State*, 547 S.W.2d 1 (Tex. Crim. App. 1976); *Feeney v. State*, 124 S.W. 944, 946 (Tex. Crim. App. 1910); Michael B. Charlton, 6 TEXAS PRACTICE: TEXAS CRIMINAL LAW § 4.3, at 41 (2d ed. 2001); cf. *Jones v. State*, 571 S.W.2d 191, 193 (Tex. Crim. App. 1978) (allegation that “act was committed ‘with intent to defraud or harm another’ . . . is the essential mental element”).

regulation and the FDA's exclusive authority to enforce it preempt state claims based on fraudulent statements to the FDA. As already explained, *Buckman* establishes that federal law preempts state tort liability theories based on alleged mis-dealings with the FDA. See *supra* Part II.A.1; Wyeth Br. 29, 52.

Similarly, under *Buckman*, a state cannot punish a company for such alleged mis-dealings with criminal sanctions or exemplary damages. Wyeth Br. 64-66. Accordingly, a state certainly cannot use such conduct to *enhance* punitive damages. Here, however, it is undisputed that the *sole* predicate for the jury's cap-busting finding was Wyeth's alleged violation of a federal duty to maintain information for filing ADE reports with the FDA. Consequently, the jury's cap-busting finding is preempted and must be reversed. Further, because the trial court refused over Wyeth's objection to segregate exemplary damages based on Wyeth's alleged mis-dealings with the FDA from those based on other alleged conduct, it is impossible to determine what part of the exemplary damages award was based on these preempted arguments. Wyeth Br. 65-66. For that reason, the entire punitive damages award must be vacated and, at the very least, a new trial granted.

In response, Plaintiffs (at 41) cite *Cartwright*. But as discussed, *Cartwright* failed to address *Buckman*, did not involve allegations of fraud on the FDA, is distinguishable, and rests on a premise that the FDA recently repudiated. See *supra* Part II.A.2.¹⁹

V. Other Erroneous Rulings, Instructions, and Findings Require a New Trial.

A. The trial court erred by submitting an erroneous spoliation instruction and by finding that spoliation had occurred as a matter of law.

1. *No basis for spoliation instruction.* Before giving a spoliation instruction, the trial court had to make preliminary findings that: (1) Wyeth had a duty to preserve the

¹⁹ In any event, the exemplary damages cannot stand. They are excessive under *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), and rest on a factor barred by *State Farm*: Wyeth's wealth as derived from legitimate, out-of-state acts. Wyeth Br. 69-75.

adverse event computer records and the hard-copy files; (2) there was some evidence that Wyeth breached its duty by deliberately spoliating this evidence with an intent to conceal it; and (3) the spoliation prejudiced Plaintiffs' ability to present their case. Wyeth Br. 76-77. Plaintiffs do not dispute these required elements, and their brief fails to show all were met.

With respect to prejudice, for example, Plaintiffs misinterpret *Cresthaven Nursing Residence v. Freeman*, 134 S.W.3d 214 (Tex. App.—Amarillo 2003, no pet.), and *Whiteside v. Watson*, 12 S.W.3d 614 (Tex. App.—Eastland 2000, vacated by agr.). Plaintiffs cite these cases (at 45-46) for the unremarkable proposition that destruction of *original* documents can be prejudicial. But the computer records and hard-copy files allegedly spoliated here were *not* the originals. Plaintiffs do not dispute that those records and files merely contained information from Dr. Davis's original reports, which *were* admitted into evidence at trial. Wyeth Br. 10, 77-78. Because the jury received the same information from another source, *Cresthaven* and *Whiteside* hold that Plaintiffs' ability to present their case was *not* prejudiced by the alleged spoliation. See *Cresthaven*, 134 S.W.3d at 226-27 (no prejudice from recopying note where original unavailable but no evidence that information in copy was falsified); *Whiteside*, 12 S.W.3d at 622 (no prejudice where copy of destroyed report available and no testimony that copy had been altered); Wyeth Br. 78 n.47.

As to breach of a duty to preserve, Plaintiffs argue (at 45) that the computer records were destroyed and the hard-copy files "lost." But they point to no proof that the computer records were destroyed with an intent to conceal evidence or that the lost files actually were destroyed. Absent such proof, the spoliation presumption does not apply. Wyeth Br. 76-77; see also *Brewer v. Dowling*, 862 S.W.2d 156, 159 (Tex. App.—Fort Worth 1993, writ denied) (no right to ask jury to infer spoliation "where evidence is merely *lost*"). Because these elements were not satisfied, the trial court erred in submitting spoliation instructions

for the jury to consider.

2. *Erroneous Spoliation Instruction.* The court compounded its error by instructing the jury as a matter of law that spoliation *had* occurred, instead of allowing the jury to decide whether to believe Wyeth's contrary evidence. Wyeth Br. 78-79. Plaintiffs' only response is to argue (at 47) that the trial judge has discretion to determine the proper remedy for spoliation based on the particular facts of the case. But the authority cited by Plaintiffs (at 45) confirms that the trial court's two spoliation instructions were erroneous: if the judge chooses to give an instruction, it must accurately state the law and find support in the evidence. *Whiteside*, 12 S.W.3d at 621. A proper spoliation instruction states that the jury *may* apply the presumption *if* it finds that all disputed elements of spoliation have been met. Wyeth Br. 78-79. By instructing the jury instead that Wyeth "deliberate[ly] destr[oyed]" documents and that its conduct "*is* spoliation," 3AP2955 (emphasis added), the trial court wrongly took disputed factual issues from the jury and decided them in Plaintiffs' favor. Wyeth Br. 17, 61, 79 & n.48. Plaintiffs cite no authority for their false statement (at 46) that this instruction "followed the recommended structure."

Plaintiffs do not dispute that, if this Court agrees that the spoliation instructions were erroneous, the error was harmful. Wyeth Br. 79. Nor could they, as the instructions improperly directed a verdict against Wyeth on the punitive damages cap-busting question, exposing it to hundreds of millions of dollars of additional liability. *Id.* at 60-61. Plaintiffs' counsel also used these improper instructions to destroy Wyeth's credibility and tilt the jury, telling them in closing that the trial judge himself had decided that Wyeth deliberately destroyed documents. 26RR213-14. Thus, this Court should grant Wyeth a new trial.

B. The trial court's evidentiary errors tainted the verdict.

1. *Diet Drugs with PPH Warnings.* The trial court erroneously excluded evidence

that Mrs. Coffey took other diet drugs with PPH warnings, including Tenuate and Meridia, and instructed the jury that other diet drugs do not cause PPH. Wyeth Br. 80-81. This excluded evidence was relevant on two distinct issues: (1) whether Pondimin caused Mrs. Coffey's PPH and (2) whether Mrs. Coffey would have taken Pondimin if it had a different warning. In response, Plaintiffs assert (at 46-47) that the excluded evidence was irrelevant because these other diet drugs are not plausible causes of PPH. As to issue (1), Plaintiffs' assertion fails on the merits. *See supra* Part I.C.

As to issue (2), Plaintiffs' assertion is non-responsive. Mr. Coffey was allowed to tell the jury that his wife *never* would have taken any drug that warned of a risk of a potentially fatal disease. Wyeth Br. 80. Regardless of whether Tenuate and Meridia are plausible alternative causes of PPH, it is undisputed that (a) both carry FDA warnings of the potential risk of PPH; (b) Mrs. Coffey's doctors warned her of that potentially fatal risk; and (c) she decided to take them anyway. Wyeth Br. 80. Wyeth thus was entitled to rebut Mr. Coffey's testimony to defend against Plaintiffs' *warning* claim. The trial court committed harmful error by preventing Wyeth from informing the jury that Mrs. Coffey's doctors warned her of a potentially fatal risk with Tenuate and Meridia and that she decided to take them anyway. *Id.* Plaintiffs offer no response to this point because they have none.

2. "Dear Doctor" Letters. Plaintiffs make no response to Wyeth's argument that the trial court's repeated instructions to the effect that Dr. Tyrrell had not received any "Dear Doctor" letters were error. As Wyeth's opening brief explains (at 83), there is a substantial likelihood that these instructions erroneously led the jury to believe that (1) he had not received any updated Pondimin warnings from any source (despite Wyeth's proof that the Pondimin label and its various PDR entries had been updated to reflect the evolving results of the IPPHS before Dr. Tyrrell ever wrote Mrs. Coffey's second and third

prescriptions for Pondimin), and/or that (2) such letters are the only effective means to communicate warnings to doctors, which they are not.²⁰

C. The trial court biased the venire by eliminating jurors who believed that damages awards should have limits. In an attempt to hide the fact that they have no substantive response on this point, Plaintiffs resort to arguing (at 48) that Wyeth said the court’s exclusion of jurors “accords with current law.” Not so. Wyeth said the trial court’s exclusion of jurors who believed that damages awards should have limits *was error* because those jurors’ *beliefs* accord with current law. Wyeth Br. 83. The seating of jurors biased in favor of limitless and unlawful awards deprived Wyeth of a fair trial. That Plaintiffs must twist Wyeth’s words to respond reveals the lack of any justification for the deliberate biasing of the jury.

D. The post-trial pleading amendment was surprising and prejudicial as a matter of law. As to the post-trial pleading amendment allowing a massive increase in the ad damnum, Plaintiffs claim (at 48) that Wyeth failed to demonstrate prejudice below. But Wyeth made the same prejudice arguments in the trial court that it makes here, CR3039-44, and on the merits, Plaintiffs have no response to the principle that prejudice may be presumed from a shockingly large amendment. Nor do they dispute that the retrospective increase in Plaintiffs’ compensatory damages prayer threatened a disproportionate increase in the maximum amount of recoverable punitive damages, which is also facially prejudicial. Wyeth Br. 84. Plaintiffs’ amendment also was clearly “surprising” because they had previously represented that “in no event” would they seek compensatory or punitive damages beyond their then-current prayer. *Id.* The trial court also abused its

²⁰ And contrary to Plaintiffs’ claim (at 47), Wyeth cited evidence from which a jury could infer that Dr. Tyrrell learned about the “Dear Doctor” letter because it had been sent to a colleague in his office. *See* Wyeth Br. 8 (citing 12RR186-88, 195-206; 18RR42, 45-47; 22RR64-65; 25RR162); Wyeth Br. 82.

discretion in allowing the amendment because Plaintiffs did not identify any new evidence to justify the increase, which was their burden in seeking the amendment. *Id.*

E. The verdict was based on unfair passion and prejudice. Plaintiffs claim (at 49) that Wyeth waived any passion-and-prejudice argument by making no objection to Plaintiffs' closing. But no objection was required; the inflammatory rhetoric was incurable. *See Otis Elevator Co. v. Wood*, 436 S.W.2d 324, 333 (Tex. 1968). Nor did Wyeth limit its argument to Plaintiffs' closing. Rather, Wyeth cited numerous other errors (and their related objections) that contributed to the extraordinarily excessive verdict. Wyeth Br. 86.

Plaintiffs assert (at 49-50) that *Pope v. Moore*, 711 S.W.2d 622 (Tex. 1986), and *Torrington Co. v. Stutzman*, 46 S.W.3d 829, 851 (Tex. 2000), preclude relief if a verdict based on passion and prejudice is theoretically supported by factually sufficient evidence. But under *World Oil Co. v. Hicks*, 103 S.W.2d 962 (Tex. 1939), a verdict cannot stand if based on passion and prejudice. *Pope* and *Torrington* do not alter this principle or deprive the Court of the power to order a new trial; they just indicate that a court of appeals cannot *suggest a remittitur* under such circumstances. Indeed, in *Torrington*, the Texas Supreme Court considered whether a new trial was warranted under *World Oil*. The Court declined to grant a new trial, but only because that case did not satisfy *World Oil's* requirement that "a shockingly excessive verdict, and the record as a whole, leave no room for doubt that the minds of jurors were so controlled and dominated by passion and prejudice as made them incapable of, or entirely unwilling to consider a case on its merits." 103 S.W.3d at 964. This remains the standard for determining whether a new trial is warranted, and it is plainly satisfied here.

CONCLUSION

Wyeth prays for all relief sought in its opening brief.

Respectfully submitted,

MAYER, BROWN, ROWE & MAW LLP

Lawrence L. Germer
State Bar No. 07824000
GERMER GERTZ, LLP
550 Fannin
Beaumont, Texas 77701
(409) 650-6700
(409) 835-2115 (fax)

Marie Yeates
State Bar No. 22150700
VINSON & ELKINS L.L.P.
1001 Fannin Street, Suite 2300
Houston, Texas 77002
(713) 758-2222
(713) 615-5544 (fax)

FEBRUARY 22, 2006

Claudia Wilson Frost
State Bar No. 21671300
J. Brett Busby
State Bar No. 24031778
Jeremy J. Gaston
State Bar No. 24012685
700 Louisiana Street, Suite 3600
Houston, Texas 77002-2730
(713) 221-1651
(713) 224-6410 (fax)

ATTORNEYS FOR APPELLANT

CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2006 a true and correct copy of **REPLY BRIEF FOR APPELLANT** was properly forwarded to all counsel of record for Plaintiffs in accordance with Rule 9.5 of the Texas Rules of Appellate Procedure, by certified mail, return receipt requested, as follows:

David W. Holman
GODWIN PAPPAS LANGLEY RONQUILLO, LLP
5 Houston Center
1401 McKinney, Suite 2700
Houston, Texas 77010

O'QUINN, LAMINACK & PIRTLE
John O'Quinn
Richard N. Laminack
Thomas W. Pirtle
440 Louisiana Street, Suite 2300
Houston, TX 77002

Richard J. Clarkson
LAW OFFICE OF RICHARD J. CLARKSON
595 Orleans Street, Suite 500
Beaumont, Texas 77701

Gilbert T. Adams
Cherly A. Schultz
LAW OFFICES OF GILBERT T. ADAMS, P.C.
1855 Calder Avenue @ Third Street
P.O. Box 3688
Beaumont, Texas 77704

Joseph D. Deshotel
1310 Calvin Street
Beaumont, Texas 77701

Claudia Wilson Frost