

**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

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

IDENTITY OF PARTIES AND COUNSEL

Appellant/Defendant

Wyeth

Counsel for Appellant/Defendant

MAYER BROWN ROWE & MAW LLP

Claudia Wilson Frost

J. Brett Busby

Jeremy J. Gaston

700 Louisiana Street, Suite 3600

Houston, Texas 77002-2730

Telephone: (713) 221-1651

Fax: (713) 224-6410

(Appellate and Post-trial)

Philip Allen Lacovara

Sanford I. Weisburst

1675 Broadway

New York, New York 10019-5820

Telephone: (212) 506-2500

Fax: (212) 849-5585

(Appellate and Post-trial)

GERMER GERTZ, LLP

Lawrence L. Germer

550 Fannin

Beaumont, Texas 77701

Telephone: (409) 650-6700

Fax: (409) 835-2115

(Trial, Post-trial, and Appellate)

ARNOLD & PORTER LLP

Tim Atkeson

Matthew J. Douglas

370 Seventeenth Street, St. 4500

Denver, Colorado 80202

Telephone: (303) 863-1000

Fax: (303) 832-0428

(Trial)

VINSON & ELKINS LLP

Marie Yeates

Thad K. Jenks

Gwen Samora

Paul E. Stallings

1001 Fannin St., Suite 2300

Houston, Texas 77002

Telephone: (713) 758-2222

Fax: (713) 615-5544

(Trial, Post-trial, and Appellate)

William D. Sims, Jr.

2001 Ross Ave., Suite 3700

Dallas, Texas 75201

Telephone: (214) 220-7700

Fax: (214) 220-7716

(Trial)

Robbi Hull

2801 Via Fortuna, #100

Austin, Texas 78746

Telephone: (512) 542-8400

Fax: (512) 542-8612

(Trial and Post-trial)

CLARK, THOMAS & WINTERS, PC

Leslie A. Benitez

David C. Duggins

300 West 6th Street, Suite 1500

Austin, Texas 78701

Telephone: (512) 472-8800

Fax: (512) 474-1129

(Trial and Post-trial)

Steven G. Reade
555 Twelfth Street, N.W. (Room 769)
Washington, DC 20004
Telephone: (202) 942-5480
Fax: (202) 942-5999
(Post-trial)

HOPE & CAUSEY, P.C.
Ruben W. Hope, Jr.
Commonwealth Center, Suite 125
2040 Loop 336 West
Conroe, Texas 77305
Telephone: (936) 441-4673
Fax: (936) 941-4674
(Trial)

Appellees/Plaintiffs

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.

Counsel for Appellees/Plaintiffs

Richard J. Clarkson
595 Orleans Street, Suite 500
Beaumont, Texas 77701
(Appellate and Post-trial)

O'QUINN, LAMINACK & PIRTLE
John O'Quinn
Richard N. Laminack
Thomas W. Pirtle
Buffy K. Martines
Dana A. Morris
440 Louisiana Street, Suite 2300
Houston, Texas 77002
Telephone: (713) 236-4870
Fax: (713) 223-4870
(Trial and Post-trial)

Attorney Ad Litem for Minor Plaintiffs

Joseph D. Deshotel
1310 Calvin Street
Beaumont, Texas 77701
Telephone: (409) 838-1000

STATEMENT REGARDING ORAL ARGUMENT

Pursuant to Texas Rules of Appellate Procedure 39.1, Wyeth requests oral argument and submits that it would materially aid the decisional process in this case.

TABLE OF CONTENTS

IDENTITY OF PARTIES AND COUNSEL	i
STATEMENT REGARDING ORAL ARGUMENT	iii
INDEX OF AUTHORITIES	ix
RECORD REFERENCES	xxi
STATEMENT OF THE CASE	xxii
ISSUES PRESENTED.....	xxiv
INTRODUCTION.....	1
STATEMENT OF FACTS	1
A. Facts relating to Mrs. Coffey’s disease (PPH).	1
Mrs. Coffey’s medical history.....	1
Mrs. Coffey’s diet drug use.....	2
Mrs. Coffey’s death from PPH.....	2
Scientific study of relationship between PPH and diet drugs.....	3
Mrs. Coffey’s experience compared to the IPPHS results.....	4
The FDA’s role in drug approval, supervision, and labeling.....	5
PPH warnings about Pondimin.....	6
PPH warnings about other diet drugs Mrs. Coffey took.....	9
B. Irrelevant facts and prejudicial themes.....	9
Heart valve abnormalities reported with Redux and Pondimin.....	9
The Mayo/Fargo reports and Wyeth’s investigation.....	10
Overwriting as “spoliation.”.....	13
“Expert” testimony about Wyeth’s allegedly unethical conduct and fraud on the FDA.....	13
SUMMARY OF THE ARGUMENT	14
STANDARDS OF REVIEW.....	19
ARGUMENT	21
SECTION ONE: NO LIABILITY	21
I. Plaintiffs Failed to Prove That Pondimin Caused Mrs. Coffey’s PPH.....	21

A.	Mrs. Coffey was not similar to the people in the Plaintiffs’ studies.....	23
B.	Plaintiffs failed to rule out other plausible causes of Mrs. Coffey’s PPH.....	25
C.	SNAPH and the IPPHS do not meet <i>Havner’s</i> “foundational” reliability requirement.....	26
II.	The Liability Findings Cannot Support the Judgment.....	28
A.	The jury’s design defect finding fails as a matter of law.....	28
1.	Texas law does not recognize a claim for “defective design” of a prescription drug.....	28
2.	Federal law preempts any claim for defective design of a prescription drug.....	29
3.	Essential elements of Plaintiffs’ claim were not submitted to the jury and are unsupported by the evidence.....	31
B.	The jury’s marketing defect finding fails as a matter of law.....	32
1.	The finding fails under the learned intermediary doctrine.....	33
2.	Failure to warn of a risk that did not materialize is not actionable.....	34
3.	There is no evidence that a different warning would have changed Dr. Tyrrell’s decision to prescribe Pondimin.....	35
4.	Plaintiffs’ defective marketing claim is preempted by federal law.....	36
C.	Plaintiffs’ negligence claim fails because it is functionally identical to their flawed design and marketing defect claims.....	37
	SECTION TWO: ERRORS IN DAMAGES.....	39
III.	The Jury Awarded Unproven and Unrecoverable Actual Damages.....	39
A.	There is no legally or factually sufficient evidence of compensatory economic damages beyond \$1.5 million.....	39
B.	The jury charge improperly failed to segregate damage elements.....	40
C.	There was no legally or factually sufficient evidence to support the <i>amounts</i> of non-economic damages awarded.....	41
D.	Alternatively, the non-economic damages awards violate the Texas and United States Constitutions.....	43
E.	Wrongful death beneficiaries cannot recover pre-death damages.....	44
IV.	The Jury’s \$900 Million Exemplary Damage Award Must Be Vacated or, at a Minimum, Massively Reduced.....	45

A.	Plaintiffs cannot recover exemplary damages because the evidence does not support the jury’s “malice” finding in Question 4.....	45
1.	Objective component: no extreme risk of PPH.....	46
2.	Subjective component: no evidence that Wyeth was actually aware of, but consciously disregarded, any extreme degree of risk.....	47
3.	Plaintiffs’ “expert” testimony on Wyeth’s state of mind is not legally or factually sufficient to support the jury’s malice finding, and its erroneous admission independently requires a new trial.....	48
4.	No evidence that a Wyeth officer or manager committed a “malicious” act.....	51
5.	No evidence that Mrs. Coffey’s PPH “resulted from” malice.....	52
B.	The Legislature’s cap on exemplary damages applies.....	54
1.	Question 5 omitted causation and intent elements that are essential to disregarding the statutory cap, and there is no legally or factually sufficient evidence of those elements.....	55
2.	As a matter of law, Amy Myers’ conduct is not covered as a felony and thus cannot trigger the cap-busting statute.....	58
3.	The trial court’s spoliation instruction tainted the jury’s verdict against Wyeth on the cap-busting issue.....	60
4.	At a minimum, a new trial is required because of omissions and/or defects in Question 5 concerning grounds for “busting” the cap.....	62
5.	Even as erroneously submitted, there was no legally or factually sufficient evidence to support the jury’s answer to Question 5.....	63
C.	All exemplary damages based on Wyeth’s dealings with the FDA are preempted by federal law.....	64
1.	The cap-busting finding must be disregarded because it was based entirely upon conduct within the FDA’s exclusive enforcement authority.....	64
2.	The remainder of the exemplary award must be set aside because it was based in part upon Wyeth’s alleged misdealings with the FDA.....	65
D.	The \$900 million award of exemplary damages in response to Questions 12, 14, and 15 cannot stand because these questions were erroneous and impermissibly duplicative.....	66
E.	The \$900 million exemplary damages award violates Texas common law because it is excessive.....	68

F.	Under Federal and Texas constitutional standards, the \$900 million exemplary damages award is grossly excessive and must be reduced substantially as a matter of law.	69
1.	The ratio of exemplary to compensatory damages is excessive.....	70
2.	The jury’s award is grossly disproportionate to analogous penalties and exemplary damage awards.	72
3.	Wyeth’s level of culpability does not justify the award.....	73
4.	The Federal Constitution prohibited the jury from using Wyeth’s out-of-state conduct or wealth as a basis for its exemplary damage award.....	74
	SECTION THREE: TRIAL ERRORS.....	75
V.	Other Erroneous Rulings, Instructions, and Findings Require a New Trial.	75
A.	The trial court erred by submitting a spoliation instruction and by finding that spoliation had occurred as a matter of law.	75
B.	The trial court’s evidentiary errors tainted the verdict.....	80
1.	The trial court erroneously excluded evidence that Mrs. Coffey took other diet drugs with PPH warnings.	80
2.	The trial court unfairly biased the jury on the issues of causation and safer alternative design by its rulings and instructions regarding the other diet drugs taken by Mrs. Coffey.....	80
3.	The trial court erroneously excluded evidence about Meridia.....	81
4.	The trial court repeatedly and erroneously instructed the jury that Dr. Tyrrell had not received Wyeth’s “Dear Doctor” letters.	82
C.	The trial court biased the venire by eliminating qualified jurors.	83
D.	It was error to allow Plaintiffs’ post-trial pleading amendment, which was surprising and prejudicial as a matter of law.	84
E.	The jury’s awards of non-economic and exemplary damages reflect a verdict based on unfair passion and prejudice.	85
	CONCLUSION AND PRAYER.....	87
	CERTIFICATE OF SERVICE	
	APPENDIX	
	Plaintiffs’ Fifth Amended Petition (CR616-36).....	Tab 1
	Plaintiffs’ Sixth Amended Petition (CR2238-57).....	Tab 2
	Jury Charge & Verdict (CR2952-77).....	Tab 3

Court’s Order on Plaintiffs’ Motion to Amend (CR3101-02).....	Tab 4
Final Judgment (CR3103-09).....	Tab 5
1997 PDR & Supplement A for Pondimin (DX939)	Tab 6
January 1997 “Dear Doctor” Letter for Pondimin (DX858).....	Tab 7
Post- <i>BMW</i> Decisions Upholding Challenged Punitive Damages Awards (CR3653-54)	Tab 8

INDEX OF AUTHORITIES

Cases

<i>Acord v. Gen. Motors Corp.</i> , 669 S.W.2d 111 (Tex. 1984).....	83
<i>Advocat, Inc. v. Sauer</i> , 111 S.W.3d 346 (Ark.), <i>cert. denied</i> , 540 U.S. 1004 (2003).....	73
<i>Alamo Nat’l Bank v. Kraus</i> , 616 S.W.2d 908 (Tex. 1981).....	68
<i>Am. Tobacco Co. v. Grinnell</i> , 951 S.W.2d 420 (Tex. 1997).....	38
<i>Aragon v. Wyeth-Ayerst Labs. Div. of Am. Home Prods. Corp.</i> , No. D-0101-200001387 (N.M. 1st Dist. Ct. Jan. 7, 2003)	51
<i>Austin v. Kerr-McGee Ref. Corp.</i> , 25 S.W.3d 280 (Tex. App.—Texarkana 2000, no pet.).....	26
<i>BMW of N. Am., Inc. v. Gore</i> , 517 U.S. 559 (1996).....	69, 72, 73, 75, 85
<i>Bentley v. Bunton</i> , 94 S.W.3d 561 (Tex. 2002).....	15, 41-43
<i>Best Steel Bldgs., Inc. v. Hardin</i> , 553 S.W.2d 122 (Tex. Civ. App.—Tyler 1977, writ ref’d n.r.e.).....	42
<i>Birchfield v. Texarkana Mem’l Hosp.</i> , 747 S.W.2d 361 (Tex. 1987).....	67
<i>Boerner v. Brown & Williamson Tobacco Co.</i> , 394 F.3d 594 (8th Cir. 2005)	73
<i>Bouchard v. Am. Home Prods. Corp.</i> , No. 3:98-CV-7541, 2002 WL 32597992 (N.D. Ohio May 24, 2002)	51
<i>Brewer v. Dowling</i> , 862 S.W.2d 156 (Tex. App.—Fort Worth 1993, writ denied).....	78
<i>Broders v. Heise</i> , 924 S.W.2d 148 (Tex. 1996).....	21, 50

<i>Brooks v. Howmedica, Inc.</i> , 273 F.3d 785 (8th Cir. 2001)	37, 38
<i>Brumfield v. Exxon Corp.</i> , 63 S.W.3d 912 (Tex. App.—Houston [14th Dist.] 2002, pet. denied)	78
<i>Buckman Co. v. Plaintiffs’ Legal Comm.</i> , 531 U.S. 341 (2001)	29, 52, 64, 65
<i>Bunton v. Bentley</i> , 153 S.W.3d 50 (Tex. 2004) (per curiam)	68
<i>Burton v. Am. Home Prods. Corp. (In re Norplant Contraceptive Prods. Liab. Litig.)</i> , 955 F. Supp. 700 (E.D. Tex. 1997), <i>aff’d</i> , 165 F.3d 374 (5th Cir. 1999)	33, 35
<i>In re C.H.</i> , 89 S.W.3d 17 (Tex. 2002)	20
<i>Capital One Bank v. Rollins</i> , 106 S.W.3d 286 (Tex. App.—Houston [1st Dist.] 2003, no pet.)	76
<i>City of Brownsville v. Alvarado</i> , 897 S.W.2d 750 (Tex. 1995)	21
<i>City of Euless v. Dallas/Fort Worth Int’l Airport Bd.</i> , 936 S.W.2d 699 (Tex. App.—Dallas 1996, writ denied)	19
<i>City of Pearland v. Alexander</i> , 483 S.W.2d 244 (Tex. 1972)	20
<i>City of San Antonio v. Rodriguez</i> , 931 S.W.2d 535 (Tex. 1996) (per curiam)	61, 83
<i>Coastal Transp. Co. v. Crown Cent. Petroleum Corp.</i> , 136 S.W.3d 227 (Tex. 2004)	49
<i>Cooper Indus., Inc. v. Leatherman Tool Group, Inc.</i> , 532 U.S. 424 (2001)	19, 70
<i>Cresthaven Nursing Residence v. Freeman</i> , 134 S.W.3d 214 (Tex. App.—Amarillo 2003, no pet.)	79
<i>Crocker v. Winthrop Labs.</i> , 514 S.W.2d 429 (Tex. 1974)	29

<i>Crown Life Ins. Co. v. Casteel</i> , 22 S.W.3d 378 (Tex. 2000).....	39, 52, 66
<i>Cuellar v. State</i> , 70 S.W.3d 815 (Tex. Crim. App. 2002).....	59
<i>Dallas Ry. & Terminal Co. v. Farnsworth</i> , 227 S.W.2d 1017 (Tex. 1950).....	85
<i>Daubert v. Merrell Dow Pharms., Inc.</i> , 43 F.3d 1311 (9th Cir. 1995)	50
<i>Dawkins v. Meyer</i> , 825 S.W.2d 444 (Tex. 1992) (orig. proceeding).....	59
<i>In re Humphreys</i> , 880 S.W.2d 402 (Tex. 1994).....	19
<i>Dempsey v. Beaumont Hosp., Inc.</i> , 38 S.W.3d 287 (Tex. App.—Beaumont 2001, pet. dism'd by agr.)	83
<i>Diamond Shamrock Ref. Co. v. Hall</i> , 48 TEX. SUP. CT. J. 354, 2005 WL 119950 (Jan. 21, 2005)	48
<i>In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine)</i> <i>Prods. Liab. Litig.</i> , No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000)	50
<i>In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine)</i> <i>Prods. Liab. Litig.</i> , No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001)	49-50
<i>E.I. du Pont de Nemours & Co. v. Robinson</i> , 923 S.W.2d 549 (Tex. 1995).....	22, 26, 27
<i>Elbaor v. Smith</i> , 845 S.W.2d 240 (Tex. 1992).....	20
<i>Exxon Corp. v. Perez</i> , 842 S.W.2d 629 (Tex. 1992) (per curiam).....	21
<i>First Am. Title Ins. Co. v. Willard</i> , 949 S.W.2d 342 (Tex. App.—Tyler 1997, writ denied).....	46
<i>Flynn v. Am. Home Prods. Corp.</i> , 627 N.W.2d 342 (Minn. Ct. App. 2001).....	29, 64

<i>Ford Motor Co. v. Durrill</i> , 714 S.W.2d 329 (Tex. App.—Corpus Christi 1986), <i>vacated by agr.</i> , 754 S.W.2d 646 (Tex. 1988).....	86
<i>Ford Motor Co. v. Miles</i> , 141 S.W.3d 309 (Tex. App.—Dallas 2004, pet. filed)	37, 38
<i>Formosa Plastics Corp. USA v. Presidio Eng’rs & Contractors, Inc.</i> , 960 S.W.2d 41 (Tex. 1998).....	40
<i>GTE S.W., Inc. v. Bruce</i> , 998 S.W.2d 605 (Tex. 1999).....	49
<i>Gammill v. Jack Williams Chevrolet, Inc.</i> , 972 S.W.2d 713 (Tex. 1998).....	27
<i>Gen. Motors Corp. v. Saenz</i> , 873 S.W.2d 353 (Tex. 1993).....	21, 22
<i>Gray v. Allen</i> , 41 S.W.3d 330 (Tex. App.—Fort Worth 2001, no pet.).....	40
<i>Green Tree Fin. Corp. v. Garcia</i> , 988 S.W.2d 776 (Tex. App.—San Antonio 1999, no pet.).....	46, 53, 66, 67, 68
<i>Greenhalgh v. Serv. Lloyds Ins. Co.</i> , 787 S.W.2d 938 (Tex. 1990).....	84
<i>Guerra v. Wal-Mart Stores, Inc.</i> , 943 S.W.2d 56 (Tex. App.—San Antonio 1997, writ denied)	21
<i>Hackett v. G.D. Searle & Co.</i> , 246 F. Supp. 2d 591 (W.D. Tex. 2002).....	28, 29
<i>Hammerly Oaks, Inc., v. Edwards</i> , 958 S.W.2d 387 (Tex. 1997).....	51, 63
<i>Harris v. Harris</i> , 765 S.W.2d 798 (Tex. App.—Houston [14th Dist.] 1989, writ denied)	20
<i>Harris County v. Smith</i> , 96 S.W.3d 230 (Tex. 2002).....	38, 39, 41, 56
<i>Hart v. Moore</i> , 952 S.W.2d 90 (Tex. App.—Amarillo 1997, pet. denied).....	67

<i>Heckler v. Chaney</i> , 470 U.S. 821 (1985).....	64
<i>Helena Chem. Co. v. Wilkins</i> , 47 S.W.3d 486 (Tex. 2001).....	21
<i>Hernandez v. Braddock</i> , 641 S.W.2d 359 (Tex. App.—Corpus Christi 1982, no writ).....	86
<i>Hilco Elec. Coop. v. Midlothian Butane Gas Co.</i> , 111 S.W.3d 75 (Tex. 2003).....	59
<i>Honda Motor Co. v. Oberg</i> , 512 U.S. 415 (1994).....	75
<i>Horizon/CMS Healthcare Corp. v. Auld</i> , 34 S.W.3d 887 (Tex. 2000).....	15, 21, 44
<i>Humble Sand & Gravel, Inc. v. Gomez</i> , 146 S.W.3d 170 (Tex. 2004).....	31
<i>In re Humphreys</i> , 880 S.W.2d 402 (Tex. 1994).....	19
<i>Huynh v. R. Warehousing & Port Servs., Inc.</i> , 973 S.W.2d 375 (Tex. App.—Tyler 1998, no pet.)	46
<i>Hyundai Motor Co. v. Rodriguez</i> , 995 S.W.2d 661 (Tex. 1999).....	37, 38
<i>In re J.W.T.</i> , 872 S.W.2d 189 (Tex. 1994).....	70
<i>K-Mart Corp. v. Martinez</i> , 761 S.W.2d 522 (Tex. App.—Corpus Christi 1988, writ denied)	67
<i>La.-Pac. Corp. v. Andrade</i> , 19 S.W.3d 245 (Tex. 1999).....	48
<i>Lee Lewis Constr., Inc. v. Harrison</i> , 64 S.W.3d 1 (Tex. App.—Amarillo 1999), <i>aff'd</i> , 70 S.W.3d 778 (Tex. 2001).....	42
<i>Lincoln v. Case</i> , 340 F.3d 283 (5th Cir. 2003)	72

<i>Linden-Alimak, Inc. v. McDonald</i> , 745 S.W.2d 82 (Tex. App.—Fort Worth 1988, writ denied).....	61, 83
<i>Lively v. Blackwell</i> , 51 S.W.3d 637 (Tex. App.—Tyler 2001, pet. denied)	79
<i>Lopez v. Am. Home Prods. Corp.</i> , No. 99-07-37723-CV (Tex. 79th Dist. Ct. Mar. 12, 2001), <i>appeal dismissed per curiam</i> , 2001 WL 1479263 (Tex. App.—San Antonio Nov. 21, 2001, no pet.)	51
<i>Loredo v. State</i> , 47 S.W.3d 55 (Tex. App.—Houston [14th Dist.] 2001, pet. dismissed).....	59
<i>Love v. CF & H Corp.</i> , 89 S.W.3d 68 (Tex. App.—El Paso 2002, pet. denied).....	42
<i>Mancorp, Inc. v. Culpepper</i> , 802 S.W.2d 226 (Tex. 1990).....	20
<i>Maritime Overseas Corp. v. Ellis</i> , 971 S.W.2d 402 (Tex. 1998).....	20
<i>Martin v. Telectronics Pacing Sys., Inc.</i> , 105 F.3d 1090 (6th Cir. 1997)	30-31, 37
<i>Meek v. Bishop, Peterson & Sharp, P.C.</i> , 919 S.W.2d 805 (Tex. App.—Houston [14th Dist.] 1996, writ denied)	79
<i>Mercy Hosp. v. Rios</i> , 776 S.W.2d 626 (Tex. App.—San Antonio 1989, writ denied)	41
<i>Merrell Dow Pharms., Inc. v. Havner</i> , 953 S.W.2d 706 (Tex. 1997).....	15, 22-27
<i>Metabolife Int'l, Inc. v. Wornick</i> , 72 F. Supp. 2d 1160 (S.D. Cal. 1999), <i>aff'd in part, rev'd in part</i> , 264 F.3d 832 (9th Cir. 2001)	50
<i>Minn. Mining & Mfg. Co. v. Nishika Ltd.</i> , 953 S.W.2d 733 (Tex. 1997).....	41
<i>Mitchell v. Collagen Corp.</i> , 126 F.3d 902 (7th Cir. 1997)	31, 38
<i>Moses v. Adams</i> , 428 S.W.2d 131 (Tex. Civ. App.—Beaumont 1968, writ refused n.r.e.)	42

<i>Murray v. State</i> , 21 Tex. App. 620 (1886)	59
<i>N. Am. Van Lines, Inc. v. Emmons</i> , 50 S.W.3d 103 (Tex. App.—Beaumont 2001, pet. denied).....	45
<i>In re Norplant Contraceptive Prods. Liab. Litig.</i> , No. MDL 1038, 1997 WL 81094 (E.D. Tex. Feb. 21, 1997)	34
<i>Nova Gulf Corp. v. Fidinam Res., Inc.</i> , 821 S.W.2d 729 (Tex. App.—Houston [14th Dist.] 1991, writ denied)	84
<i>Offshore Pipelines, Inc. v. Schooley</i> , 984 S.W.2d 654 (Tex. App.—Houston [1st Dist.] 1998, no pet.)	76
<i>Ordonez v. M.W. McCurdy & Co.</i> , 984 S.W.2d 264 (Tex. App.—Houston [1st Dist.] 1998, no pet.)	77
<i>Owens-Corning Fiberglas Corp. v. Malone</i> , 972 S.W.2d 35 (Tex. 1998).....	67, 75
<i>Pennington v. Singleton</i> , 606 S.W.2d 682 (Tex. 1980).....	70
<i>Perez v. State</i> , 11 S.W.3d 218 (Tex. Crim. App. 2000) (en banc).....	59
<i>Placencio v. Allied Indus. Int’l, Inc.</i> , 724 S.W.2d 20 (Tex. 1987).....	20
<i>Pope v. Moore</i> , 711 S.W.2d 622 (Tex. 1986).....	40
<i>R&R Contractors v. Torres</i> , 88 S.W.3d 685 (Tex. App.—Corpus Christi 2002, no pet.)	62
<i>Redman v. John D. Brush & Co.</i> , 111 F.3d 1174 (4th Cir. 1997)	50
<i>Robinson v. Warner-Lambert Co.</i> , 998 S.W.2d 407 (Tex. App.—Waco 1999, no pet.)	50
<i>Romo v. Ford Motor Co.</i> , 6 Cal. Rptr. 3d 793 (Cal. Ct. App. 2003).....	73

<i>Russell v. Ingersoll-Rand Co.</i> , 841 S.W.2d 343 (Tex. 1992).....	44
<i>Saenz v. Fid. & Guar. Ins. Underwriters</i> , 925 S.W.2d 607 (Tex. 1996).....	15, 41
<i>San Antonio Credit Union v. O’Connor</i> , 115 S.W.3d 82 (Tex. App.—San Antonio 2003, pet. denied).....	39
<i>San Antonio Press, Inc. v. Custom Bilt Mach.</i> , 852 S.W.2d 64 (Tex. App.—San Antonio 1993, no writ).....	77
<i>Schindler Elevator Corp. v. Anderson</i> , 78 S.W.3d 392 (Tex. App.—Houston [14th Dist.] 2001, pet. granted, judgment vacated).....	43
<i>Signal Peak Enters. of Tex., Inc. v. Bettina Invs., Inc.</i> , 138 S.W.3d 915 (Tex. App.—Dallas 2004, pet. stricken).....	54, 58
<i>Spencer v. Eagle Star Ins. Co.</i> , 876 S.W.2d 154 (Tex. 1994).....	32, 58
<i>State v. Gonzalez</i> , 82 S.W.3d 322 (Tex. 2002).....	17, 76
<i>State Bar v. Kilpatrick</i> , 874 S.W.2d 656 (Tex. 1994) (per curiam).....	21
<i>State Dep’t of Highways & Pub. Transp. v. Payne</i> , 838 S.W.2d 235 (Tex. 1992).....	20, 58
<i>State Employees Workers’ Comp. Div. v. Evans</i> , 889 S.W.2d 266 (Tex. 1994).....	21
<i>State Farm Lloyds v. Nicolau</i> , 951 S.W.2d 444 (Tex. 1997).....	21
<i>State Farm Mut. Auto. Ins. Co. v. Campbell</i> , 538 U.S. 408 (2003).....	16, 46, 60, 67, 69-75, 85
<i>State Farm Mut. Auto. Ins. Co. v. Zubiarte</i> , 808 S.W.2d 590 (Tex. App.—El Paso 1991, writ denied).....	70
<i>Steak & Ale of Tex., Inc. v. Borneman</i> , 62 S.W.3d 898 (Tex. App.—Fort Worth 2001, no pet.).....	67

<i>Stewart v. Janssen Pharmaceutica, Inc.</i> , 780 S.W.2d 910 (Tex. App.—El Paso 1989, writ denied)	35
<i>S.W. Bell Tel. Co. v. Garza</i> , 48 TEX. SUP. CT. J. 226, 2004 WL 3019205 (Dec. 31, 2004)	20, 47
<i>Technical Chem. Co. v. Jacobs</i> , 480 S.W.2d 602 (Tex. 1972).....	34
<i>Tex. Farmers Ins. Co. v. Soriano</i> , 844 S.W.2d 808 (Tex. App.—San Antonio 1992), <i>rev'd on other grounds</i> , 881 S.W.2d 312 (Tex. 1994).....	68
<i>Texaco, Inc. v. Pennzoil Co.</i> , 729 S.W.2d 768 (Tex. App.—Houston [1st Dist.] 1987, writ ref'd n.r.e.).....	69
<i>Thomas v. State</i> , 3 S.W.3d 89 (Tex. App.—Dallas 1999), <i>aff'd</i> , 65 S.W.3d 38 (Tex. Crim. App. 2001).....	59
<i>Tractebel Energy Mktg., Inc. v. E.I. DuPont De Nemours & Co.</i> , 118 S.W.3d 929 (Tex. App.—Houston [14th Dist.] 2003, no pet.).....	62
<i>Transp. Ins. Co. v. Moriel</i> , 879 S.W.2d 10 (Tex. 1994).....	15, 16, 45, 47
<i>Trevino v. Ortega</i> , 969 S.W.2d 950 (Tex. 1998).....	76, 78
<i>Uniroyal Goodrich Tire Co. v. Martinez</i> , 977 S.W.2d 328 (Tex. 1998).....	32
<i>United States v. Lanier</i> , 520 U.S. 259 (1997).....	59
<i>Universal Servs. Co. v. Ung</i> , 904 S.W.2d 638 (Tex. 1995).....	16, 46, 47
<i>Wal-Mart Stores, Inc. v. Johnson</i> , 106 S.W.3d 718 (Tex. 2003).....	17, 79
<i>Wells v. Dallas I.S.D.</i> , 793 F.2d 679 (5th Cir. 1986)	87
<i>Whiteside v. Watson</i> , 12 S.W.3d 614 (Tex. App.—Eastland 2000, vacated by agr.).....	79

<i>World Oil Co. v. Hicks</i> , 103 S.W.2d 962 (Tex. 1937).....	87
<i>Worthy v. Collagen Corp.</i> , 967 S.W.2d 360 (Tex. 1998).....	30
<i>Wyeth-Ayerst Labs. Co. v. Medrano</i> , 28 S.W.3d 87 (Tex. App.—Texarkana 2000, no pet.).....	33, 35

Constitutions

U.S. CONST. art. VI, cl. 2.....	29
U.S. CONST. amend. V.....	43
U.S. CONST. amend. VII.....	43
U.S. CONST. amend. XIV, § 1.....	43
TEX. CONST. art. I, § 13.....	70
TEX. CONST. art. I, § 15.....	43, 84
TEX. CONST. art. I, § 19.....	43, 70, 85
TEX. CONST. art. V, § 10.....	43, 84

Statutes and Rules

21 C.F.R. pt. 201.....	6, 36
21 C.F.R. § 314.70.....	36
21 U.S.C. § 331.....	64, 72
21 U.S.C. § 332.....	64
21 U.S.C. § 333.....	64, 72
21 U.S.C. § 334.....	64
21 U.S.C. § 337.....	64
21 U.S.C. § 355.....	5, 29, 36, 64

21 U.S.C. § 393	29
TEX. CIV. PRAC. & REM. CODE ANN. § 41.001(3) (Vernon 1994 & Supp. 1995).....	69
TEX. CIV. PRAC. & REM. CODE ANN. § 41.001 (Vernon 1997 & Supp. 2004-2005)	41, 45, 69
TEX. CIV. PRAC. & REM. CODE ANN. § 41.003 (Vernon Supp. 2004-2005)	45, 46, 62, 67
TEX. CIV. PRAC. & REM. CODE ANN. § 41.008 (Vernon 1997 & Supp. 2004-2005)	xxvi, 54, 55, 57, 58, 64, 67, 87
TEX. CIV. PRAC. & REM. CODE ANN. § 41.011 (Vernon 1997).....	67, 69
TEX. CIV. PRAC. & REM. CODE ANN. § 71.010 (Vernon 1997).....	44
TEX. CIV. PRAC. & REM. CODE ANN. § 71.021 (Vernon 1997).....	44-45
TEX. PEN. CODE ANN. § 1.04 (Vernon 2003)	60
TEX. PEN. CODE ANN. § 2.01 (Vernon 2003).....	62
TEX. PEN. CODE ANN. § 7.22 (Vernon 2003)	63
TEX. PEN. CODE ANN. § 32.47 (Vernon 2003).....	54, 56, 58-61, 64
TEX. R. APP. P. 9.5.....	89
TEX. R. APP. P. 39.1	iii
TEX. R. APP. P. 44.1(a)(1), (2).....	21
TEX. R. CIV. P. 274	32
TEX. R. CIV. P. 277.....	61, 83
TEX. R. EVID. 702.....	49

Other Authorities

Michael B. Charlton, 6 TEXAS PRACTICE: TEXAS CRIMINAL LAW § 19.12
(2d ed. 2001) 58

William V. Dorsaneo, III, 2 TEX. LITIG. GUIDE § 20.01 (2003) 69

Lisa K. Gregory, *Plaintiff’s Rights to Punitive or Multiple Damages When Cause
of Action Renders Both Available*, 2 A.L.R.5th 449 (1992) 67

Hon. Paul V. Niemeyer, *Awards for Pain and Suffering:
The Irrational Centerpiece of Our Tort System*, 90 VA. L. REV. 1401 (2004) 44

RESTATEMENT (SECOND) OF TORTS § 402A (1965)..... 28, 32

RESTATEMENT (SECOND) OF TORTS § 908 (1979)..... 72

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) 32, 38

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c), (d) (1998)..... 31, 32

RECORD REFERENCES

The clerk's record is cited "CR__," where the blank refers to the page number.

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.

Items in the appendix to this Brief are cited "__AP__," where the first blank refers to the appendix tab number and the second blank refers to the page number of the item.

TO THE HONORABLE NINTH COURT OF APPEALS:

STATEMENT OF THE CASE

Nature of the Case: This is a pharmaceutical products liability case in which the jury awarded over one *billion* dollars in damages to the four-member family of one person. The case involves the prescription diet drug Pondimin (fenfluramine), distributed by Wyeth and prescribed to Cynthia Cappel Coffey. Some five years after receiving three one-month prescriptions of Pondimin, followed by prescriptions for a host of other diet drugs, Mrs. Coffey was diagnosed with a rare lung disease called primary pulmonary hypertension (PPH). She died within a year of diagnosis. Her surviving spouse sued Wyeth in his individual capacity and on behalf of her estate and their three minor children. Plaintiffs claimed that Pondimin caused her PPH, that the drug was defectively designed and marketed, and that Wyeth was negligent. 1AP7.

Trial Court: After the court denied Wyeth's dispositive motions, the case was tried to a jury in the 172nd Judicial District Court of Jefferson County, Texas, Judge Donald Floyd, presiding. The proceedings began on March 3, 2004, and the verdict was returned on April 27, 2004.

Trial Court's Disposition: Plaintiffs filed their sixth amended petition on the eve of trial, requesting a maximum of \$50 million in actual damages and \$800 million in punitive damages. 2AP18. Over objection, the court submitted "cap busting" issues to the jury, which returned a verdict for Plaintiffs and awarded \$1,013,353,000 in damages. This award included \$113,353,000 in "actual damages" (of which only about \$1.5 million were tangible economic damages), as well as \$900 million in exemplary damages. 3AP2962-71. Because these damages exceeded the amount pleaded by Plaintiffs, the court (over Wyeth's objection) allowed them to amend their petition again after trial to seek the additional \$163

million awarded by the jury in excess of the already extravagant amount sought. 4AP5; CR3035, 3039, 3052, 3067; Supp. Tr. 3-11 (Plaintiffs' Motion to Amend Petition, Wyeth's Response, and Court's Order). Thereafter, on May 17, 2004, the court entered judgment on the verdict. 5AP1.

Wyeth timely filed post-trial motions addressing numerous errors. The court heard argument on these motions in July 2004 and promptly denied them without explanation. This appeal followed.

ISSUES PRESENTED

Section One: No Liability

1. No causation.
 - (a) Is Wyeth entitled to judgment because Plaintiffs failed to introduce legally sufficient evidence of causation, an essential element of all of their liability claims?
 - (b) Alternatively, was the evidence of causation factually insufficient, requiring a new trial?
2. No liability for design defect.
 - (a) Is Wyeth entitled to judgment on Plaintiffs' drug design defect claim because the claim is not cognizable under Texas law?
 - (b) Alternatively, is Wyeth entitled to judgment on Plaintiffs' claim that Wyeth's FDA-approved prescription drug was defectively designed because that claim is preempted by federal law?
 - (c) In the further alternative, was the evidence legally or factually insufficient to support the jury's design defect finding?
 - (d) At a minimum, is Wyeth entitled to judgment or a new trial on design defect because the jury was improperly charged?
3. No liability for marketing defect.
 - (a) Is Wyeth entitled to judgment on Plaintiffs' marketing defect claim because:
 - (i) failure to warn about a risk of injury that did not materialize cannot support the jury's finding,
 - (ii) there is no evidence that the learned intermediary was inadequately warned, and/or
 - (iii) there is no evidence that a different warning would have changed Dr. Tyrrell's decision to prescribe Pondimin to Mrs. Coffey?
 - (b) Alternatively, is Wyeth entitled to judgment on Plaintiffs' claim that Wyeth's FDA-approved prescription drug was defectively marketed because that claim is preempted by federal law?
 - (c) At a minimum, is Wyeth entitled to a new trial on Plaintiffs' marketing defect claim because:
 - (i) factually insufficient evidence supports the jury's liability finding, and/or
 - (ii) the jury was improperly charged with regard to the claim?
4. No liability for negligence.
 - (a) Is Wyeth entitled to judgment on Plaintiffs' negligence claim because no evidence supports the jury's finding and because the negligence claim is duplicative of Plaintiffs' product defect claims?
 - (b) Alternatively, is Wyeth entitled to judgment on Plaintiffs' negligence claim because that claim is preempted by federal law?

- (c) At a minimum, is Wyeth entitled to a new trial on Plaintiffs' negligence claim because:
 - (i) the broad-form question included negligence theories that were invalid, preempted, and/or supported by legally insufficient evidence, and/or
 - (ii) the jury's finding was not supported by factually sufficient evidence?

Section Two: Errors in Damages

- 5. Excessive, unsupported, and unsegregated actual damages.
 - (a) Is Wyeth entitled to judgment as a matter of law or a new trial because no legally sufficient evidence supports the jury's actual damages findings or the amounts of those findings?
 - (b) Alternatively, is Wyeth entitled to a new trial or remittitur because:
 - (i) factually insufficient evidence supports the jury's actual damages findings or the amounts of those findings,
 - (ii) the amounts of those findings are excessive and the result of passion and prejudice, and/or
 - (iii) Wyeth cannot obtain meaningful appellate review of the sufficiency of the evidence supporting the jury's "pecuniary loss" award or mental anguish and loss of consortium awards because the damage elements were not properly segregated and were submitted to the jury over Wyeth's objections?
 - (c) Must the award of pre-death damages to the surviving Plaintiffs be vacated because, as a matter of law, such damages cannot be awarded?
 - (d) Must the awards of non-economic damages be disregarded or reduced as a matter of law because they violate Wyeth's constitutional rights under the United States and Texas Constitutions?
- 6. Excessive and unsupported punitive damages.
 - (a) Is Wyeth entitled to judgment or a new trial on Plaintiffs' exemplary damages claim because there is legally or factually insufficient evidence to support the jury's predicate finding of malice?
 - (b) Alternatively, must the award of exemplary damages be set aside because it is excessive and/or unsupported by legally or factually insufficient evidence?
 - (c) Must the award of exemplary damages in excess of the statutory cap be set aside because:
 - (i) there was no evidence to support the "cap-busting" findings,
 - (ii) there was no evidence of the facts necessary to bust the punitive damages cap,
 - (iii) the findings themselves do not permit avoidance of the cap, and/or
 - (iv) as a matter of law, the findings cannot be sustained?

- (d) Must the award of punitive damages be set aside as a result of trial errors relating to punitive damages, such as admission of so-called “expert” testimony concerning Wyeth’s alleged malice and corporate intent?
- (e) In any event, is a new trial required because there was
 - (i) no factually sufficient evidence to support the “cap-busting” findings,
 - (ii) no factually sufficient evidence of the facts necessary to bust the punitive damages cap,
 - (iii) trial error, and/or
 - (iv) charge error because the jury was improperly instructed?
- (f) Alternatively, must the uncapped award be set aside because Plaintiffs’ attempt to exceed the cap is preempted by federal law?
- (g) Must the exemplary damages award be set aside or reduced substantially because it is unconstitutional as a matter of law under the United States and Texas Constitutions?

Section Three: Trial Errors

7. Additional erroneous rulings and instructions that require a new trial.

- (a) Must a new trial be ordered because the trial court
 - (i) submitted an erroneous spoliation instruction,
 - (ii) improperly ruled that spoliation had occurred as a matter of law,
 - (iii) committed evidentiary errors that tainted the verdict, including
 - (A) exclusion of evidence that Mrs. Coffey took other diet drugs,
 - (B) exclusion of evidence of PPH warnings on Meridia,
 - (C) instructing the jury that the other diet drugs Mrs. Coffey took did not cause PPH, and/or
 - (D) repeatedly and incorrectly instructing the jury that there was no evidence that Dr. Tyrrell received warning information from Wyeth,
 - (iv) eliminated qualified jurors, and/or
 - (v) granted Plaintiffs’ prejudicial motion for a post-verdict trial amendment?
- (b) Alternatively, must a new trial be ordered
 - (i) because of cumulative error, and/or
 - (ii) in the interest of justice?
- (c) At a minimum, must the judgment be modified, corrected and/or reformed to
 - (i) address the errors outlined above,
 - (ii) limit the actual and exemplary damages to the amount pleaded in the sixth amended petition, and/or
 - (iii) cap the exemplary damages in accordance with section 41.008(b) of the Texas Civil Practice and Remedies Code?

INTRODUCTION

The jury in this single-injury case awarded over a billion dollars in damages. The way the trial court conducted the trial made it inevitable that there would be a runaway verdict. On all of the critical issues, the only side of the case the jury heard was the Plaintiffs'. A review of the numerous, rejected offers of proof containing Wyeth's case, which the jury was not allowed to consider, dramatically illustrates the one-sided nature of the trial. The significant rulings also went for the Plaintiffs and against Wyeth and, in many instances, the trial court's rulings essentially instructed a verdict for Plaintiffs. In short, there was nothing fair about the trial. Although Wyeth seeks rendition of judgment in its favor, at the very least the Court should order a new trial and provide sufficient guidance to ensure that, on remand, Wyeth will receive the fair trial it is due.

STATEMENT OF FACTS

This statement is divided into two sections. The first details the facts relevant to Mrs. Coffey's disease, many of which the jury was not allowed to consider. The second chronicles irrelevant facts and prejudicial themes the jury heard much about during the seven-week trial.

A. Facts relating to Mrs. Coffey's disease (PPH).

Mrs. Coffey's medical history. Experts on both sides of this case agreed that obesity is a major health problem and one that poses significant life-threatening risks. 9RR95; 13RR131-33; 18RR193-97. Those experts also agreed that Cynthia Cappel Coffey was extremely obese. *Id.* In fact, in November 1996, Mrs. Coffey was 35 years old, 5'1" tall, and weighed 285 pounds. 18RR178, 192-99, 212-13. Her body mass index was over 50, ten points higher than is considered "morbidly obese." *Id.* at 193-94. Her weight posed life-threatening health risks, including heart disease, diabetes, and high blood pressure. *Id.*

at 195-98, 200-04, 212-13, 229-30; DX560. Mrs. Coffey was especially at risk because she had a family history of cardiovascular disease and diabetes and a personal history of toxemia, edema, and gestational diabetes. 18RR212-30.

Mrs. Coffey's diet drug use. For a number of years, Mrs. Coffey had tried to lose weight. *Id.* at 178-79. Although she had some periodic success, she had been unable to achieve any significant long-term weight loss. *Id.* Because she worked as an x-ray technician at Tower Medical, a small medical facility in Beaumont and Orange, Mrs. Coffey had ready access to doctors and diet pills. 24RR91-94; 25RR19-24, 161-62; 24OP104-13. Several different doctors at Tower Medical prescribed at least six different prescription diet drugs to Mrs. Coffey during the five years she was employed there. *Id.*; 8RR156-57; 9RR166-67; 14RR183. For example, Dr. Tyrrell prescribed three one-month (100 pill) supplies of Pondimin (fenfluramine) in November 1996, February 1997, and June 1997. Dr. Tyrrell also wrote five Phentermine prescriptions for her in 1996-97. Dr. Potvin gave her three prescriptions for Tenuate in 1998-99. Dr. Reyes and Dr. Potvin wrote her six to nine prescriptions for Meridia in 2001. 8RR147-48, 234; 9RR25, 36, 59-60; 14RR192; 18RR234; 23OP22, 27; 24RR92-94; 25RR19-24, 104-13; 25OP187-91; *cf.* 8RR20-21. Of all these drugs, only Pondimin was a Wyeth product. Mrs. Coffey also took over-the-counter weight loss drugs. 18RR230-31.

Mrs. Coffey's death from PPH. Mrs. Coffey was 42 years old when she died on January 1, 2003. 9RR29-30. The cause of her death was primary pulmonary hypertension (PPH), a rare and often fatal lung disease that occurs in approximately 1-2 people per million per year in the general population. 12RR184-86. PPH occurs "idiopathically" – for no known reason – but has been observed more frequently in the obese, in women Mrs. Coffey's age, and in women who have been pregnant, taken oral contraceptives, or used

diet drugs for at least three months and developed symptoms within one year thereafter. 8RR190-91; 9RR97-99, 100-01, 104-05; CXHH.

According to Mrs. Coffey's treating physician, who also was Plaintiffs' PPH expert, "her [PPH] symptoms started" in December 2001, nearly four-and-a-half years after Mrs. Coffey briefly used Wyeth's drug. 9OP70. Mrs. Coffey was diagnosed with PPH in March 2002. 9RR22-23.

Scientific study of relationship between PPH and diet drugs. In August 1996, the final results of a European epidemiological study known as the International Primary Pulmonary Hypertension Study (IPPHS) were published. 11RR53; 12RR45-46; 17RR32-33.¹ The IPPHS studied a group of diet drugs (anorexigens) and is the most complete, reliable study to date on the potential risk factors of PPH. 9RR64; 13RR115; 19RR142, 144. Previously, there had been anecdotal evidence of a possible association between diet drugs and PPH, but the IPPHS was the only case-controlled epidemiological study to analyze any association scientifically. 8RR170-71; 9RR126-27; 11RR220-21; 12RR43-44.

The IPPHS found that the use for *more than three months* of one or more of the drugs studied was associated with a statistically significant increase in the risk of developing PPH. 7RR156-57; 9RR133-34, 164, 169; 12RR63-64, 168-69; 17RR20-21; 11RR201-02. But the study found *no* statistically significant association between diet drug use and PPH for patients whose PPH symptoms arose *more than one year* after they last used the drugs. 8RR194-96; 12RR65, 169; 17RR20-21; 21RR111. In addition, because the IPPHS examined diet drugs as a group, it never determined if the use of any particular drug was associated with an increased incidence of PPH. 9RR108-10; 11RR224-25.

¹ The interim results of the IPPHS study were released in 1995. 11RR114-15, 201. The final IPPHS results indicated that, although the odds of certain diet drug users contracting PPH were less than 1 in 10,000 (23 to 46 cases out of a million people), they were higher than reported in the interim results. *Id.* at 203-05.

The IPPHS also confirmed what had been previously believed: the risk of developing PPH is extremely rare. 8RR175-76; 13RR53-54, 101-03, 114-15. Indeed, even among those who have used diet drugs, the risk of contracting it is far less than 1 in 10,000 (less than .01%). 8RR176. All of the witnesses who testified at trial acknowledged that the risk is minuscule.² The causes of PPH thus largely remain a mystery, as the vast majority of PPH patients have never used a diet drug. 9RR97-105; 13RR100-01; CXHH at 614. Even among users of diet drugs, the vast majority (over 99.9%) never developed PPH. No epidemic of PPH has occurred in the United States, even though Pondimin was sold here beginning in the early 1970s, and the use of prescription diet drugs, including those in the IPPHS, increased significantly in the mid-1990s. 9RR105-06; 13RR96-97; 20RR129.

Mrs. Coffey's experience compared to the IPPHS results. The group of drugs that the IPPHS studied included fenfluramine (Pondimin) and dexfenfluramine (Redux), which were distributed by Wyeth, as well as diethylpropion (Tenuate), which was not Wyeth's product. 13RR165-68. Mrs. Coffey took Pondimin in 1996-97. 38RR146-48. She did not take Redux. 9RR168-69. She took the non-Wyeth drug Tenuate in 1998-99. 13RR164-65; 23RR21-22, 26-27, 29-30; 20RR111-12.

Each of Mrs. Coffey's three Pondimin prescriptions was for approximately one month's dose (100 pills each, to be taken three times a day). 8RR147-48. If she had taken all of the medication as prescribed, she would have taken Pondimin for 3 months and 10 days. 8RR149-50. According to her husband, however, she did not complete all of her Pondimin prescriptions. CXZ, Ex. 1 at 94. How much of the medication she took is unknown, because she died before her deposition was taken. Her PPH symptoms appeared

² 8RR175-76 (Dr. Busch); 9RR99-100 (Dr. Frost: 23 to 46 cases per million people); 11RR201-03 (Dr. Moye: conservative estimate is 6.3 cases per million people); 13RR114 (Dr. Rubin: PPH very rare even among people who use diet drugs); 16RR210, 216-17, 228-29 (Dr. Constantine: IPPHS and SOPHIA studies showed diet drug users had very small risk of developing PPH).

over four-and-a-half years after her last Pondimin use, but much closer in time to her subsequent use of Tenuate and other non-Wyeth drugs.

As discussed above, the IPPHS only found a statistically significant association between diet drug use and PPH for patients who took the drugs for more than three months *and* whose PPH symptoms arose less than one year after they last used the drugs. Yet Mrs. Coffey's approximately three months of Pondimin usage was either less than or on the cusp of what the IPPHS identified as a duration of use associated with a statistically significant increase in risk, and her symptoms appeared more than *four years* after her last Pondimin use. 13RR134-35.

The FDA's role in drug approval, supervision, and labeling. Before a prescription drug like Pondimin may be legally dispensed to the public, it must be approved by the FDA. 21 U.S.C. § 355(a). Because all drugs have some risks of side effects, the FDA ultimately balances the competing goals of safety and effectiveness to decide whether to approve the drug. 21 U.S.C. § 355(d); CR3531; 20RR70-72. Only if the FDA determines that the drug's benefits outweigh its risks will it be approved. *Id.* The FDA first approved the use of Pondimin in 1973. DX22.

The FDA's regulatory and supervisory role continues after a drug is approved. 21 U.S.C. § 355(e). After a drug is on the market, the manufacturer must report to the FDA periodically regarding information it receives from patients, doctors, and others about any adverse or unusual effects of its drugs. 21 U.S.C. § 355(k). Throughout the period in 1996-97 when Mrs. Coffey was taking Pondimin, the FDA continued to receive and study the very latest data available on the risks of Pondimin, including the IPPHS results. *E.g.*, 10RR107-10; 22RR80; 23RR148-51.

The FDA also controls the manner in which the risks of any drug are communicated

to prescribing physicians and the public. 8RR68-78; 12RR53. The FDA considers the labeling and package insert that will accompany the drug and approves the drug as safe and effective “as labeled.” 21 CFR pt. 201; *id.* § 201.57; 8RR76-79. This ensures that the warnings accompanying the drug correctly report what the FDA considers to be the dangers of the product reasonably knowable at the time. *Id.* As additional information is gathered after a drug has been approved and is on the market, the FDA and drug manufacturer coordinate in making any appropriate changes in the label. 8RR178-85; 16RR204-05.

Information and warnings about prescription drugs are communicated not only through the labeling materials and package inserts that accompany the drug when sold by the manufacturer and dispensed by a pharmacy, but also through reference works such as the industry-standard PHYSICIANS’ DESK REFERENCE (PDR), which contains the latest FDA-approved labels for pharmaceuticals. The PDR is issued annually, usually in November for the following year, and supplemented six months later.³ Pharmaceutical companies often send out “Dear Doctor” and “Dear Pharmacist” letters advising of labeling changes. 9OP162-71; 17RR12-13; DX855-60, 5401; 7AP.

PPH warnings about Pondimin. Dr. Tyrrell prescribed Pondimin to Mrs. Coffey for her morbid obesity in November 1996, February 1997, and June 1997. 25RR9; *see also* 8RR147-48; 18RR25-26, 234; DX5408. During this time period, Pondimin’s label warned of the potential risk of developing PPH from using appetite suppressants. 9RR155-57; DX1067 at 13-14. Specifically, in June 1996, five months before her first prescription,

³ 8RR68-70, 177-79; 9RR166-68; 12RR53; 15RR202-03; 17RR10-11; 20RR71-73. Concerning schedule for publication and supplementation: 15RR135-36; 17RR10-19. The PDR is a compendium of drug labels approved by the FDA. 8RR84-85, 178-79, 184. The PDR also contains information to guide physicians in obtaining the latest information about the particular drugs they are prescribing, including toll-free numbers and other contact references. 11RR186; 16RR199-201; 17RR10-13.

Pondimin's label had been updated to reflect the interim IPPHS results and to include more comprehensive warnings about PPH. *Id.* The 1997 PDR, which included these results in the warnings for Pondimin, came out in late 1996. 6AP. In November 1996, the Pondimin label was updated yet again to reflect the final IPPHS results and warnings. It read, in pertinent part, as follows:

Warnings

Primary Pulmonary Hypertension

Fenfluramine is an appetite suppressant, and appetite suppressants increase the risk of developing primary pulmonary hypertension, an often fatal disorder.

A 2-year international (5 country), case-control (epidemiological) study identified 95 primary pulmonary hypertension (PPH) cases. 30 of these cases were classified as having been exposed to appetite suppressants in the past, either to commercially available medications, pharmacist compounded preparations or unknown weight loss agents. Of the 30 cases, 18 had been exposed to appetite suppressants for longer than three months. In this study, the use of appetite suppressants for longer than 3 months was associated with an increase in the risk of developing PPH (odds ratio = 23.1, 95% confidence interval = 6.9:77.7). There was no significant increase in risk for persons who had used these agents for 3 months or less. In the general population, the yearly occurrence of PPH is estimated to be about 1-2 cases per 1,000,000 persons. Therefore, the case-controlled study estimated risk associated with long-term use of appetite suppressants to be about 23-46 cases per million persons exposed per year based upon a background estimate of 1-2 cases per million persons. According to the case controlled study, obesity alone (body mass index ≥ 30 kg/m²) was also associated with an increase of about two-fold in the risk of developing PPH.

PPH is a serious condition; the 4-year survival rate has been reported to be 55%.

DX1067 at 15-16. The FDA approved this warning and, in doing so, reaffirmed that Pondimin was "safe and effective for use as recommended." DX693; 17RR35-36.

In addition to warning health care professionals and patients through the conventional means discussed above, in January 1997, Wyeth also prepared "Dear Doctor" and "Dear Pharmacist" letters to advise hundreds of thousands of physicians and

pharmacists of the final IPPHS results and the revised PPH warning labels. 12RR185-86, 22RR40; 7AP. By mid-February, these letters had been sent to Mrs. Coffey's pharmacy as well as to at least one doctor at Tower Medical, where Dr. Tyrrell worked part-time. 12RR186-88, 195-206; 18RR42, 45-47; 22RR64; 25RR162.⁴

Apart from the question whether Dr. Tyrrell personally saw a "Dear Doctor" letter, by the time he wrote Mrs. Coffey's last Pondimin prescription in June 1997 (the one that would have taken her close to or, if completed, slightly beyond the three-month duration of use identified in the IPPHS), the FDA-approved Pondimin label indisputably contained the final IPPHS results and PPH warnings, and the 1997 PDR had been supplemented to include those results and warnings for Pondimin. 17RR18; 6AP, Ex. 287 at 2.

There was no credible evidence that Dr. Tyrrell failed to act in the same professional manner as his colleagues, Drs. Reyes and Potvin. Those doctors expressly warned Mrs. Coffey about the PPH risks of other diet drugs they later prescribed for her (as reported on their labels and in the PDR), but she took the drugs anyway. 14RR175-77; 25OP187-195. Unfortunately, Dr. Tyrrell had died without having been deposed. 12RR193-94. Indeed, no record of Mrs. Coffey's Pondimin treatment by Dr. Tyrrell exists. Tower Medical did not create records for diet drug prescriptions, even though the drugs were "scheduled" controlled substances. 25RR166-69, 178-79. What Mrs. Coffey's records actually disclosed will never be known, because she personally removed all available records from Tower Medical in 2002 (the year in which this suit was filed) and they have never been seen again. *Id.* at 180-81.

Mr. Coffey speculated that his wife would not have taken a drug with a fatal risk

⁴ The final IPPHS report also was published in *The New England Journal of Medicine*, and it received other local and national publicity. See 19RR171-75; 22RR4-9; CXCCC-EEE; CXHH; DX359.

associated with it. Mr. Coffey admitted, however, that he was unaware of what his spouse and Dr. Tyrrell had discussed about the risks of Pondimin. 24RR94, 99. The details of her treatment by Dr. Tyrrell died with the two of them. Drs. Reyes and Potvin, however, would have testified that they gave her such warnings about the other diet drugs they prescribed and she took after using Pondimin, but the court kept their testimony from the jury. 14RR175-77; 25OP187-195.

PPH warnings about other diet drugs Mrs. Coffey took. Both the label for Tenuate and the label for Meridia (another prescription diet drug Mrs. Coffey took after she took Pondimin) warned of the potential risk of PPH. 13RR162-64; 15RR116-23; 15RR225-27; 20RR111-17, 20RR119-20; 25RR104-13; 9OP60; CXKKK. Yet the trial judge not only kept this information from the jury, but also allowed one of Plaintiffs' experts to testify that, while treating Mrs. Coffey, she never asked Mrs. Coffey about her use of diet drugs other than Pondimin because those drugs had *never* been linked to PPH. 13RR153-54. The judge also prevented the jury from learning that, contrary to her husband's speculation, she chose to take these two drugs after the prescribing doctors expressly warned her of the risks of developing fatal PPH. 14RR175-77; 15RR116-23, 221-27; 23RR4-37.

B. Irrelevant facts and prejudicial themes.

Heart valve abnormalities reported with Redux and Pondimin. In early 1997, after Dr. Tyrrell began prescribing Pondimin for Mrs. Coffey's morbid obesity, reports about potentially serious heart valve abnormalities began to surface in patients taking Redux or Pondimin. It could not be ascertained immediately whether the users of the drug were at an increased risk and, if so, how serious or extensive the risk might be. After learning of additional instances of heart valve abnormality, Wyeth voluntarily withdrew the

drugs from the market in September 1997. 17RR128-29. Mrs. Coffey, however, did not suffer or die from any heart valve abnormality. Nor did Mrs. Coffey take Redux. 9RR168-69. Nonetheless, the jury heard as much about heart valve injuries and Redux as it did about PPH and Pondimin.

The Mayo/Fargo reports and Wyeth's investigation. In February 1997, Wyeth received an inquiry from a Mayo Clinic doctor concerning a patient who had taken Pondimin and Redux. 16RR85; 19RR18-19. That patient had PPH and valvular heart disease. DX960. At the beginning of March, Wyeth sent the FDA a report – known as an “adverse drug event” or ADE report – on this patient’s condition. 16RR84-86; 19RR19-21; DX960.

Around this same time, Dr. Kelly Davis, one of Wyeth’s medical monitors for Pondimin, received information regarding 13 more cases of valvular heart disease from the Mayo Clinic and from a doctor in Fargo, North Dakota. 16RR87-88, 115-18; 19RR20-21; DX318-19. None of these cases involved PPH. 19RR18-19, 37-38, 58-59, 116-20, 168-69. Dr. Davis gave a summary of the information to Amy Myers, an employee in Wyeth’s safety surveillance group. Based on her notes of that conversation, Ms. Myers had 14 computer records created in Wyeth’s database, one for each of the 14 cases about which Wyeth had received some preliminary information. 16RR71; 18RR82, 84; 19RR23, 28-30, 131. Fourteen hard-copy files containing Ms. Myers’ notes and printed copies of these records were also generated. PX1330, at 23-24.

The reports about heart valve conditions were unusual and surprising, and there was initially some confusion about the cases and the identity of the drugs being taken. For an ADE report to be called for, the specific identity of the drug in question must be known. 10RR160. Thus, doctors from Wyeth – including Dr. Davis’s supervisor, Dr. Ginger

Constantine – decided to visit with the Mayo Clinic and Fargo doctors in person to obtain more information. 16RR94-95; 17RR112-29; DX327, 330. Wyeth’s need for more information was discussed at a safety meeting on March 11, 1997. By the end of that meeting, Ms. Myers concluded that the 14 database files had been created without sufficient information and prematurely. 19RR26-32, 72-75. Dr. Olsen, Wyeth’s assistant vice president of Medical Affairs, told her to cancel those internal files. 16RR73-74, 91-92; 19RR68-70.

Contrary to those instructions, Ms. Myers decided to “overwrite” the computer files. 16RR92-93; 19RR29-36. When a file is cancelled, it remains in the database with a notation that it has been cancelled. *Id.* When a file is overwritten, it is permanently deleted from the database and the computer-generated report number is re-used for another report. *Id.*; 22RR116. Nevertheless, despite the overwriting and Ms. Myers’ inability to locate the hard-copy files, all of the original source documents, including Dr. Davis’s phone logs from which the 14 files were created, remained intact and were introduced at trial. 19RR30-33, 58-60; DX312, 314, 318-19, 327, 330.

Following the March 11 meeting, Wyeth doctors traveled to the Mayo Clinic and Fargo, where they obtained complete information on the heart valve cases. 16RR94-95; 17RR116-22, 126-29; 19RR159; DX327, 330. During April, Wyeth sent ADE reports to the FDA on all additional heart valve cases. DX960-76, 1070-71. Wyeth preserved a complete record of this investigation in its files, and all of the ADE reports were admitted at trial. *Id.*; 17RR122; 18RR84-85; 19RR13-14, 30-31.

Aware of the Mayo and Fargo information, the FDA continued to approve the marketing and use of Redux and Pondimin. 17RR127; 23RR152-54; DX339, 364, 408. In mid-September, Wyeth subsequently learned of some additional cases of heart valve

*Timeline of Wyeth's 1997 Heart Valve Investigation*⁵

- November 1996 Mrs. Coffey receives her first month's prescription for Pondimin.
- February 1997 Mrs. Coffey receives her second month's prescription for Pondimin.
- February 10 The Mayo Clinic informs Wyeth about a Pondimin patient with PPH and heart valve disease.
- Late February/
Early March The Mayo Clinic and a doctor from Fargo inform Wyeth's Dr. Davis of 13 additional heart valve cases that did not involve PPH.
- Dr. Davis tells Wyeth employee Amy Myers about these 14 (total) cases, and she creates 14 preliminary computer records for these cases on Wyeth's computer database.
- March 7 Wyeth sends the FDA an ADE report on the one case involving PPH and heart valve disease and then writes to Mayo and Fargo for more information on the other heart valve cases.
- March 11 Wyeth's Dr. Olsen tells Myers to cancel the preliminary records she created, but Myers decides to have them overwritten instead.
- March 14 & 29 Wyeth's Dr. Constantine goes to Mayo and Fargo to get more information on the heart valve cases. She discovers there are 19 total heart valve cases rather than the 14 initially reported.
- April 3 – 11 Wyeth sends ADE reports to the FDA on all but one of the heart valve cases.
- April 21 Wyeth sends an ADE report to the FDA on the last heart valve case.
- May The FDA concludes that reports of heart valve problems have not reached an incidence requiring any action.
- June Mrs. Coffey receives her third month's prescription for Pondimin.
- July The FDA requests physicians to report any additional cases of heart valve disease but concludes that Pondimin remains safe and effective if labeled to warn of a potential heart valve risk.
- September 12 The FDA informs Wyeth about new reports of additional heart valve cases associated with Pondimin use.
- September 15 Wyeth withdraws Pondimin from the market because of growing concerns of a potential risk of heart valve disease.

⁵ See 10RR66-67; 16RR71-74, 85-96, 115-18; 17RR115-29; 19RR18-38, 124, 151-52, 159; 22RR54-55, 102-15, 120-24, 128-29; 23RR152-58; 24RR24-25; 25RR9; DX318-19, 327, 330, 339, 364, 408, 960-76, 1070-71.

disease among users of its drugs as a result of new information from clinics that specialized in obesity therapy. 17RR128-29. Concerned about the increasing evidence of a potential association between heart valve damage and its diet drugs, Wyeth withdrew them from the market within days. 16RR132-34; 17RR128-29; 22RR54-55; 24RR24-25. The withdrawal was not prompted by any new or changed information *regarding PPH*. *Id.* (For the Court’s convenience, a timeline of the above events is included on the facing page.)

Overwriting as “spoliation.” Even though Wyeth had preserved the source of the heart valve information and promptly developed and reported follow-up information about the heart-valve incidents, and even though Mrs. Coffey had a lung disease, not heart valve problems, the trial court told the jury:

The Court instructs you that the deliberate alteration of the CDSSS [adverse event] records by Wyeth *is spoliation or destruction of evidence relevant to this case*. You may presume that the evidence in the CDSSS records which were destroyed would have been unfavorable to Wyeth.

The Court instructs you that the deliberate destruction, by Wyeth, of the 14 files from the Mayo Clinic and Fargo, North Dakota *is spoliation or destruction of evidence relevant to this case*. You may presume that the information contained in the 14 files from the Mayo Clinic and Fargo, North Dakota, which were destroyed would have been unfavorable to Wyeth.

3AP2955 (emphasis added). Plaintiffs used these instructions to argue that the jury should “bust” the punitive damages cap by finding that Wyeth had fraudulently destroyed or altered a legally protected writing. 3AP2960; 26RR147-49.

“Expert” testimony about Wyeth’s allegedly unethical conduct and fraud on the FDA. Plaintiffs’ witnesses (whom the court qualified as experts over Wyeth’s objections) testified that Wyeth defrauded and unduly influenced the FDA in its decision-making on PPH labeling before June 1996, and that Wyeth did the same in 1997 with respect to heart valve issues. 11RR22-79; 12RR98-108; 15RR188-95, 209-12; 16RR53-

57. They also testified that Wyeth did not act ethically or responsibly in connection with Pondimin and the FDA and had acted with malice. 7RR13-20; 11RR27-28, 30-32; 26RR92-93. One of Plaintiffs' experts drew an analogy to Enron and referenced corporate scandals. 14RR77-78, 101, 103-04, 114. The judge prohibited Wyeth from presenting rebuttal testimony from FDA and other industry experts that its conduct was responsible, appropriate, and in compliance with applicable rules and regulations. 22RR80-82. The jury found that Wyeth acted with malice.

SUMMARY OF THE ARGUMENT

The jury's billion-dollar-plus verdict in this single injury case was staggering, catching off guard even the Plaintiffs' counsel, who had to seek a \$163 million post-verdict pleading amendment to conform the *ad damnum* to the jackpot verdict the jury had returned. That the verdict would be a blockbuster was not altogether surprising, however, as that often happens when juries are motivated by something other than the relevant evidence, as the jury in this case was.

Myriad reasons support the relief Wyeth requests in this appeal. At virtually every turn, the trial court made rulings that gave the jury a one-sided view of the case. Those rulings also led the jury to award wildly exaggerated damages. Only by examining the trial court's numerous, significant errors can this Court get an accurate sense of why the judgment in this case is so pervasively tainted. To provide that perspective, this brief is subdivided into three sections: (1) No Liability, (2) Errors in Damages, and (3) Trial Errors. Although either the unprecedented size of the damages or the trial court's critical errors alone would require reversal, the brief begins with legal issues of liability because they require rendition of judgment in Wyeth's favor. As the following examples demonstrate, this Court need look no further than controlling Texas and United States Supreme Court

authority to conclude that the billion-dollar judgment must be reversed.

Liability: Plaintiffs were required to establish causation – an essential element of all of their liability claims. The Texas Supreme Court decision in *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997), resolves this pivotal legal issue in Wyeth’s favor. *Havner* specifies how Plaintiffs must prove causation in cases like this one that involve epidemiological studies. Among other requirements, *Havner* demands that plaintiffs show that they were “similar” to the patients in the studies in relevant respects. In addition, plaintiffs must negate alternative causes of their injury. Yet the trial court ignored *Havner*’s requirements, allowing litigation experts to try to supply the required causation evidence that epidemiological studies did not.

Actual damages: The actual damages awarded in the judgment are also infirm under established supreme court authority. Plaintiffs’ counsel admitted that the actual economic damages in this case were only **\$1.5 million**. Yet the jury awarded an **additional \$25.3 million** in economic/“pecuniary” damages and an astounding **\$86.63 million** in non-economic damages. These amounts included an award of \$9,763,000 to the four wrongful death beneficiaries for injuries arising before Mrs. Coffey’s death, which must be reversed because, as a matter of law, such damages are not recoverable. *Horizon/CMS Healthcare Corp. v. Auld*, 34 S.W.3d 887, 903 (Tex. 2000). Even excluding the \$9,763,000, the remaining amount – roughly \$100 million – was arbitrary and lacked any evidentiary foundation of fairness and reasonableness. *Bentley v. Bunton*, 94 S.W.3d 561, 605-06 (Tex. 2002) (jury cannot award an arbitrary amount of non-economic damages); *Saenz v. Fid. & Guar. Ins. Underwriters*, 925 S.W.2d 607, 614 (Tex. 1996) (requiring evidence that amount of non-economic damages is fair and reasonable).

Exemplary damages: The Texas Supreme Court decision in *Transportation*

Insurance Co. v. Moriel, 879 S.W.2d 10, 22-23 (Tex. 1994), compels reversal of the \$900 million award. Plaintiffs failed to prove by clear and convincing evidence that Wyeth acted with either objective or subjective malice, as *Moriel* requires. In particular, *Moriel*'s objective component "is not satisfied if the defendant's conduct merely creates a remote possibility of serious injury; rather, the defendant's conduct must create the 'likelihood of serious injury' to the plaintiff." *Universal Servs. Co. v. Ung*, 904 S.W.2d 638, 641 (Tex. 1995) (emphasis added). Here, no such likelihood was present, because all witnesses agreed that the *probability* of harm was minuscule. *See id.* The possibility of contracting PPH is extremely remote: less than 1/100th of one percent, even among diet drug users. Plaintiffs' failure to prove this objective component of malice, standing alone, is fatal to the exemplary damage award.

In addition, Plaintiffs submitted no evidence that a Wyeth vice-principal had actual subjective awareness of, but consciously disregarded, any extreme degree of risk or that Mrs. Coffey's PPH was caused by any such disregard – all of which is legally required to show malice.

Moreover, the jury's staggering \$900 million award of exemplary damages is unconstitutionally excessive under the guidepost analysis of *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408, 418 (2003). No similar case has affirmed an exemplary damage award even remotely approaching the one here. 8AP1-2.

Legislative Cap: Independently, the Legislature's cap on punitive damages requires that any exemplary damages award here be reduced to less than \$2.3 million.

At trial, Plaintiffs sought to invoke a statutory exception to this cap by arguing that the overwriting or loss of internal computer files relating to reports of heart valve damage, which Mrs. Coffey did not have, by a Wyeth employee in Pennsylvania constituted

felonious document destruction under the Texas Penal Code. This theory was fundamentally flawed from the outset, however, because the underlying Texas offense only covers documents affecting property interests (such as mortgages), does not reach out-of-state conduct, and could not have caused Mrs. Coffey's PPH in any event.

Even so, it was inevitable that the jury would affirmatively answer the trial court's "cap-busting" question regarding document destruction, because (i) that question erroneously omitted most elements of the actual felony offense (particularly the intent to defraud), and (ii) the trial court's related spoliation instruction virtually compelled the jury to find all remaining felony elements as well as malice, regardless of the evidence, by instructing the jury that "the deliberate destruction, by Wyeth, of the 14 files from the Mayo Clinic and Fargo, North Dakota is spoliation or destruction of evidence relevant to this case." 3AP2955.

The court's spoliation instruction was not only prejudicial, but was legally erroneous under Texas Supreme Court precedent. Before a party may properly obtain a spoliation instruction, it must show that the allegedly destroyed evidence was relevant to a fact in issue. *State v. Gonzalez*, 82 S.W.3d 322, 330 (Tex. 2002). Here, the allegedly spoliated documents and data related to heart valve injuries having nothing to do with Mrs. Coffey's PPH. Moreover, spoliation instructions allow the jury to presume that missing evidence would be unfavorable only "if [they] find" that any disputed elements of spoliation were met. *Wal-Mart Stores, Inc. v. Johnson*, 106 S.W.3d 718, 720-21 (Tex. 2003). The trial court failed to follow *Wal-Mart* or *Gonzalez*; the court itself resolved all factual disputes against Wyeth and erroneously instructed the jury as a matter of law that "the deliberate destruction, by Wyeth, of the 14 files . . . is spoliation or destruction of evidence relevant to this case." 3AP2955 (emphasis added). The prejudicial impact of the instruction on the

exemplary damages cap aside, this error alone requires reversal.

Trial errors: The deck was stacked against Wyeth from the start of the trial. The judge struck for “cause” potential jurors who said they respected established legal limitations on the magnitude of their verdicts. By contrast, Wyeth was forced to use peremptory challenges on jurors who should have been disqualified without question.

The jury that was chosen was never allowed to hear the full story on any major issue or theme in the case – only the Plaintiffs’ side. For example, the judge barred Wyeth from presenting evidence that Mrs. Coffey had taken the diet drug Tenuate, even though the Tenuate label warned of the risk of PPH and the study Plaintiffs used to support their claim that Pondimin had caused Mrs. Coffey’s PPH also implicated Tenuate as a plausible cause. Indeed, her use of Tenuate was much closer in time to the onset of her PPH symptoms. Then, to ensure the jury would conclude that Pondimin caused Mrs. Coffey’s PPH, the court instructed the jury during closing argument that the other un-named diet drugs she took did *not* cause PPH, even though those drugs actually warned of the risks of contracting PPH. 26RR164-65.

In addition, the court repeatedly instructed the jury during trial and then, for emphasis, during closing argument that Dr. Tyrrell did not receive a “Dear Doctor” letter from Wyeth about Pondimin, suggesting that he was not aware of any of the various warnings about the potential PPH risk of Pondimin. Yet there was no evidence that he was ignorant of these warnings.

Remarkably, the court allowed Mr. Coffey to testify that his wife would never have taken drugs with a PPH risk if she had been warned of such a risk. The court, however, refused to let Wyeth present testimony from doctors who had warned her of that specific risk when they subsequently prescribed other diet drugs. They would have testified that she

actually did choose to take the risk with these other drugs.

Seeking to inflame the jury to reach a result not supported by the evidence, Plaintiffs contrived as the centerpiece of their case an “issue” that had nothing to do with Mrs. Coffey’s illness or death (and that was preempted by federal law): whether Wyeth misled the FDA and destroyed documents that had to be provided to the FDA. The court even permitted Plaintiffs’ “experts” to opine about Wyeth’s malice, business ethics, and motivations. Those so-called “experts” spun speculation and hearsay into a yarn about alleged corporate deception, greed, and scandal fit for front-page tabloid news. One carefully prompted expert suggested that deception had occurred because Wyeth’s trial lawyers also were Enron’s lawyers. Even Watergate was mentioned. Exacerbating this drumbeat of prejudicial and irrelevant themes was the exclusion of rebuttal expert evidence that Wyeth acted responsibly and had not deceived or misled the government with regard to any of the matters about which Plaintiffs’ experts regaled the jury.

* * *

For these reasons and the others stated in this brief, the judgment cannot stand and must be reversed. Judgment should be rendered for Wyeth or, in the alternative, the cause should be remanded for a new trial. At a minimum, the judgment must be modified and a remittitur ordered.

STANDARDS OF REVIEW

This Court reviews questions of law *de novo*. *In re Humphreys*, 880 S.W.2d 402, 404 (Tex. 1994). These questions include (1) federal preemption, *City of Euless v. Dallas/Fort Worth Int’l Airport Bd.*, 936 S.W.2d 699, 702 (Tex. App.—Dallas 1996, writ denied), (2) the constitutionality of a jury’s punitive damages award, *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 437 (2001), (3) the applicability of the Texas

punitive damages cap to a jury's punitive damages award, and (4) all other legal issues.

For legal sufficiency (“no evidence”) issues, this Court reviews the evidence tending to support the jury's verdict, disregards all evidence to the contrary, and upholds the finding if supported by more than a scintilla of evidence. *Mancorp, Inc. v. Culpepper*, 802 S.W.2d 226, 227-28 (Tex. 1990). In conducting a no-evidence review, the Court must reverse a finding of malice if “no reasonable factfinder could form a firm belief or conviction” that the defendant acted maliciously. *S.W. Bell Tel. Co. v. Garza*, 48 TEX. SUP. CT. J. 226, 2004 WL 3019205, at *15 (Dec. 31, 2004) (not yet released for publication).

As to factual sufficiency (“insufficient evidence”) issues, this Court reviews all record evidence, not just that supporting the verdict, and determines if a finding is “so against the great weight and preponderance of the evidence that it is manifestly unjust, shocks the conscience, or clearly demonstrates bias.” *In re C.H.*, 89 S.W.3d 17, 25 (Tex. 2002). In reviewing the jury's damage awards for excessiveness, this Court applies the same factual sufficiency standard of review and makes its own “detailed appraisal of the evidence bearing on damages.” *Maritime Overseas Corp. v. Ellis*, 971 S.W.2d 402, 406-07 (Tex. 1998).

Charge issues implicating legal errors are reviewed *de novo*, including whether (1) the form and content of the questions properly submitted the parties' theories of recoveries and defenses; (2) the instructions and definitions correctly stated the law; (3) the questions, instructions, and definitions were supported by the evidence; (4) any questions, definitions, and instructions were improperly omitted; and (5) the charge improperly commented on the weight of the evidence. *See, e.g., Elbaor v. Smith*, 845 S.W.2d 240, 243 (Tex. 1992).⁶

⁶ *See also, e.g., State Dep't of Highways & Pub. Transp. v. Payne*, 838 S.W.2d 235, 240-41 (Tex. 1992); *Placencio v. Allied Indus. Int'l, Inc.*, 724 S.W.2d 20, 22 (Tex. 1987); *City of Pearland v. Alexander*, 483 S.W.2d 244, 249 (Tex. 1972); *Harris v. Harris*, 765 S.W.2d 798, 801 (Tex. App.—Houston [14th Dist.] 1989, writ denied).

Other charge errors ordinarily are reviewed for abuse of discretion. *See State Farm Lloyds v. Nicolau*, 951 S.W.2d 444, 451-52 (Tex. 1997). Charge error is reversible if it probably “caused the rendition of an improper judgment” or “prevented the appellant from properly presenting the case to the court of appeals,” as when “a party is denied proper submission of a valid theory of recovery or a vital defensive issue raised by the pleadings and evidence.” TEX. R. APP. P. 44.1(a)(1), (2); *Exxon Corp. v. Perez*, 842 S.W.2d 629, 631 (Tex. 1992) (per curiam).

Finally, this Court reviews the entire record and applies an abuse of direction standard in assessing the trial court’s (1) denial of Wyeth’s motion for new trial, *State Employees Workers’ Compensation Div. v. Evans*, 889 S.W.2d 266, 268 (Tex. 1994), (2) allowance of Plaintiffs’ trial amendment, *State Bar v. Kilpatrick*, 874 S.W.2d 656, 658 (Tex. 1994) (per curiam), (3) disqualification of potential jurors for cause, *Guerra v. Wal-Mart Stores, Inc.*, 943 S.W.2d 56, 59 (Tex. App.—San Antonio 1997, writ denied), (4) rulings on expert qualifications and the reliability of expert testimony, *Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486, 499 (Tex. 2001); *Broders v. Heise*, 924 S.W.2d 148, 151 (Tex. 1996), and (5) all other evidentiary rulings, *Horizon/CMS Healthcare*, 34 S.W.3d at 906; *City of Brownsville v. Alvarado*, 897 S.W.2d 750, 753 (Tex. 1995). Evidentiary error is reversible if it probably resulted in an improper judgment. *City of Brownsville*, 897 S.W.2d at 753.

ARGUMENT

SECTION ONE: NO LIABILITY

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

For each of the liability theories submitted to the jury (design defect, marketing defect, and negligence), Plaintiffs had to prove “cause in fact.” *Gen. Motors Corp. v.*

Saenz, 873 S.W.2d 353, 357 (Tex. 1993). This is a difficult burden to meet when a few people may develop an illness after using a drug, but most do not, and most people with the illness did not use the drug and thus necessarily developed it from other causes. Because Plaintiffs did not offer legally or factually sufficient evidence that Pondimin was the cause in fact of Mrs. Coffey's injury and death, judgment must be rendered for Wyeth.⁷

In *Merrell Dow Pharmaceuticals Inc. v. Havner*, 953 S.W.2d 706, 715 (Tex. 1997), the Texas Supreme Court adopted strict standards for proving causation in cases like this one, where there is no direct biological evidence that the defendant's product caused the plaintiff's illness or injury and, therefore, she must use epidemiological studies to show causation. In this kind of case, a plaintiff can raise a fact issue on causation only by proving she is *similar* to the test subjects in at least two epidemiological studies whose results indicate that it is "statistically more likely than not that [each test subject's] disease was caused by the drug." *Id.* at 717; *see also id.* at 714-24.⁸ In addition, *Havner* requires a plaintiff's expert to rule out alternative plausible causes of her illness or injury to a reasonable degree of medical certainty. *Id.* at 711-12; *E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 556-57 (Tex. 1995). These requisites are not mere technicalities: as the *Havner* court explained, epidemiological studies standing alone just show correlation and cannot establish the probable, actual cause of *any* plaintiff's injury, unless certain additional requirements are met. 953 S.W.2d at 715. In this case, Plaintiffs failed to meet each of *Havner*'s requirements.

⁷ Although Wyeth did not dispute at trial that Pondimin can cause PPH in some people under some circumstances, that does not relieve Plaintiffs of their burden to prove that Pondimin causes PPH in people like Mrs. Coffey and, more specifically, that Pondimin more-probably-than-not was the actual cause of Mrs. Coffey's PPH. *See Havner*, 953 S.W.2d at 714-15, 720; *Saenz*, 873 S.W.2d at 357.

⁸ *Havner* requires that a plaintiff have at least two epidemiological studies meeting its requirements because a single study does not reliably indicate "that it is 'more probable than not' that an association [between the substance and the disease] exists." 953 S.W.2d at 727.

A. Mrs. Coffey was not similar to the people in the Plaintiffs' studies.

Havner requires a plaintiff to prove that she is similar to the people tested in at least two epidemiological studies with respect to both “exposure or dose levels” and “timing of the onset of injury.” *Havner*, 953 S.W.2d at 720. Thus, the duration of Mrs. Coffey’s Pondimin exposure had to be “comparable to or greater than those in the studies” and the timing of her PPH onset had to be “consistent with that experienced by those in the study.” *Id.* Plaintiffs relied on two diet-drug studies: the IPPHS and SNAPH (Surveillance of North American Pulmonary Hypertension). Mrs. Coffey, however, was not similar to test subjects in either study who had an enhanced risk of developing PPH from using diet drugs.

Duration of Exposure. Mrs. Coffey was not like the test subjects in SNAPH because that study reported statistically significant results only for people who took Pondimin for ***more than six months***. CXZ, Ex. 4 at 870, 872. Plaintiffs offered no evidence that Mrs. Coffey took Pondimin for more than six months. Rather, the evidence was that she received three 100-pill prescriptions to be taken three times a day. 8RR146-48; 9RR25. If taken as prescribed, Mrs. Coffey would have ingested Pondimin for only three months and ten days, well short of SNAPH’s benchmark of at least six months’ usage. 9RR147-50.⁹

The IPPHS found a statistically significant association between diet drug use and PPH, but *not* among test subjects who took such drugs for three months or less. DX5204.10 at 29, 46; CXHH at 612. Plaintiffs did not prove that Mrs. Coffey even finished her third prescription, and there is evidence she did not. CXZ, Ex. 1 at 94. Thus,

⁹ Dr. Coulter, one of Mrs. Coffey’s treating physicians, testified that Mrs. Coffey told her that she had taken “diet drugs” for six months and that she had taken Pondimin. 14RR58. Dr. Coulter apparently mistook this to mean that Mrs. Coffey had taken Pondimin for six months because Mrs. Coffey failed to mention any of the other diet drugs she had taken. *Id.* at 68-69.

there was legally insufficient evidence – or, at the very least, factually insufficient evidence – that her exposure even exceeded the over-three-month minimum identified by the IPPHS.

In any event, even if Mrs. Coffey’s exposure to PPH had met the “more than three months” threshold of the IPPHS, her failure to meet SNAPH’s “more than six months” threshold remains determinative. *Havner* requires proof that Mrs. Coffey’s duration of exposure was similar to the test subjects in *two studies*, not just one. See note 8, *supra*.

Timing of Disease Onset. Plaintiffs also failed to show that the timing of Mrs. Coffey’s PPH onset was similar to the test subjects in either study.

According to Plaintiffs’ PPH expert (who also was Mrs. Coffey’s treating physician), Mrs. Coffey’s first symptom of PPH was shortness of breath, which began in December 2001 – roughly *four-and-a-half years* after she last took Pondimin. 9OP70; DX5408. SNAPH, however, reported no statistically significant results for test subjects whose PPH symptoms arose more than *six months* after last using Pondimin or Redux. 13RR112; CXZ, Ex. 4 at 872. Similarly, the IPPHS found no statistically significant association between diet drug use and PPH for those whose PPH symptoms arose more than *one year* after their last exposure. DX5204.10; 8RR195-96.

Thus, as to timing of disease onset, Plaintiffs’ PPH and causation expert conceded that the IPPHS failed to show any cause-and-effect relationship for people like Mrs. Coffey. 9RR122. In fact, Plaintiffs’ primary causation expert – an author of the IPPHS – testified that the IPPHS provided statistical evidence *against* any association between diet drug use and PPH for people whose PPH symptoms developed more than a year after their last exposure. 13RR145, 149, 151-53. Under *Havner*, Plaintiffs certainly cannot rely on a study to prove that Pondimin caused Mrs. Coffey’s PPH when that study provides evidence to the contrary for people in her situation.

In sum, Plaintiffs' evidence fails under *Havner* because Mrs. Coffey was not similar to the test subjects in SNAPH or the IPPHS with respect to either duration of exposure or timing of disease onset. Either failure, standing alone, means that Plaintiffs' proof was neither legally nor factually sufficient evidence of causation.

B. Plaintiffs failed to rule out other plausible causes of Mrs. Coffey's PPH.

Despite *Havner's* additional requirement that a claimant rule out alternative plausible causes of her illness, Plaintiffs' experts failed to rule out other causes of Mrs. Coffey's PPH, including one implicated by the IPPHS upon which Plaintiffs relied. Tenuate, a non-Wyeth product, was one of the diet drugs the IPPHS examined. DX5204.10 at 12; 9RR62. Mrs. Coffey took Tenuate at least as frequently as Pondimin. 9RR59; 25OP190-91. She also took Tenuate much closer in time to the onset of her PPH symptoms, a highly relevant fact for assessing causation. 13OP164; *Havner*, 953 S.W.2d at 720.

The onset of Mrs. Coffey's symptoms occurred more than a year after she took Tenuate (and even longer after she took Pondimin). Thus, neither drug could have been a plausible cause of her PPH according to the IPPHS. Nevertheless, over Wyeth's repeated objections, the trial court allowed Plaintiffs to rely on the IPPHS to show that Mrs. Coffey's more remote Pondimin use caused her PPH. If Plaintiffs could rely on the IPPHS for that purpose, however, their experts had to rule out Tenuate as an alternative plausible cause because the IPPHS had reported the *same* increased occurrence of PPH for all diet drug users it studied, including those who used Tenuate. 9RR108-09; *see also* 18OP159.

Rather than deal with this, Plaintiffs just relied on the IPPHS results when Pondimin was at issue and ignored those results when Tenuate was at issue. But Plaintiffs cannot have it both ways, and as their primary causation expert conceded in Wyeth's offer of

proof, which was not allowed before the jury, “it’s certainly possible that [Mrs. Coffey] developed PPH from [Tenuate].” 13OP167. Because none of Plaintiffs’ experts ruled out Tenuate as a cause of Mrs. Coffey’s PPH, their opinions regarding causation were unreliable as a matter of law. *Havner*, 953, S.W.2d at 711-12.

Plaintiffs cannot argue that the IPPHS was insufficient to establish Tenuate as a plausible cause because it did not *separately* report an increased incidence of PPH among those who only used Tenuate. The very same objection could be made about Pondimin; the IPPHS studied diet drugs as a group and reported no results specific to *any* individual drug. Thus, if the IPPHS were insufficient to show that Tenuate may cause PPH, it also would be insufficient to support Plaintiffs’ claim that Pondimin actually caused Mrs. Coffey’s PPH.

Plaintiffs’ causation expert contended that a “plausible cause” may be derived from case reports when epidemiological studies are lacking. 13RR62. The record includes several case reports, outside the confines of the IPPHS, of Tenuate users developing PPH. 9OP60-62. Further, Plaintiffs’ PPH and causation expert admitted that those case reports raised at least a concern of a causal relationship between Tenuate and PPH. 9RR62. Thus, under *Havner*, Plaintiffs’ experts had to rule out Tenuate as an alternative plausible cause of Mrs. Coffey’s PPH for their *methodology* to be reliable. Their failure to do so means their opinions cannot provide legally or factually sufficient evidence of causation. *Robinson*, 923 S.W.2d at 558-59; *Austin v. Kerr-McGee Ref. Corp.*, 25 S.W.3d 280, 292-93 (Tex. App.—Texarkana 2000, no pet.).

C. SNAPH and the IPPHS do not meet *Havner*’s “foundational” reliability requirement.

Under *Havner*, epidemiological studies cannot raise a fact issue on causation unless they show that persons exposed to the drug have more than *double* the chance of developing a particular disease as compared with the “background” risk or incidence of that disease.

Havner, 953 S.W.2d at 717, 723, 727. Both of Plaintiffs’ studies failed this standard. SNAPH never compared the incidence of PPH in exposed individuals with its incidence in an unexposed control group and thus never measured whether exposure to Pondimin “more than doubled” the *background risk* of the disease. CXZ, Ex. 4 at 870-73.¹⁰

The IPPHS also could not raise a fact issue on causation under the *Havner* standard, because that study did not measure exposure to Pondimin alone. Rather, it broadly measured exposure to *any* diet drug from a group that contained not only Pondimin (and the related drug Redux), but also Tenuate (amfepramone/diethylpropion) and three others. DX 5204.10 at 12. Indeed, the test subjects who had used *any* diet drugs had, on average, used more than one of the drugs in that group. *Id.* at 41. Thus, the IPPHS did not and simply could not assess whether *exposure to any particular drug*, standing alone, was associated with any increased incidence of PPH. Plaintiffs’ PPH and causation expert thus had to concede that the IPPHS did not show that Pondimin alone was associated with *any* statistically significant increased risk of PPH. 9RR108-09; 18OP159.

In sum, neither SNAPH nor the IPPHS concluded that exposure to Pondimin alone was associated with a more-than-doubled risk of PPH. Plaintiffs’ expert testimony on causation was, therefore, improperly admitted. *Havner*, 953 S.W.2d at 714 (“If the foundational data underlying opinion testimony are unreliable, an expert will not be permitted to base an opinion on that data because any opinion drawn from that data is likewise unreliable.”); *id.* at 711-12, 715-24; *see also Robinson*, 923 S.W.2d at 556-57; *Gammill v. Jack Williams Chevrolet, Inc.*, 972 S.W.2d 713, 726 (Tex. 1998).

* * *

¹⁰ As even Plaintiffs’ PPH and causation expert admitted, Plaintiffs’ other study – the IPPHS – was “the only case controlled perspective [*sic*, prospective] epidemiological study” in the literature. 9RR127.

Plaintiffs failed to prove causation by legally sufficient evidence. The judgment should therefore be reversed and rendered for Wyeth. Alternatively, Plaintiffs failed to prove causation by factually sufficient evidence, and this Court should vacate and remand for a new trial.

II. The Liability Findings Cannot Support the Judgment.

The Plaintiffs submitted three liability theories to the jury: design defect, marketing defect, and negligence. 3AP2956-58. As discussed below, the jury’s findings on each theory are invalid, preempted, and/or unsupported by legally (or, at the very least, factually) sufficient evidence. For these additional reasons, Wyeth is entitled to rendition of judgment in its favor. Alternatively, at a minimum, a new trial should be granted.

A. The jury’s design defect finding fails as a matter of law.

In response to Question 3, the jury found that Pondimin was defectively designed and that the defect injured Mrs. Coffey. 3AP2958. This finding cannot support the judgment.

1. Texas law does not recognize a claim for “defective design” of a prescription drug.

Texas does not recognize a design defect cause of action for prescription drugs. *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002). In *Hackett*, the court canvassed Texas law and concluded that prescription drugs are “unavoidably unsafe” products that cannot be “defectively designed.” *Id.* (citing RESTATEMENT (SECOND) OF TORTS § 402A & cmt. k (1965)). It also observed that “[t]o allow plaintiffs to sue for defective design of prescription drugs would provide a disincentive to companies to develop new drugs, and would allow juries to second-guess the FDA’s approval of the drugs for marketing.” *Id.* Therefore, the court held that under Texas law, a drug manufacturer can be strictly liable only for marketing a drug without adequate warnings –

not for designing it “defectively.” *Id.*; *see Crocker v. Winthrop Labs.*, 514 S.W.2d 429, 432-33 (Tex. 1974) (because a drug “cannot be made perfectly safe to all users,” court instead considered whether it had been “made reasonably safe by being marketed with adequate warning”).

2. Federal law preempts any claim for defective design of a prescription drug.

In addition, the jury’s finding that Pondimin was defectively designed because its risks outweighed its utility (3AP2958) is preempted by federal law. Federal law preempts state law that undermines federal objectives. U.S. CONST. art. VI, cl. 2; *see Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that FDA regulation preempts state tort claims based on federally regulated activities); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 349 (Minn. Ct. App. 2001) (holding that *Buckman* applies to tort claims against pharmaceutical manufacturers as well as medical device manufacturers). Here, the jury’s finding that an indisputably small risk of PPH meant that Pondimin should not have been sold conflicts with the FDA’s expert judgment to the contrary.

In approving a drug, the FDA must consider its effectiveness and projected benefits as well as its safety and potential risks. *See* 21 U.S.C. §§ 355(d), 393(b)(1), (b)(2)(B); CR3531-33. With respect to Pondimin, the FDA balanced these competing concerns, concluding that the drug’s benefits for morbidly obese patients like Mrs. Coffey outweighed its remote risks and that, on balance, it was “safe and effective.” DX22; *see* 21RR86-89. Throughout the 1996-97 period when Mrs. Coffey was taking Pondimin, the FDA continued to receive and study the latest data available on the risks of Pondimin and the related drug Redux, including the final IPPHS published in August 1996.¹¹ In

¹¹ 10RR107-10 (IPPHS data showing association between diet drugs and PPH was presented to FDA advisory committee, which concluded it “wasn’t really a major issue”); 12RR87; 17RR23; 21RR109-10, 113-14, 119-27,

November 1996, the same month in which Mrs. Coffey began taking Pondimin, the FDA concluded that the benefits of Pondimin outweighed its risks and denied a petition to withdraw it from the market. 22RR27-28. In its decision, the FDA discussed the final IPPHS results and concluded that the risk of developing PPH from taking Pondimin “remains very low” and could be addressed by monitoring case reports and revising the package insert. DX276.¹² In May 1997, the FDA reviewed reports of PPH and heart valve abnormalities and again concluded they had not reached an incidence requiring action. 23RR152-54; DX339.

Despite this extensive FDA review and determination, Plaintiffs asked the jury to find that Pondimin’s design was defective because Wyeth allegedly should have withdrawn Pondimin from the market before Mrs. Coffey began taking it in 1996. 26RR219. To protect the balance struck by the FDA, however, exclusive federal regulation of pharmaceutical product approval preempts state tort claims challenging what the FDA has approved. As the Texas Supreme Court held in *Worthy v. Collagen Corp.*, the FDA’s determination that a product was “safe and effective” and its recurring investigation of the product preempted a plaintiff’s DTPA claims, which were similar to common-law products liability and negligence claims for injuries caused by the product. 967 S.W.2d 360, 375-77 (Tex. 1998); *see also Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1099 (6th

130-36, 140-44, 147-48; 22RR21, 25-27 (discussing history of FDA review of PPH risk); 22RR80 (in 1994-97, FDA had as much information about association between PPH and diet drugs as anyone else in the world); DX705 (FDA review of risk and benefit data for Redux).

¹² *See also* 21RR111 & DX147 at 8-9 (FDA medical officer’s review of IPPHS in September 1995 concluded “absolute incidence of PPH is sufficiently low that the risk associated with anorexigen use is low”); DX154 (FDA medical officer’s conclusion in October 1995 that incidence of PPH is low and risk is therefore acceptable); 12RR172-76, 21RR145-47 & DX210 (FDA concluded in April 1996 that “the adverse reaction . . . PPH which may be associated with [Redux] use is considered an acceptable risk”); 12RR183-85 & DX247 (FDA reviewed final IPPHS results in August 1996 and concluded that the estimated incidence of PPH in users of appetite suppressant drugs “remains low”); 17RR127 (following adverse drug event reports of heart valve problems in March-April 1997, FDA continued to approve Pondimin for sale); 23RR152-54 & DX339 (FDA conclusion in May 1997 that reports of PPH and heart problems have not reached an incidence requiring action); *see also* 23RR148-51.

Cir. 1997); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997).

The holding of *Worthy* applies equally to the FDA's actions in this case. As the FDA itself has explained in arguing for preemption in cases like this one, allowing a jury to second-guess the FDA's risk/benefit conclusions would alter the federal balance and potentially "harm the public health." CR3593 (FDA brief). Under the Supremacy Clause, Wyeth was entitled to rely on the FDA's judgment that, on balance, Pondimin could lawfully be made available for prescription use. For these reasons, Plaintiffs' design defect claim is preempted and fails as a matter of law.

3. *Essential elements of Plaintiffs' claim were not submitted to the jury and are unsupported by the evidence.*

Even if a claim for defective drug design were legally cognizable, Wyeth would be entitled to judgment because Plaintiffs presented no evidence to support an essential element of such a claim. In order to hold a drug manufacturer liable for defective design under section 6(c) of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY,¹³ "the foreseeable risks of harm posed by the drug . . . [must be] sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients." Plaintiffs presented no evidence to satisfy this standard. *See, e.g.*, 9RR95-96; 10RR107-12; 25RR14-19. Indeed, Wyeth proffered testimony from two of Mrs. Coffey's doctors (which the trial judge kept the jury from hearing, 15RR116-22) that, in the exercise of their professional judgment, they had prescribed other similar diet drugs for her because her morbid obesity made the disclosed risk of PPH the lesser of two evils. 23OP29; 25OP188-89. Therefore, Plaintiffs lack legally or, at a minimum, factually sufficient

¹³ Although Texas does not recognize a defective drug design claim, Texas courts have followed section 6 of the Restatement in other contexts. *See Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 185 n.41, 191 n.52 (Tex. 2004) (applying Restatement § 6(d) & cmt. b to marketing defect claim).

evidence to support their design defect claim.

Moreover, Plaintiffs' failure to include this section 6(c) standard in the charge renders the jury's finding of a design defect immaterial. Over Wyeth's objection (CR2615-16), the trial court failed to instruct the jury that a defectively designed drug is one that reasonable physicians would not prescribe for any class of patients. Because the jury was not required to find this essential element before imposing design defect liability, its finding that Pondimin was defectively designed cannot support the judgment.

Alternatively, if section 6(c) of the Third Restatement did not govern any non-preempted design defect claim Texas might recognize, Texas case law interpreting RESTATEMENT (SECOND) OF TORTS § 402A (1965) and RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) would require design-defect plaintiffs to prove a safer alternative design. *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 334-35 (Tex. 1998). Over Wyeth's objection, however, the court also refused to instruct the jury regarding this safer alternative design requirement. CR2617-20.

Because Wyeth objected to the omission of these essential elements from the charge, the jury's finding of design defect is immaterial under any arguable legal standard and cannot support the judgment. *Spencer v. Eagle Star Ins. Co.*, 876 S.W.2d 154, 157 (Tex. 1994). At a minimum, the trial court's erroneous charge regarding the proper elements of the Plaintiffs' design defect claim requires a new trial. TEX. R. CIV. P. 274.

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

In response to Question 2, the jury found that Pondimin was defectively marketed and that the defect injured Mrs. Coffey. 3AP2957. This finding fails under the "learned intermediary" doctrine, is erroneously premised on an alleged failure to warn of a risk that did not materialize, is unsupported by legally or factually sufficient evidence, and is

preempted by federal law.

1. The finding fails under the learned intermediary doctrine.

Under the learned intermediary doctrine, a prescription drug manufacturer is required to warn only the prescribing physician about reasonably foreseeable potential risks associated with the drug. If it provides such warnings, the patient may not claim that the manufacturer also had a duty to warn her directly. *See, e.g., Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 91 (Tex. App.—Texarkana 2000, no pet.); *Burton v. Am. Home Prods. Corp. (In re Norplant Contraceptive Prods. Liab. Litig.)*, 955 F. Supp. 700, 703 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999).

Plaintiffs failed to prove that Dr. Tyrrell was not adequately warned of the risks of PPH that were foreseeable when he prescribed Pondimin to Mrs. Coffey. Wyeth used numerous channels to inform medical professionals of the potential association between Pondimin and PPH. Wyeth updated the Pondimin label in June 1996 – five months before Dr. Tyrrell wrote Mrs. Coffey’s first prescription – to warn of the interim IPPHS results. 23RR58; DX1067. As one of Plaintiffs’ experts agreed, changing the label is “informing the public” because the label is “a well-designed communication conduit, a route to get to physicians and patients.” 12RR53. This label also was incorporated into the 1997 PDR, which was on the shelves of doctors by November 1996. The PDR “is the place that [doctors] often go to look for risks and benefits . . . [on] a large compendium of drugs” – “kind of [their] Bible, if you will.” 20RR37. *See also* 11RR71; 15RR191, 202-03 (doctors commonly rely on the PDR); 20RR68-69 (medical students are taught to look up a drug in the PDR to determine its adverse effects).

After the final IPPHS results were published in August 1996, Wyeth revised the Pondimin label in November 1996 to warn of those results. 17RR33; DX1067 at 15-16.

Wyeth then sent letters to hundreds of thousands of doctors and pharmacists discussing those results. 12RR185-86; 22RR40; 7AP. This label – which even today represents the most complete and reliable information about the potential risks of PPH in association with diet drugs, 13RR115; 17RR28, 35-36 – was in effect well before Dr. Tyrrell wrote Mrs. Coffey’s third Pondimin prescription in June 1997. 17RR33; 18RR25; 19RR140, 161; 25RR9.

Furthermore, before Dr. Tyrrell wrote this third prescription, the label warning of the final IPPHS results was published in a supplement to the 1997 PDR. 6AP, Ex. 237 at 2; 17RR18; *see also* 17RR35-36; 18RR129-30. This warning is particularly important, because it was Mrs. Coffey’s third 100-pill prescription that, if completely taken, would have placed her at or near the threshold of increased PPH risk identified in the IPPHS. By this time, even Plaintiffs’ PPH expert agreed that the potential risk of PPH associated with Pondimin was widely known. *See* 9RR95. Thus, there is no legally or factually sufficient evidence that Dr. Tyrell was inadequately warned of the PPH risks. His expert decision to prescribe the drug forecloses any claim that Wyeth “defectively marketed” Pondimin.

2. *Failure to warn of a risk that did not materialize is not actionable.*

To decide whether warnings were adequate in a case involving prescription drugs, courts and juries may consider only whether the warnings sufficiently informed the doctor of the risk of the particular condition or disease that allegedly caused the plaintiff’s injury or death. *See In re Norplant Contraceptive Prods. Liab. Litig.*, No. MDL 1038, 1997 WL 81094, at *1 (E.D. Tex. Feb. 21, 1997); *Technical Chem. Co. v. Jacobs*, 480 S.W.2d 602, 605 (Tex. 1972) (“[W]hen a product is defective due to inadequate labeling, ‘the aspect of the defendant’s conduct that made the sale of the product unreasonably dangerous (i.e., the label) must be found to have contributed to the plaintiff’s injury.’ ”); *see also* CR3302 n.6

(citing cases). Thus, any alleged failure to warn of heart valve risks or other conditions that Mrs. Coffey did not suffer is not legally or factually sufficient evidence of a marketing defect. For these reasons, the jury's answer to Question 2 should be disregarded or, alternatively, a new trial ordered.

3. *There is no evidence that a different warning would have changed Dr. Tyrrell's decision to prescribe Pondimin.*

A marketing defect claim also requires proof that a proper PPH warning would have changed the physician's decision to prescribe the drug. *Medrano*, 28 S.W.3d at 91, 94; *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 912 (Tex. App.—El Paso 1989, writ denied); *In re Norplant*, 955 F. Supp. at 710-11. Thus, Plaintiffs were required to show that, but for the allegedly inadequate PPH warning, Dr. Tyrrell would not have prescribed Pondimin for Mrs. Coffey. In this case, however, there is no legally or factually sufficient evidence that any change in the warning regarding the risks of PPH would have caused Dr. Tyrrell not to prescribe Pondimin.

Instead, the evidence showed that Pondimin had measurable weight loss benefits and related health benefits for profoundly obese people like Mrs. Coffey.¹⁴ By contrast, the risk of developing PPH from taking Pondimin for even extended periods remained very rare. Plaintiffs stipulated that the late Dr. Tyrrell acted reasonably in evaluating the risks and benefits of Pondimin and prescribing it to Mrs. Coffey. 18RR219. Wyeth's experts agreed.¹⁵ Moreover, two other doctors who treated Mrs. Coffey for her life-threatening

¹⁴ *E.g.*, 9RR150-54 (weight loss studies); 18RR200-08 (study regarding health benefits of weight loss and evidence that Pondimin was effective in helping patients initiate weight loss program); *id.* at 203 (Mrs. Coffey lost 35 lbs. while taking Pondimin); 20RR39 (Dr. Elders' testimony that her patients had good results with Pondimin); *see also* DX154, 178, 181, 210 (FDA data on related drug Redux show weight loss and expected reduction in health risks).

¹⁵ *See* 18RR231, 234 (it was appropriate for Dr. Tyrrell to prescribe Pondimin for Mrs. Coffey because "her obesity was a very huge risk for her, not only at the present time but also in the future. And I felt that she was a good, very good candidate to take anorexigen drugs."); 20RR73, 75 (balancing risks and benefits, it was appropriate for a doctor to prescribe Pondimin to an obese patient in 1996-97); 25RR14-16 (prescribing Pondimin

obesity were prepared to testify that they prescribed for her other diet drugs with PPH warnings, after balancing minimal risks against substantial benefits. Even Plaintiffs' PPH expert stated that she was not critical of Dr. Tyrrell's decision to prescribe Pondimin to Mrs. Coffey. 9RR94-95. This evidence, together with Plaintiffs' stipulation, forecloses their marketing defect claim. At a minimum, the evidence is factually insufficient to support the jury's marketing defect finding.

4. Plaintiffs' defective marketing claim is preempted by federal law.

Federal law preempts Plaintiffs' defective marketing claim. Plaintiffs urged the jury to find the FDA-approved warning defective because it did not say: "Warning, this drug is unsafe and unreasonably dangerous. . . . Use it at your own risk." 26RR154. The jury's "defective warning" finding conflicts with the FDA's expert decision to approve Pondimin as safe and effective *as labeled*.

The FDA heavily regulates both the substance and format of drug labeling. *See* 21 CFR pt. 201; *id.* § 201.57. It has authority to withdraw approval of a drug if its labeling is "false or misleading in any particular" and is "not corrected within a reasonable time after receipt of written notice" of the problem. 21 U.S.C. § 355(e). *See generally* 21 U.S.C. § 355(b)(1)(F); 21 CFR pt. 201 (labeling requirements); 21 CFR § 314.70 (labeling changes).

In approving Pondimin's initial label, the FDA balanced competing concerns. These concerns included the possible incremental benefit of additional warnings to certain patients, as well as the risk that additional warnings would dilute the effectiveness of other warnings or over-deter patients who might benefit from the drug. CR3556. The FDA determined that the label Wyeth used provided the appropriate mix of warnings. *See* DX22

was reasonable because "the benefits . . . of getting her to lose weight and have her sustain that over a period of time . . . far outweigh that small and rare risk [of PPH]").

(finding drug “safe and effective for use as recommended in the submitted labeling”). After approving this label, the FDA continued to monitor safety data regarding Pondimin, to approve or reject labeling changes proposed by the manufacturer, and to require labeling changes when necessary.¹⁶

The exclusive federal regulation of pharmaceutical warning labels preempts tort claims challenging as inadequate what the FDA has approved. *See Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796-98 (8th Cir. 2001); *Martin*, 105 F.3d at 1099. In this case, “[t]he record demonstrates that the FDA was aware of a possible link between” Pondimin and PPH and the FDA expressly approved the disclosures and warnings Wyeth was providing when Dr. Tyrrell prescribed Pondimin for Mrs. Coffey. Plaintiffs’ claim that the labeling was “defective” is, therefore, preempted. *Brooks*, 273 F.3d at 797-98.

C. Plaintiffs’ negligence claim fails because it is functionally identical to their flawed design and marketing defect claims.

When a plaintiff relies on the same alleged defect to support both negligence and strict liability claims and offers no independent evidence of negligence, the claims are functionally identical and stand or fall together. *See Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 665-67 (Tex. 1999); *Ford Motor Co. v. Miles*, 141 S.W.3d 309, 315 (Tex. App.—Dallas 2004, pet. filed). Here, Plaintiffs offered the same legally and factually insufficient evidence to support both their negligence claims and their flawed claims that Pondimin’s design and warnings were defective. Thus, for all the same reasons that

¹⁶ *See, e.g.*, DX23, 24, 27, 29, 31, 36 (labeling changes for Pondimin 1976-83); DX49 (FDA requested inclusion of precaution regarding pulmonary hypertension in 1987); 22RR72-73 & DX84 (FDA considered changing label regarding PPH risk in 1994 but decided against it); 17RR14-15, 22RR31-32, 34-36, 23RR58 (based on discussions with FDA and “what they would like to see included,” Pondimin label updated June 1996 to warn of interim IPPHS results); 17RR33 (FDA approved update of Pondimin label in November 1996 to warn of final IPPHS results); 17RR39, 44; 22RR40 & 7AP (Wyeth sent “Dear Doctor” letters to doctors and pharmacists with updated product labels); 22RR35-37, 57-58 (FDA rejected proposed label for related drug Redux that would update warning of PPH risks); DX217 (revising Pondimin labeling based on FDA suggestions); DX1067 (showing changes in Pondimin labeling).

Plaintiffs cannot recover on their strict liability claims for design and marketing defect, including preemption by federal law, they cannot recover under theories of negligent design or warning. *See, e.g., Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) (negligent design and manufacturing claims failed as a matter of law for same reason strict liability design defect claim failed); *Brooks*, 273 F.3d at 796-98 (negligent failure-to-warn claim preempted by exclusive FDA regulation of labeling); *Mitchell*, 126 F.3d at 913 (negligent design claim preempted by FDA determination that product was safe and effective).

Furthermore, because Plaintiffs' negligence claim is functionally identical to their design and marketing defect claims, it should not even have been submitted to the jury. 3AP2956 (Question 1); *Hyundai*, 995 S.W.2d at 665 ("to avoid confusing the jury and the possibility of inconsistent findings" court should not submit two claims that call for same defect finding); *Miles*, 141 S.W.3d at 315-18; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. n (1998) ("[T]wo or more factually identical defective-design claims or two or more factually identical failure-to-warn claims should not be submitted to the trier of fact in the same case under different doctrinal labels.").

At a minimum, the court's erroneous broad-form negligence charge included theories of negligent design and marketing that are invalid, preempted, and/or supported by insufficient evidence for the reasons discussed above. CR2585 (charge objection). Thus, it is impossible to tell whether the jury answered the negligence question "yes" based on one or more invalid theories. In addition, because the trial court submitted only one set of damages questions for all of Plaintiffs' claims, it is impossible to tell whether the jury awarded damages based on one or more invalid negligence theories. Therefore, Wyeth is entitled at least to a new trial. *Harris County v. Smith*, 96 S.W.3d 230, 232-34 (Tex. 2002);

Crown Life Ins. Co. v. Casteel, 22 S.W.3d 378, 387-89 (Tex. 2000); *San Antonio Credit Union v. O'Connor*, 115 S.W.3d 82, 102-03 (Tex. App.—San Antonio 2003, pet. denied).

* * *

As demonstrated above, the jury's findings on Plaintiffs' three liability theories fail as a matter of law and Wyeth is entitled to rendition of judgment in its favor. Alternatively, the evidence is factually insufficient to support the jury's findings on Plaintiffs' three liability theories. Even if this Court reverses only one or two of the liability theories, however, a new trial is required. Because the trial court submitted only one set of damages questions for all of Plaintiffs' claims, it is impossible to tell whether the jury's damage awards were based on any reversed liability theories. Therefore, Wyeth is entitled to a new trial on all issues. *Harris County*, 96 S.W.3d at 232-34; *Crown Life Ins. Co.*, 22 S.W.3d at 387-89; *San Antonio Credit Union*, 115 S.W.3d at 102-03.

SECTION TWO: ERRORS IN DAMAGES

III. The Jury Awarded Unproven and Unrecoverable Actual Damages.

Plaintiffs' only evidence about any specific amount of actual damages supported an award of about \$1.5 million, yet the jury awarded them over \$113 million in supposedly "actual" damages. If judgment is not rendered for Wyeth or a new trial ordered, this award must be reduced or remitted substantially. It includes damages unrecoverable as a matter of law as well as damages that were not supported by legally or factually sufficient evidence.

A. There is no legally or factually sufficient evidence of compensatory economic damages beyond \$1.5 million.

The parties stipulated that Mrs. Coffey's medical expenses were \$444,351. 15RR62-64, 68-69. The only other testimony on economic damages was that Mrs.

Coffey's lost earning capacity was \$428,179 at most,¹⁷ and that the value of her lost household services was \$637,035 at most. 15RR54-56. These three figures total \$1,509,566, which includes \$12,862 in lost household services suffered by Mr. Coffey before Mrs. Coffey's death that as a matter of law are not recoverable. 15RR54-55; *see supra* Part III.E. Thus, the maximum amount of recoverable economic ("pecuniary") damages recoverable on this record is \$1,496,704, almost exactly what Plaintiffs' counsel claimed in closing. 26RR227 ("The pecuniary loss with the death is \$1.5 million.").

The jury, however, awarded \$26,723,000 in damages for economic and "pecuniary" loss. 3AP2961-68 (Questions 6(a)-9(a)). Because no legally or factually sufficient evidence supports this amount, Wyeth is entitled to a new trial. *See Formosa Plastics Corp. USA v. Presidio Eng'rs & Contractors, Inc.*, 960 S.W.2d 41, 51 (Tex. 1998). Alternatively, this Court should remit the jury's award of economic/pecuniary damages to \$1.5 million because the evidence supporting an award above this level is so factually insufficient and against the great weight and preponderance of the evidence as to be manifestly unjust. *See Pope v. Moore*, 711 S.W.2d 622, 624 (Tex. 1986) (per curiam); *Gray v. Allen*, 41 S.W.3d 330, 332 (Tex. App.—Fort Worth 2001, no pet.).

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

The jury's decision to award an amount of economic damages more than fifteen times greater than the amount claimed by Plaintiffs' counsel likely resulted from the way the questions were asked. At Plaintiffs' request, and over Wyeth's objections, CR2654, the court commingled economic and non-economic damages in its definition of "pecuniary loss." Specifically, the charge allowed the jury to award loss of care, maintenance, support, services, advice, and counsel as a form of economic or "pecuniary" damage. *See* 3AP2961,

¹⁷ Plaintiffs' expert Dr. Mayor testified that Mrs. Coffey's maximum loss was \$535,224 and that would have to be reduced by at least 20% for personal consumption. 15RR40-50, 53-55.

2963. But those forms of loss are intangible and non-economic in nature: in fact, they fall within the court’s definitions for loss of parental and spousal consortium, *see* 3AP2968, 2970, which are defined as non-economic by statute. *See* TEX. CIV. PRAC. & REM. CODE ANN. (hereinafter, “CPRC”) § 41.001 (Vernon Supp. 2004-2005); *see also* *Mercy Hosp. v. Rios*, 776 S.W.2d 626, 635-36 (Tex. App.—San Antonio 1989, writ denied) (holding that loss of services, advice, counsel, nurture, and care are intangibles to the extent they go beyond actual financial contributions). Because it cannot be determined what portion of the jury’s award here is economic versus non-economic damages, Wyeth cannot obtain meaningful appellate review of whether each damage element is supported by sufficient evidence. Therefore, a new trial is required. *See Harris County*, 96 S.W.3d at 232-34.

Similarly, with respect to non-economic damages, the jury awarded the amazing sum of \$69,380,000 for “loss of society and companionship and mental anguish” and “physical pain and mental anguish.” Despite Wyeth’s objection, the jury was not asked to segregate mental anguish damages from other non-economic damages as the law requires.¹⁸

C. There was no legally or factually sufficient evidence to support the amounts of non-economic damages awarded.

Although a jury has some discretion to determine non-economic damages, it cannot award any arbitrary amount. *See Saenz v. Fid. & Guar. Ins. Underwriters*, 925 S.W.2d 607, 614 (Tex. 1996) (“Not only must there be evidence of the existence of compensable mental anguish, there must also be some evidence to justify the amount awarded.”); *id.* (“There must be evidence that the amount found is fair and reasonable compensation, just as there must be evidence to support any other jury finding.”); *Bentley v. Bunton*, 94

¹⁸ *See Minn. Mining & Mfg. Co. v. Nishika Ltd.*, 953 S.W.2d 733, 739 (Tex. 1997) (an “unsegregated damages award . . . ordinarily requires a remand” for new trial); *Harris County*, 96 S.W.3d at 232-34 (reversing and remanding where damages questions commingled several elements, including some that were supported by no evidence).

S.W.3d 561, 605-07 (Tex. 2002) (plurality) (holding that “no evidence” supported jury’s finding of \$7 million in mental anguish damages, where evidence justifying that amount was lacking). Here, the jury awarded non-economic damages of at least \$38,130,000 to Mrs. Coffey’s children, \$30,000,000 to Mr. Coffey, and \$18,500,000 to Mrs. Coffey’s estate. These massive and unprecedented amounts were simply plucked out of the air.

In judging the reasonableness of non-economic damages awards, courts may also examine results from other cases.¹⁹ No Texas decision in a wrongful death case has affirmed an award of non-economic damages that even remotely approaches the one in this case. Rather, the highest recently-affirmed award was only \$3 million on a per-plaintiff basis.²⁰ Indeed, there is nothing in this case that would justify awarding non-economic damages at the highest level ever allowed in a wrongful death case. Thus, no legally or factually sufficient evidence supports the *amount* of the jury’s awards of \$86 million in non-economic damages. A remittitur or new trial is required. *See Best Steel Bldgs., Inc. v. Hardin*, 553 S.W.2d 122, 133 (Tex. Civ. App.—Tyler 1977, writ ref’d n.r.e.).

As the verdict reflects, the jury’s award was based on a one-sided record. For example, Mr. Coffey was allowed to assert that he and his wife had been married for eleven years, when in fact they had only been married eight *months* when Mrs. Coffey died. 10RR6; 14RR119; 14OP194-200. The court erroneously excluded evidence that Wyeth proffered showing that Mr. and Mrs. Coffey actually had not married until May 2002, one month before Plaintiffs filed this suit. 14OP194-95; 14RR195-99; 15RR12-15, 89-93; CR2. The excluded evidence was relevant not only to the issue of Mr. Coffey’s credibility,

¹⁹ *See Lee Lewis Constr., Inc. v. Harrison*, 64 S.W.3d 1, 14-16 (Tex. App.—Amarillo 1999), *aff’d*, 70 S.W.3d 778 (Tex. 2001); *Moses v. Adams*, 428 S.W.2d 131, 134 (Tex. Civ. App.—Beaumont 1968, writ ref’d n.r.e.).

²⁰ *See Love v. CF & H Corp.*, 89 S.W.3d 68 (Tex. App.—El Paso 2002, pet. denied) (\$9.03 million damages award divided among estate and two beneficiaries).

but also to the amount of actual damages that could be awarded, including for loss of consortium and loss of household services. 15RR12-15. There is no way to tell what a properly informed jury would have awarded, so Wyeth is entitled to a new, untainted trial.

D. Alternatively, the non-economic damages awards violate the Texas and United States Constitutions.

Non-economic damages are not prone to precise calculation and, if left unchecked, can become the source of arbitrary exactions and an improper form of punishment. If the preceding arguments regarding the jury's awards of non-economic damages did not demonstrate that Wyeth is entitled to a substantial remittitur or new trial, then current Texas procedure for reviewing non-economic damages awards would be constitutionally inadequate.²¹

Trial courts and appellate courts must subject jury awards of non-economic damages to the same substantive and procedural protections that apply to awards of exemplary damages. Under those standards, a new trial would be required here. The jury's award of non-economic damages was unconstitutional because, among other things, it was more than fifty times Plaintiffs' actual economic damages. In addition, the charge contained no provisions to prevent jurors from using non-economic damages to punish, and Plaintiffs' counsel exhorted the jury to do just that. 26RR226; *see Bentley*, 94 S.W.3d at 605-07 (plurality) (expressing concern that large non-economic damages award showed disapproval of defendant rather than compensation for plaintiff); *Schindler Elevator Corp. v. Anderson*, 78 S.W.3d 392, 417-23 (Tex. App.—Houston [14th Dist.] 2001, pet. granted, judgment vacated) (Brister, C.J., dissenting from denial of rehearing en banc) (mere factual sufficiency review may cause constitutional error, if it allows compensatory damages to be

²¹ *See* U.S. CONST. amend. V (Due Process Clause); U.S. CONST. amend. VII (right to trial by jury); U.S. CONST. amend. XIV, § 1 (Due Process Clause); TEX. CONST. art. I, § 15 (right to trial by jury); TEX. CONST. art. I, § 19 (due course of law provision); TEX. CONST. art. V, § 10 (right to trial by jury).

imposed that are punitive in nature without adequate procedural protections); *see also* Hon. Paul V. Niemeyer, *Awards for Pain and Suffering: The Irrational Centerpiece of Our Tort System*, 90 VA. L. REV. 1401, 1415 (2004) (concluding that “awards for pain and suffering are even more vulnerable to constitutional attack” than punitive damages). Thus, at a minimum, Wyeth is entitled to a new trial that includes procedural and substantive protections against the punitive use of non-economic damages.

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

Over Wyeth’s objection, the jury was allowed to award \$9,763,000 to Mr. Coffey and the three children for damages incurred before Mrs. Coffey’s death. 3AP2968, 2970. But such pre-death damages are not recoverable by a decedent’s family under Texas law. As a threshold matter, *all* common-law claims are extinguished when a decedent dies:

At common law . . . no personal injury cause of action survived a victim’s death. The victim’s heirs could not sue on behalf of the victim or for their own losses due to the tortious act. Because wrongful-death and survival actions would not exist absent legislative enactment, they are derived not from the common law but from a statute.

Horizon Healthcare Corp. v. Auld, 34 S.W.3d 887, 903 (Tex. 2000) (citations omitted).

In this case, no statute authorizes an award of pre-death damages to Mrs. Coffey’s relatives. The statute governing wrongful death actions limits damages to those “resulting from the [decedent’s] death,” which by definition excludes pre-death damages. CPRC § 71.010(a) (Vernon 1997). Under the statute governing survival actions, some pre-death damages are recoverable, but only those incurred by the *decedent* (whose estate here received a separate and excessive award of \$19,270,000). *See Russell v. Ingersoll-Rand Co.*, 841 S.W.2d 343, 345 (Tex. 1992) (holding that “[t]he damages recoverable [in a survival action] are those which [the decedent] himself sustained while he was alive *and not any damages claimed independently by the survival action plaintiffs*”); CPRC

§ 71.021(a) (Vernon 1997) (emphasis added). Thus, as a matter of law, that portion of the judgment awarding \$9,763,000 in pre-death damages to Mrs. Coffey’s relatives must be vacated and judgment rendered against those Plaintiffs on their claims for such damages.

IV. The Jury’s \$900 Million Exemplary Damage Award Must Be Vacated or, at a Minimum, Massively Reduced.

A. Plaintiffs cannot recover exemplary damages because the evidence does not support the jury’s “malice” finding in Question 4.

To hold Wyeth liable for exemplary damages, Plaintiffs had to prove by clear and convincing evidence that the injury to Mrs. Coffey “resulted from malice.” 3AP2959 (Question 4); *see* CPRC § 41.003(a) (Vernon Supp. 2004-2005). The trial court defined “malice” as “an act or omission by Wyeth:

- a. which, when viewed *objectively* from the standpoint of Wyeth at the time of its occurrence, involved an *extreme degree of risk*, considering the *probability* and magnitude of the potential harm to others; and
- b. of which Wyeth had actual subjective awareness of the risk involved, but nevertheless proceeded with *conscious indifference* to the rights, safety, or welfare of others.”

3AP2959 (emphasis added); *see* CPRC § 41.001(7)(b) (Vernon 1997).²² Part (a) is the “objective” component of malice and part (b) is the “subjective” component. *Transp. Ins. Co. v. Moriel*, 879 S.W.2d 10, 22-23 (Tex. 1994); *N. Am. Van Lines, Inc. v. Emmons*, 50 S.W.3d 103, 127-28 (Tex. App.—Beaumont 2001, pet. denied). If proof of either component is lacking, a finding of malice cannot stand. *Emmons*, 50 S.W.3d at 128.

Here, the allegedly malicious conduct could only have been Wyeth’s conduct in connection with the sale and marketing of its prescription drug Pondimin. As discussed elsewhere in this brief, however, the FDA’s conscious decision to authorize Wyeth to market Pondimin during the period in question preempts a state court from resting any

²² For cases filed beginning September 1, 2003, this definition appears in CRPC § 41.001(11) (Vernon Supp. 2004-2005) under the heading “gross negligence.”

form of tort liability on that federally-authorized conduct. In any event, the jury's finding that Wyeth acted with malice is not supported by legally or factually sufficient evidence of either the objective or subjective components, especially under the clear and convincing evidence standard.

1. Objective component: no extreme risk of PPH

For purposes of deciding whether Wyeth's conduct in selling and marketing Pondimin involved an "extreme degree of risk," the only pertinent risk is the risk of PPH in association with Pondimin. Only Wyeth's conduct in connection with that risk could possibly have "resulted" in "injury" to Mrs. Coffey. CPRC § 41.003(a) (Vernon Supp. 2004-2005); 3AP2959. This statutory conclusion is reinforced by Texas and United States Supreme Court authority requiring a causal link between the conduct upon which a malice finding authorizing exemplary damages is based and the injury claimed by the plaintiff.²³

The objective component "is not satisfied if the defendant's conduct merely creates a remote possibility of serious injury; rather, the defendant's conduct must create the 'likelihood of serious injury' to the plaintiff." *Universal Servs. Co. v. Ung*, 904 S.W.2d 638, 641 (Tex. 1995) (emphasis added). Admittedly, PPH is a serious disease. But the *probability* of harm is slight, as Plaintiffs' own experts conceded. 12RR206; 13RR114. As discussed in Part I, there is no evidence that Mrs. Coffey's Pondimin use caused her (or others in her category of durational use) to be at increased risk of developing PPH, but even people who are at an increased risk according to the IPPHS have an extremely low risk. Indeed, the undisputed evidence shows that the risk of developing PPH is less than 1/100th of one percent, even among diet drug users. *See* Part II.B.3., *supra*. Thus, any risk was

²³ *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003); *Green Tree Fin. Corp. v. Garcia*, 988 S.W.2d 776, 787 (Tex. App.—San Antonio 1999, no pet.); *Huynh v. R. Warehousing & Port Servs., Inc.*, 973 S.W.2d 375, 378 (Tex. App.—Tyler 1998, no pet.); *First Am. Title Ins. Co. v. Willard*, 949 S.W.2d 342, 351 (Tex. App.—Tyler 1997, writ denied).

remote and unlikely at worst. In light of this evidence, the risk to Mrs. Coffey did not, as a matter of law, involve the type of extreme degree of risk required by *Moriel*, *Ung*, and similar cases.

In *Ung*, for example, a highway construction worker died when a car hit a pothole that the defendant knew existed and that had caused at least one prior accident. The Texas Supreme Court held that, even though the magnitude of the harm was as severe as here (death), no extreme degree of risk was present because the probability of harm was so low. 904 S.W.2d at 641.

The same analysis applies here. Because there was no more than a one-in-ten-thousand chance of developing PPH from using this potentially life-saving drug, no reasonable jury could form “a firm belief or conviction” that Wyeth’s conduct was so extreme as to create the “*likelihood*” of serious injury to Mrs. Coffey. *S.W. Bell Tel. Co. v. Garza*, 48 TEX. SUP. CT. J. 226, 239, 2004 WL 3019205, at *15 (Dec. 31, 2004) (not yet released for publication). Thus, there is no legally or factually sufficient evidence that Wyeth’s conduct in selling Pondimin created an extreme degree of risk of the sort necessary to constitute malice.

2. Subjective component: no evidence that Wyeth was actually aware of, but consciously disregarded, any extreme degree of risk.

Nor is there legally or factually sufficient evidence that Wyeth was actually aware of an extreme degree of risk but that it proceeded with “conscious indifference” to safety, resulting in injury to Mrs. Coffey. The final IPPHS results were published in the *New England Journal of Medicine* in August 1996, and Wyeth then sent letters to hundreds of thousands of doctors and pharmacists discussing those results so that doctors could evaluate potential risks and benefits for their morbidly obese patients. 12RR185-86; 22RR40. Then, in November 1996, Wyeth revised the Pondimin label to include the final

IPPHS results and consequent warnings. 7AP. Even today, this label represents the most complete and reliable information about the potential risks of PPH in association with diet drugs. 13RR115; 17RR28. In addition, this label was published in a supplement to the 1997 PDR before Dr. Tyrrell wrote Mrs. Coffey's third prescription in June 1997. Throughout this period, the FDA was reviewing the same data and was satisfied that Wyeth could responsibly continue making Pondimin available for prescription.

Given this history of warnings regarding the IPPHS results, no reasonable jury could form a firm conviction, based on clear and convincing evidence, that Wyeth was "consciously indifferent" to the safety risks presented by PPH during the time frame that Mrs. Coffey took the drug. To the contrary, the warnings demonstrate that Wyeth did care about these risks and took extensive steps to enable physicians to make informed medical judgments about whether to prescribe the drug. *Cf. Diamond Shamrock Ref. Co. v. Hall*, 48 TEX. SUP. CT. J. 354, 2005 WL 119950, at *8 (Jan. 21, 2005) (not yet released for publication) (to prove malice, plaintiff must offer clear and convincing evidence "that the defendant knew about the peril, but his acts or omissions demonstrate that he did not care"). Although Plaintiffs may argue that, in hindsight, Wyeth should have warned about the IPPHS earlier or should have tried to warn Dr. Tyrrell in a different manner, those arguments would imply negligence at worst – not malice. *La.-Pac. Corp. v. Andrade*, 19 S.W.3d 245, 247 (Tex. 1999) ("Evidence of simple negligence alone is not sufficient to establish gross negligence.").

3. Plaintiffs' "expert" testimony on Wyeth's state of mind is not legally or factually sufficient to support the jury's malice finding, and its erroneous admission independently requires a new trial.

Plaintiffs' only direct "evidence" to support a finding of malice consisted of conclusory characterizations by their experts. 8RR140-41; 11RR189-92; 15RR203, 209.

However, as the Texas Supreme Court recently held in *Coastal Transport Co. v. Crown Central Petroleum Corp.*, 136 S.W.3d 227, 231-33 (Tex. 2004), an “expert’s” conclusory assertions do not constitute legally sufficient evidence of malice or gross negligence (or anything else) and certainly are not sufficient to support an award of exemplary damages.

Moreover, the trial court erred in permitting Plaintiffs’ “experts” to testify (over Wyeth’s objections) about Wyeth’s alleged mental state and to speculate whether it supported an award of exemplary damages. 7RR122-24; 11RR30-31. Plaintiffs’ science and medical experts, Drs. Moye and Busch, testified that they believe that Wyeth used underhanded tactics to mislead the public, doctors, and the FDA about the heart valve and PPH risks of Redux and Pondimin; employed a policy of intentional ignorance regarding the risks of Pondimin; acted with malice; was motivated by corporate greed; and should have acted differently as a matter of basic morality.²⁴ These opinions were based on the doctors’ own characterizations of disputed facts regarding Wyeth’s corporate conduct. Moreover, they were couched in the strongest of terms, including “conscious indifference,” “dangerously misleading,” “inexcusable,” “shameful,” “reprehensible,” “disembowel,” and “kiss of death.” 8RR141; 11RR74, 110, 152; 15RR188-92.

The court erred in admitting this “expert” evidence, because it was not based on scientific, technical, or other specialized knowledge. *See* TEX. R. EVID. 702. “Except in highly unusual circumstances, expert testimony concerning extreme and outrageous conduct” does not meet this requirement. *GTE S.W., Inc. v. Bruce*, 998 S.W.2d 605, 620 (Tex. 1999). *See also In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine)*

²⁴ As to alleged misleading, see 8RR140-41; 11RR61, 83-86, 91-93, 132-33; 11RR93, 95-96, 97-105, 166, 178; 15RR154-55, 188-92, 194-95, 201-204, 210-11. On alleged underhanded tactics, see 11RR105-12, 123-25, 135-136, 138-39, 142-44, 147-52, 179-80, 181-84; 8RR131-32. Regarding alleged intentional ignorance, see 8RR46-48, 74, 122. As to alleged malice, see 11RR189-92, 15RR203, 209; 8RR140-41. With respect to alleged greed, see 8RR92, 126-28; 11RR74, 80-82. On alleged immorality, see 15RR209.

Prods. Liab. Litig., No. MDL 1203, 2001 WL 454586, at *24 (E.D. Pa. Feb. 1, 2001) (granting motions to exclude expert testimony of five witnesses on Wyeth’s corporate intent based on its conduct). This case is no exception, as there is no such thing as a reliable “scientific method” to ascertain corporate intent. Instead, that issue “is a classic jury question and not one for experts.” *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000). Plaintiffs’ witnesses did not even attempt to establish any scientific basis for their opinions or for their resolution of disputed fact issues that were the foundation for their opinions. At best, these witnesses formed litigation-based opinions from a review of documents selected by Plaintiffs’ counsel. That method has not been shown to be reliable by any scientific standard.²⁵

Even if testimony regarding corporate intent theoretically could be the subject of expert testimony, *these* particular witnesses failed to demonstrate any qualifications to render such opinions in this case. *See Broders v. Heise*, 924 S.W.2d 148, 152-53 (Tex. 1996); *Robinson v. Warner-Lambert Co.*, 998 S.W.2d 407, 411 (Tex. App.— Waco 1999, no pet.). Plaintiffs’ witnesses were medical doctors with specialized knowledge in statistics and pharmacology, respectively. Neither purported to have any expertise in assessing corporate intent based on corporate conduct, let alone with respect to the major issues in this case. Indeed, other courts, including another Texas trial court, have precluded these *same* two professional plaintiffs’ witnesses, Drs. Moye and Busch, from giving “expert

²⁵ *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (an important issue in assessing reliability is whether an expert’s testimony grew out of research independent of litigation or whether it was litigation driven); *see also Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1179 (4th Cir. 1997) (excluding litigation driven expert testimony); *Metabolife Int’l, Inc. v. Wornick*, 72 F. Supp. 2d 1160, 1168-69 (S.D. Cal. 1999) (same), *aff’d in part, rev’d in part*, 264 F.3d 832 (9th Cir. 2001).

testimony” on Wyeth’s corporate intent in other diet drug cases.²⁶ For these reasons, their testimony should have been excluded and cannot support the jury’s malice finding in this case. Likewise, the erroneous admission of such unfairly prejudicial evidence was harmful error requiring, at a minimum, a new trial.

4. No evidence that a Wyeth officer or manager committed a “malicious” act.

Furthermore, the malice finding must be set aside because Plaintiffs failed to prove that the specific, allegedly malicious act on which they focused was committed by a person of the requisite level of management responsibility. Throughout the trial and in closing argument, Plaintiffs argued that Amy Myers had acted with the requisite “malice” when she overwrote the preliminary computer files concerning heart valve disease instead of merely canceling them pending receipt of additional information. Yet Texas law is well settled that, except in limited circumstances, the conduct of a mere employee cannot be imputed to the corporation for purposes of assessing exemplary damages. *Hammerly Oaks, Inc., v. Edwards*, 958 S.W.2d 387, 391 (Tex. 1997).

The only *Hammerly Oaks* factor in issue was whether a “vice principal” of Wyeth had committed malicious conduct. 3AP2955. The jury was told that a vice principal must be a corporate officer of Wyeth, someone who had the authority to employ, direct, and discharge Wyeth employees, or someone to whom Wyeth confided the management of the company or a department or division of its business. *Id.* Plaintiffs failed to prove that any

²⁶ See CXZ, Ex. 28 at 161 (*Lopez v. Am. Home Prods. Corp.*, No. 99-07-37723-CV (Tex. 79th Dist. Ct. Mar. 12, 2001) (precluding Dr. Busch from offering his interpretation of Wyeth’s corporate intent), *appeal dism’d per curiam*, 2001 WL 1479263 (Tex. App.—San Antonio Nov. 21, 2001, no pet.)); CXZ, Ex. 15 at 4 (*Aragon v. Wyeth-Ayerst Labs. Div. of Am. Home Prods. Corp.*, No. D-0101-200001387) (N.M. 1st Dist. Ct. Jan. 7, 2003) (precluding Dr. Moyer “from rendering opinions as to the motives or intent of the defendants, from rendering any moral judgments as to the Defendants’ conduct, and from rendering any opinions as to legal issues in the case.”); *Bouchard v. Am. Home Prods. Corp.*, No. 3:98CV7541, 2002 WL 32597992, at *6 (N.D. Ohio May 24, 2002) (unpublished) (“[Dr. Busch’s] opinion about the content or significance of certain Wyeth corporate documents . . . is [not] distinguishable from . . . the sort of evidence [relating to Wyeth’s corporate intent] excluded by the transferee court. The Defendants’ motion to exclude this testimony will be granted.” (internal quotation marks omitted)).

of the alleged malicious conduct was committed by such a person.

There is no legally or factually sufficient evidence that Amy Myers was a vice principal. The undisputed evidence showed that Ms. Myers had no authority to make decisions on behalf of Wyeth, had no authority to speak on behalf of Wyeth, and was not a manager of any department at Wyeth. 16RR31-34, 89-93; 19RR10-13, 17, 34-37, 68-71.

Over Wyeth's objection, the Plaintiffs convinced the court to include an additional theory for attributing malice to Wyeth based on the misguided notion that any employee performing and breaching a "non-delegable duty" of her employer is effectively a vice-principal. 3AP2955. According to Plaintiffs, the relevant non-delegable duty here was Wyeth's duty to keep records and provide reports to the FDA.

Even assuming that this duty would be non-delegable, any breach of it could not form the basis for a malice finding that would support an award of punitive damages, because that duty is exclusively federal. Any theory of liability based on alleged breach of such a duty to the FDA is preempted, as the United States Supreme Court squarely held in *Buckman*. The FDA's exclusive power to deal with any such misconduct bars the States from using state tort law to impose liability based on the conduct. *See infra* Part IV.C.1. The jury's malice finding, therefore, fails as a matter of law. Alternatively, at a minimum, the erroneous inclusion of a non-delegable duty theory requires a new trial. *Crown Life Ins. Co.*, 22 S.W.3d at 387-89.

5. No evidence that Mrs. Coffey's PPH "resulted from" malice.

Finally, there is no legally or factually sufficient evidence that Mrs. Coffey's PPH "resulted" from malicious conduct by Wyeth. As discussed above, Wyeth warned about the IPPHS findings, and there is no clear and convincing evidence that a different warning would have altered Dr. Tyrrell's decision to prescribe Pondimin for her. In fact, the PDR

supplement contained the final IPPHS results – the most current data on the PPH risks of taking Pondimin – before Dr. Tyrrell decided to write Mrs. Coffey’s third prescription. *See supra* Part II.B.1.

Nor could any conduct that concerns matters other than PPH be the cause of Mrs. Coffey’s injury. For example, the lack of warnings regarding valvular heart disease (or any other condition that Mrs. Coffey did not develop) could not have “caused” Mrs. Coffey’s PPH.

Similarly, Amy Myers’ conduct with respect to the overwriting of computer files regarding valvular heart disease could not have harmed Mrs. Coffey or caused her subsequent death from PPH. *See infra* Part IV.B.1. This conduct occurred *after* Mrs. Coffey’s doctors began prescribing Pondimin for her life-threatening obesity. Indeed, even after Wyeth submitted the overwritten information to the FDA a few weeks later, the FDA took no steps to remove Pondimin from the market, but in fact reaffirmed it as safe and effective. 17RR127. Moreover, there was no evidence that any short delay in notifying the FDA that may have resulted from Ms. Myers’ actions had any impact on whether Pondimin was available to be prescribed to Mrs. Coffey. Accordingly, Ms. Myers’ conduct – even if it violated a non-delegable duty – cannot support the jury’s finding that Mrs. Coffey’s PPH was *caused* by malicious conduct. 3AP2959.

For these reasons, judgment should be rendered for Wyeth on Plaintiffs’ claims for exemplary damages. Alternatively, at a minimum, the jury’s malice finding is supported by factually insufficient evidence and must be vacated, requiring a new trial on both liability and damages. *See Green Tree Fin. Corp. v. Garcia*, 988 S.W.2d 776, 785 (Tex. App.—San Antonio 1999, no pet.).

B. The Legislature’s cap on exemplary damages applies.

Even if Plaintiffs had offered sufficient evidence of malice, any award of exemplary damages may not exceed the statutory cap imposed by the Legislature. *Signal Peak Enters. of Tex., Inc. v. Bettina Invs., Inc.*, 138 S.W.3d 915, 928 (Tex. App.—Dallas 2004, pet. stricken). As relevant here, the statutory cap provides that exemplary damages cannot exceed (A) twice the amount of economic damages plus (B) the amount of non-economic damages up to \$750,000. CPRC § 41.008(b) (Vernon Supp. 2004-2005). The only amount of purely economic damages awarded by the jury was \$770,000 for lost earning capacity and medical expenses. 3AP2966. Because the court (at Plaintiffs’ request and over Wyeth’s objection) erroneously commingled economic damages with non-economic damages in its definition of “pecuniary loss,” *see* Part III.C., *supra*, the jury’s pecuniary loss awards in Questions 6 and 7 cannot be treated as economic damages when calculating the cap. *See* CPRC § 41.008(a) (requiring separate jury determination of economic damages). Thus, exemplary damages are capped at twice the amount of economic damages ($2 \times \$770,000 = \$1,540,000$) plus the amount of non-economic damages affirmed by the Court (if any) up to \$750,000, for a total of not more than \$2,290,000.²⁷

Plaintiffs attempted to “bust” this cap by invoking one statutory exception. They contended that Wyeth committed the felony of fraudulently destroying a particular kind of writing. *See* CPRC § 41.008(c)(12); TEX. PEN. CODE ANN. § 32.47 (Vernon 2003). Specifically, they argued that Amy Myers’ re-use (or “overwriting”) of computer files concerning valvular heart disease reports and her inability to locate handwritten notes and

²⁷ At the hearing on its post-trial motions, Wyeth pointed out that all parties agreed the maximum amount of economic damages supported by the evidence was approximately \$1.5 million. *See supra* Part IV.A. Wyeth asked the court to remit the economic damages to that level and apply the cap accordingly. Absent a remittitur, however, the only pure economic damages amount found by the jury was \$770,000. Thus, the cap must be calculated on that basis.

file folders relating to the reports constituted a felony. 26RR35, 147-52. Based on this argument, as well as the trial court’s erroneous spoliation instruction, the jury answered “yes” to Question 5. That question asked:

Did Wyeth knowingly or intentionally either destroy, remove, conceal, alter, substitute, or otherwise impair either the legibility, or availability of a writing for which the law provides for public recording or filing?

3AP2960. For the reasons below, this finding provides no lawful basis for avoiding the statutory cap on exemplary damages.

1. Question 5 omitted causation and intent elements that are essential to disregarding the statutory cap, and there is no legally or factually sufficient evidence of those elements.

Wyeth clearly explained all the elements essential to disregarding the statutory cap in its requested jury instruction, charge objections, and other motions. *E.g.*, CR2440-52, 2456-59, 2631-41, 2725-35. Yet the trial court erroneously refused to submit all of these elements to the jury.

No causation. First, to invoke the statutory exception to the cap, a plaintiff must prove that her “cause of action” and “recovery of exemplary damages” are “***based on*** conduct described as a felony” in certain Penal Code sections. CPRC § 41.008(c) (emphasis added).²⁸ Thus, there must be more than some felonious conduct floating somewhere in the background. The felonious conduct (1) must be the basis for the plaintiff’s claims and (2) must be the *cause* of the injury about which she complains. Despite Wyeth’s objection, the charge erroneously failed to ask the jury to consider only felony conduct that formed a basis of Plaintiffs’ causes of action. CR2639. Furthermore, the charge failed to ask the jury to state what *portion* of its exemplary damage award (if

²⁸ Section 41.008(c) states that the cap “does not apply to a cause of action against a defendant from whom a plaintiff seeks recovery of exemplary damages based on conduct described as a felony in the following sections of the Penal Code if . . . the conduct was committed knowingly or intentionally: . . . (12) Section 32.47 (fraudulent destruction, removal, or concealment of writing).”

any) was “based on” this conduct. CR2638-39, 2772-73. Thus, the jury’s answers provided no basis for imposing any amount of exemplary damages in excess of the cap. Alternatively, the charge’s failure to segregate the portion of the award based on felony conduct prevents Wyeth from challenging that portion in this Court. Therefore, at a minimum, a new trial is required. *Harris County*, 96 S.W.3d at 235.

Moreover, Plaintiffs offered no legally or factually sufficient evidence that their causes of action were “based on” the alleged felony. Instead, they candidly admitted below that “we’re seeking exemplary damages based upon certain conduct that’s a felony. *We are not having a cause of action based on the conduct that’s described as a felony.*” 26RR60 (emphasis added). Indeed, Plaintiffs have pointed to no cause of action that arises from destruction of a corporation’s internal computer files, and they certainly never alleged such a claim. Nor is there any evidence that Mrs. Coffey developed PPH “based on” Amy Myers’ conduct in overwriting reports of heart valve injury, which at worst, delayed submission of heart valve reports to the FDA for about one month (until April 1997 instead of March). 16RR85, 94-96; 17RR127-28; 19RR19-20, 31-32. In the crucial statutory terms, Plaintiffs’ “causes of action” were not “based on” Ms. Myers’ conduct, even if that conduct could be characterized as a felony (which it cannot). Therefore, Wyeth’s motion for directed verdict should have been granted, and the cap-busting issue should not have been submitted to the jury. CR2378.

No intent to defraud or harm. Second, to commit the felony of “Fraudulent Destruction . . . of [a] Writing” (and thereby remove the statutory cap on exemplary damages), a person must destroy or impair a writing “*with intent to defraud or harm another.*” TEX. PEN. CODE ANN. § 32.47(a) (emphasis added). The cap statute also requires that the conduct allegedly nullifying the cap – here, the destruction of the writing –

be “committed knowingly or intentionally.” CPRC § 41.008(c). Thus, as Plaintiffs knew, they had to prove not only that Wyeth knowingly or intentionally destroyed a writing, but also that Wyeth did so with an intent to defraud or harm another. Yet, despite Wyeth’s objection, the charge only included the knowing destruction requirement and a definition of “knowingly.” It crucially omitted the specific mental state element required by the felony statute – *i.e.*, an intent to defraud or harm. CR2641; *see also infra* Part IV.B.4.

Furthermore, as Wyeth pointed out in its motion for directed verdict, “[t]here is no evidence to support a finding of intent to defraud or harm another in the record.” CR2457. To the contrary, the evidence showed that, shortly before Ms. Myers overwrote the initial database entries, Wyeth sent written correspondence to both the Mayo Clinic and the doctor in Fargo requesting additional information on the patients who had experienced adverse events. 16RR71-72; 19RR24-27; DX321-22. Not only did the letters acknowledge that reports had been received regarding patients who experienced valvular heart disease coincident with Pondimin therapy, they advised the third-party doctors of Wyeth’s intent to prepare ADEs based on these reports, which Wyeth soon prepared and filed with the FDA. Moreover, Wyeth retained all the information regarding these patients that Ms. Myers initially entered into the database and subsequently overwrote. The information was never lost and, indeed, was ultimately sent to the FDA. *See* Part V.A., *infra*. The sending of the follow-up letters to the reporting doctors and the creation and maintenance of this information negates any intent to defraud. Thus, there is neither legally nor factually sufficient evidence to support the intent to defraud element needed to bust the cap.

In sum, because Question 5 did not require the jury to find the essential elements of causation and intent to harm needed to disregard the statutory cap, that question is

immaterial and cannot support an uncapped award of exemplary damages to Plaintiffs.²⁹ Moreover, because Plaintiffs offered no legally or factually sufficient evidence of these elements, the jury's cap-busting finding fails. Therefore, this Court should reform the judgment and apply the cap. At a minimum, it should order a new trial.

2. As a matter of law, Amy Myers' conduct is not covered as a felony and thus cannot trigger the cap-busting statute.

This Court also should reform the judgment to apply the cap, because there is no evidence that the overwriting conduct on which Plaintiffs rely is "conduct described as a felony in [§ 32.47] of the Penal Code." CPRC § 41.008(c). First, as a matter of law, Ms. Myers' conduct did not involve a "writing" as defined by the felony portion of section 32.47. Although a misdemeanor offense of fraudulent destruction may involve a wide variety of writings, including "printing or any other method of recording information," the destruction is a felony only if the writing:

- (1) is a will or codicil of another, whether or not the maker is alive or dead and whether or not it has been admitted to probate; or
- (2) is a deed, mortgage, deed of trust, security instrument, security agreement, or other writing for which the law provides public recording or filing, whether or not the writing has been acknowledged.

TEX. PEN. CODE ANN. § 32.47(b)(1), (d).

Whether or not a company's internal computer records could ever be considered writings "for which the law provides public recording or filing," the "writings" covered by this felony statute include only documents representing property interests that would be impaired if the document were destroyed. *See* Michael B. Charlton, 6 TEXAS PRACTICE: TEXAS CRIMINAL LAW § 19.12 (2d ed. 2001) ("The offense is a . . . misdemeanor unless

²⁹ *Signal Peak*, 138 S.W.3d at 927 (jury must find that elements of felony offense were met in order to bust cap); *see also Spencer v. Eagle Star Ins. Co.*, 876 S.W.2d 154, 157 (Tex. 1994) (immaterial jury finding should be disregarded); *State Dep't of Highways & Pub. Transp. v. Payne*, 838 S.W.2d 235, 241 (Tex. 1992) (jury finding that omits essential element cannot support judgment).

the writing is a will, codicil, or *instrument affecting property interests* that the law provides may be filed of record” (emphasis added)). This conclusion flows from the canon of statutory construction known as *ejusdem generis* (“things of the same nature”). *E.g.*, *Dawkins v. Meyer*, 825 S.W.2d 444, 447 (Tex. 1992) (orig. proceeding).³⁰ Moreover, because the term appears in a criminal statute, it must be given this sharply focused construction under the due process “rule of lenity.”³¹ This construction, treating covered documents as limited to those affecting property interests, is consistent with the importance of documents representing property interests and with the placement of this statute in the title of the Texas Penal Code concerning property offenses. A company’s internal computer files recording information about potential medical problems do not embody or determine property interests. Destroying those reports cannot be conduct described as a felony under section 32.47 and cannot trigger the narrow exception to the statutory cap on exemplary damages.

Second, Ms. Myers’ conduct cannot be described as a felony under section 32.47 because her allegedly improper destruction of reports occurred in Pennsylvania (where she worked at the Wyeth facility), not in Texas.³² 19RR17-18. Under the Penal Code, a felony is cognizable by Texas courts only if “either the conduct or a result that is an *element of the*

³⁰ See also *Hilco Elec. Coop. v. Midlothian Butane Gas Co.*, 111 S.W.3d 75, 78 (Tex. 2003). Texas appellate courts routinely apply *ejusdem generis* to limit the scope of general statutory language. See, e.g., *Loredo v. State*, 47 S.W.3d 55, 57-58 (Tex. App.—Houston [14th Dist.] 2001, pet. dismissed) (phrase “bribery, perjury, forgery, or other high crimes” excludes petty theft); *Perez v. State*, 11 S.W.3d 218, 221 (Tex. Crim. App. 2000) (en banc) (same phrase excludes felony DWI); *Thomas v. State*, 3 S.W.3d 89, 93-94 (Tex. App.—Dallas 1999) (“note, bond, debenture, mortgage certificate or other evidence of indebtedness” includes only similar evidence of indebtedness and thus requires a writing), *aff’d*, 65 S.W.3d 38 (Tex. Crim. App. 2001).

³¹ “[T]he canon of strict construction of criminal statutes, or rule of lenity, ensures fair warning by so resolving ambiguity in a criminal statute as to apply it only to the conduct clearly covered.” *United States v. Lanier*, 520 U.S. 259, 266 (1997); see also *Cuellar v. State*, 70 S.W.3d 815, 822 (Tex. Crim. App. 2002) (Cochran, J., concurring) (citing *Murray v. State*, 21 Tex. App. 620, 633 (1886)) (“[B]efore a man can be punished, his case must be plainly and unmistakably within the statute, and, if there be any fair doubt whether the statute embraces it, that doubt is to be resolved in favor of the accused.” (emphasis in original)).

³² See CR2442-45 (Wyeth’s motion for directed verdict).

offense occurs inside this state.” TEX. PEN. CODE ANN. § 1.04(a) (Vernon 2003) (emphasis added). No conduct or result that was an “element” of the alleged offense of wrongful destruction of a protected document occurred in Texas. Any alleged consequences of such destruction that may have been felt in Texas do not constitute an “element” of the offense, as the statute requires.

Moreover, the Federal Constitution compels this result. There was no evidence that Pennsylvania law prohibited Ms. Myers’ conduct. As the U.S. Supreme Court has held, Texas “cannot punish a defendant for conduct that may have been lawful where it occurred.” *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 421 (2003). In any event, it would make no difference if Pennsylvania had regulated Ms. Myers’ conduct. Texas does not “have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State’s jurisdiction.” *Id.*

For these reasons, the destruction in Pennsylvania of a writing that does not affect property interests cannot, as a matter of law, be described as a felony under section 32.47. Therefore, this Court should reform the judgment and apply the cap that the Legislature intended should limit exemplary damages in all tort cases, except in extraordinary circumstances not present here.

3. *The trial court’s spoliation instruction tainted the jury’s verdict against Wyeth on the cap-busting issue.*

As discussed above, Question 5 asked: “Did Wyeth knowingly or intentionally either destroy . . . [or] alter . . . a writing . . . ?” 3AP2960. Yet the court instructed the jury “that the deliberate destruction, by Wyeth, of . . . files” and “the deliberate alteration of . . . records by Wyeth *is* spoliation or destruction of evidence” 3AP2955 (emphasis added). Plaintiffs cannot rely on Question 5 to bust the cap because the trial court – through its erroneous spoliation instructions – improperly told the jury to answer that

question against Wyeth.

In closing argument, Plaintiffs' counsel emphasized the link between this question and instruction: "That's the court's instruction because they destroyed evidence. . . . You're going to get a question . . . 5, right here. . . . The answer to that question is yes." 26RR148-49. Plaintiffs returned to the same theme in rebuttal, asking the jury to reject Wyeth's arguments that its conduct did not violate section 32.47:

If you don't want to trust me the lawyer, would you please trust Judge Floyd, the judge. Read with me, these are Judge Floyd's words that will be in your hands when you go back to deliberate. "The Court instructs you that deliberate destruction by Wyeth of the 14 files from the Mayo [Clinic] is spoilage [*sic*] or destruction of evidence relevant to this case."

[Wyeth's lawyer] tried to persuade you . . . there is no evidence that we destroyed those Mayo records. . . . Judge Floyd says, bunk. They deliberately destroyed them.

26RR213-14.

Thus, as Plaintiffs' own arguments confirm, the trial court's instructions erroneously directed a verdict against Wyeth on the hotly-disputed question whether its conduct violated section 32.47. *See City of San Antonio v. Rodriguez*, 931 S.W.2d 535, 536 (Tex. 1996) (per curiam) (instruction amounting to directed verdict on contested issue is harmful error); *Linden-Alimak, Inc. v. McDonald*, 745 S.W.2d 82, 85 (Tex. App.—Fort Worth 1988, writ denied) (instruction "suggest[ing] to the jury the trial judge's opinion concerning the matter about which the jury is asked" is improper comment on weight of the evidence and presents reversible error); TEX. R. CIV. P. 277; *see also* Part V.A., *infra* (discussing additional reasons why the court's spoliation instructions are erroneous). Therefore, the jury's answer to Question 5 is immaterial and, as a matter of law, cannot provide a basis for busting the cap. Alternatively, at a minimum, Wyeth is entitled to a new trial.

4. At a minimum, a new trial is required because of omissions and/or defects in Question 5 concerning grounds for “busting” the cap.

Wyeth repeatedly informed the trial court of the problems with Plaintiffs’ cap-busting question. Counsel objected to the failure of the charge to include “language that would require a causal connection between the conduct inquired about in Question 5 and Mrs. Coffey’s PPH.” CR2637. In addition, counsel repeatedly informed the court that Plaintiffs had to obtain a finding that Wyeth acted “with an intent to defraud or harm another” in order to bust the cap. CR2456-57, 2641, 2726.³³ Nevertheless, the cap-busting question submitted to the jury failed to include either requirement. *See* Part IV.B.1., *supra*. At the very least, the omission of these necessary elements from the charge requires a new trial.

Wyeth also objected to two other erroneous instructions that accompanied the cap-busting question. CR2634-35, 2640-41. First, the charge directed the jury to answer that question based on a preponderance of the evidence. 3AP2953. But for conduct to qualify as a felony, it must be proven beyond a reasonable doubt. TEX. PEN. CODE ANN. § 2.01 (Vernon 2003). At a minimum, the law governing recovery of exemplary damages mandates that any conduct on which a plaintiff relies for an award of exemplary damages must be proven by clear and convincing evidence. *See* CPRC § 41.003(b). Because the charge did not contain either of these heightened standards of proof, *see* CR2634-65, a new trial must be granted. *R&R Contractors v. Torres*, 88 S.W.3d 685, 696 (Tex. App.—Corpus Christi 2002, no pet.) (“Submission of a lesser standard of proof is reversible

³³ Because Question 5 was missing the cap-busting requirement that the defendant have acted “with an intent to defraud or harm another,” the question was an “incomplete” rather than “defective” jury submission. *See Tractebel Energy Mktg., Inc. v. E.I. DuPont De Nemours & Co.*, 118 S.W.3d 929, 932 (Tex. App.—Houston [14th Dist.] 2003, no pet.) (Brister, C.J.). Further, the matters missing from Question 5 were so significant as to render Question 5 immaterial. But regardless of whether Question 5 is viewed as an “incomplete” or “defective” question, Wyeth adequately brought the problem with the question to the court’s attention, as demonstrated. CR2456-57, 2641, 2726.

error.”).

Another instruction directed the jury in answering Question 5 to consider the acts of Wyeth’s vice principals in the course and scope of their employment. 3AP2954. The standard PJC definition of vice principal, however, is far too broad in the cap-busting context. The cap-busting statute requires proof that the defendant committed a covered felony. For a cap-busting felony to be attributed to a corporation such as Wyeth, the crime must be authorized or recklessly tolerated by either (1) a majority of its board, or (2) a “high managerial agent acting in behalf of the corporation.” TEX. PEN. CODE ANN. § 7.22(b) (Vernon 2003). Despite Wyeth’s objection and requests, CR2640-41, the Court failed to instruct the jury about this statutory requirement. There is no legally or factually sufficient evidence that meets this requirement. The overwriting was inconsistent with the instructions of Ms. Myers’ superior, Dr. Olsen, which would have preserved the data. 16RR73-74, 91-92. No high managerial agent even knew about, let alone approved of, the overwriting. *E.g.*, 17RR121, 123. Therefore, at a minimum, Wyeth is entitled to a new trial.

5. *Even as erroneously submitted, there was no legally or factually sufficient evidence to support the jury’s answer to Question 5.*

In answering “yes” to Question 5, the jury found that Wyeth “knowingly or intentionally either destroy[ed], remove[d], conceal[ed], alter[ed], substitute[d], or otherwise impair[ed] either the legibility, or availability of a writing for which the law provides for public recording or filing.” 3AP2960. But there was no legally or factually sufficient evidence to support such a finding, because there was no legally or factually sufficient evidence that Amy Myers was a vice principal of Wyeth, even within the meaning of *Hammerly Oaks*. *See supra* Part IV.A.4. Thus, this Court should reform the judgment and apply the cap or at least order a new trial.

C. All exemplary damages based on Wyeth’s dealings with the FDA are preempted by federal law.

In *Buckman*, 531 U.S. at 348, the Supreme Court held that the comprehensive federal scheme of drug regulation and the FDA’s exclusive authority to enforce it preempt a state-law tort claim based upon fraudulent statements made to the FDA. Federal law thus prevents a state jury from relying on alleged mis-dealings with the FDA to punish the defendant. The FDA has exclusive authority to determine whether and to what extent to punish for such alleged misconduct.

1. The cap-busting finding must be disregarded because it was based entirely upon conduct within the FDA’s exclusive enforcement authority.

The only basis for avoiding the statutory cap on exemplary damages was the jury’s finding that Wyeth destroyed “a writing for which the law provides for public recording or filing.” 3AP2960 (Question 5); CPRC § 41.008; TEX. PEN. CODE ANN. § 32.47. Plaintiffs asserted that Wyeth’s overwriting violated an administrative duty under federal law to maintain information necessary for filing reports of “adverse drug events” with the FDA. This was the *sole* predicate for the jury’s cap-busting finding.

Yet *Buckman* establishes that *state* law cannot authorize a jury even to impose civil liability on a defendant, much less to “punish” the defendant, for allegedly violating obligations to the FDA, a federal agency. *Buckman* held that a state-law “fraud-on-the-FDA” claim was preempted because it would interfere with the FDA’s ability to use its exclusive enforcement powers to maintain a “delicate balance” of competing federal objectives. 531 U.S. at 348-49.³⁴ If a State may not impose *any* liability based on a

³⁴ The FDA may seek injunctions, civil penalties, and criminal penalties for violations of the FDCA. See 21 U.S.C. §§ 331(e), 332(a), 333(a), 334, 337(a), 355(k). The FDA has exclusive prosecutorial authority and discretion to punish FDCA violations. *Heckler v. Chaney*, 470 U.S. 821, 835 (1985); 21 U.S.C. § 337(a); see also *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 349 (Minn. Ct. App. 2001) (holding *Buckman* applies to pharmaceutical manufacturers as well as medical device manufacturers).

defendant's intentionally fraudulent representations to the FDA, Wyeth's alleged mishandling of information related to FDA reporting requirements surely may not serve as a basis for *enhancing* exemplary damages by nearly a billion dollars. In fact, in supporting preemption, the FDA itself has concluded that additional common-law liability should be preempted, because the federal agency "has the tools necessary to protect the public health" from reporting problems. CR3592, 3594.

Here, the jury's cap-busting finding distorted the federal balance by "exert[ing] an extraneous pull on the scheme established by Congress." *Buckman*, 531 U.S. at 353. This distortion is evident when one compares the \$897,710,000 in exemplary damages enabled by the cap-busting finding (*i.e.*, the difference between the jury's \$900 million exemplary damages award and the otherwise-applicable cap of \$2.29 million) with the maximum \$10,000 penalty authorized by Congress, which the FDA did not even consider warranted in this matter. Indeed, although the FDA reviewed Wyeth's ADE reporting system and could have sanctioned or fined Wyeth if it had found willful or culpable conduct, it did not do so. 11RR176-77; 19RR59-62. Instead, the FDA issued a report calling for improved internal procedures, and in response, Wyeth made changes to its database to prevent future overwriting. PX1330; 19RR37-38. Accordingly, this Court must disregard the cap-busting finding and vacate that portion of the jury's award above the statutory cap.

2. *The remainder of the exemplary award must be set aside because it was based in part upon Wyeth's alleged mis-dealings with the FDA.*

Plaintiffs' reliance on Wyeth's alleged mis-dealings with the FDA went beyond their attempt to escape the Legislature's cap on exemplary damages. In addition, they invoked these alleged mis-dealings to support their arguments that Wyeth acted with malice and should pay exemplary damages. 26RR18-20, 143-53. Yet despite Wyeth's objection, the trial court did not instruct the jury to apportion any exemplary damages

award between Wyeth’s alleged FDA mis-dealings – which could not support an award, even in theory, because of preemption and other legal bars – and any other alleged misconduct. CR2638-39. Given this improper commingling, the entire punitive damages award is tainted and must be set aside. *Crown Life Ins. Co. v. Casteel*, 22 S.W.3d 378, 387-89 (Tex. 2000). In addition, setting aside the exemplary damages award requires a new trial on liability and compensatory damages as well. *Green Tree*, 988 S.W.2d at 785.

D. The \$900 million award of exemplary damages in response to Questions 12, 14, and 15 cannot stand because these questions were erroneous and impermissibly duplicative.

Questions 12, 14, and 15 gave the jury three opportunities to award exemplary damages against Wyeth. 3AP2971, 2973-74. The jury awarded \$400 million in response to Question 12, \$250 million in response to Question 14, and \$250 million in response to Question 15, for a total of \$900 million. *Id.* These exemplary damage awards must be reversed because the charge contained two major errors to which Wyeth objected. CR2668-69, 72, 75-76.

First, these questions were based on an incorrect legal theory of exemplary damages. Instead of instructing the jury to set an amount based on whatever malicious conduct they found, each question asked the jury to make an exemplary damage award “for the matters in” specific *actual damages* questions. *Id.* Question 12 requested an amount of exemplary damages for the matters in the wrongful death damages questions for Mr. Coffey and the three children. Question 14 requested such an amount relating to the survival damages question for Mrs. Coffey. Question 15 requested yet another exemplary amount for the matters in the pre-death damage questions for Mr. Coffey and the children. *Id.*³⁵

³⁵ Because the “actual damages” referenced in Question 15 were not recoverable as a matter of law, *see supra*

No Texas authority permits a jury to set exemplary damages based on “matters” of actual damages. Rather, exemplary damages must only be assessed based on a defendant’s wrongful *conduct* that meets the strict standards set by the Legislature. See CPRC §§ 41.003(a), 41.008(c) (Vernon Supp. 2004-2005), 41.011(a) (Vernon 1997). Because the charge erroneously asked the jury to impose exemplary damages for “matters” that cannot, as a matter of law, support recovery of such damages, the jury’s findings are immaterial. Furthermore, by failing to instruct the jury to focus on the malicious conduct in setting an amount, the charge allowed the jury to award exemplary damages based on the acts of people who were not managers of Wyeth.³⁶ Therefore, judgment must be rendered for Wyeth on Plaintiffs’ claims for exemplary damages. Alternatively, the jury’s exemplary damage findings are corrupted by this error and must be reversed, requiring a new trial on all issues. *Green Tree*, 988 S.W.2d at 785.

Second, the trial court erred by allowing the jury to make three separate awards of exemplary damages against Wyeth based *on the same Wyeth conduct* and by entering judgment cumulatively on all three awards. As courts in Texas and nationwide have held, an impermissible duplicative recovery occurs when a plaintiff receives two (or more) awards of exemplary damages for the same conduct.³⁷ In addition, both the Texas and United States Supreme Courts recognize that imposing multiple punishments for the same conduct offends due process. *State Farm*, 538 U.S. at 423; *Owens-Corning Fiberglas Corp. v. Malone*, 972 S.W.2d 35, 48-52 (Tex. 1998). Because there is no way to tell what

Part III.A., the \$250 million award based on those damages cannot stand.

³⁶ Over Wyeth’s objection, the “vice principal” instruction was limited to Question 4 (malice) and Question 5 (cap-busting). 3AP2954.

³⁷ *Birchfield v. Texarkana Mem’l Hosp.*, 747 S.W.2d 361, 367 (Tex. 1987); *K-Mart Corp. v. Martinez*, 761 S.W.2d 522, 524-25 (Tex. App.—Corpus Christi 1988, writ denied); see also *Steak & Ale of Tex., Inc. v. Borneman*, 62 S.W.3d 898, 909-10 (Tex. App.—Fort Worth 2001, no pet.); *Hart v. Moore*, 952 S.W.2d 90, 98 (Tex. App.—Amarillo 1997, pet. denied); Lisa K. Gregory, *Plaintiff’s Rights to Punitive or Multiple Damages When Cause of Action Renders Both Available*, 2 A.L.R. 5th 449 (1992).

amount of exemplary damages (if any) a properly-instructed jury would have awarded, the various overlapping exemplary damage awards must be vacated and a new trial ordered. *See Green Tree*, 988 S.W.2d at 785.

E. The \$900 million exemplary damages award violates Texas common law because it is excessive.

Apart from these flaws in the instructions, the exemplary damages award must be reversed under Texas common law. First, Texas common law requires that “[e]xemplary damages must be reasonably proportioned to actual damages.” *Alamo Nat’l Bank v. Kraus*, 616 S.W.2d 908, 910 (Tex. 1981). Any award that exceeds the test of reasonable proportionality shows that the jury exceeded its proper function, and the trial court must suggest a remittitur of the excess or order a new trial. *Tex. Farmers Ins. Co. v. Soriano*, 844 S.W.2d 808, 830 (Tex. App.—San Antonio 1992), *rev’d on other grounds*, 881 S.W.2d 312 (Tex. 1994).

In this case, the ratio of exemplary damages (\$900 million) to actual damages awarded (\$113 million) is about 9:1. This is an unreasonable ratio, even before substantially reducing the compensatory award, as Wyeth contends is necessary. *See supra* Part III. As the table reproduced in the Appendix (8AP1-2) shows, there are no awards in comparable Texas cases involving product liability claims or wrongful death in which juries have awarded and appellate courts have sustained exemplary damages on a scale even remotely approaching this case. When compensatory damages are reduced, the ratio becomes even more unreasonable and cannot stand. *See Bunton v. Bentley*, 153 S.W.3d 50, 53 (Tex. 2004) (per curiam) (because “exemplary damages must be reasonably proportionate to compensatory damages, . . . adjustment of compensatory damages therefore requires reevaluation of the factors supporting an award of exemplary damages”).

In cases like this one, where the actual and exemplary damage awards are enormous,

Texas courts have ordered remittiturs of exemplary damage awards to levels substantially below a 1:1 ratio. For example, in *Texaco, Inc. v. Pennzoil Co.*, 729 S.W.2d 768 (Tex. App.—Houston [1st Dist.] 1987, writ ref’d n.r.e.), unlike in this case, top management had approved the wrongful conduct. Nevertheless, the court of appeals relied on the facts that – just as in the present case – there had been no intent to injure the plaintiff and that the compensatory award was substantial. The court concluded that the verdict should be reduced to a ratio of exemplary to actual damages of 0.13:1.³⁸ The court explained that a more massive award would “serve to confiscate rather than to deter or punish.” *Id.* at 866.

Here, there is no question that the jury was responding to the improper demand by Plaintiffs’ counsel in closing argument to *confiscate* enough of Wyeth’s net worth to make the total verdict reach a billion dollars. *See* 26RR134 (“[H]ow much punishment should be assessed on an \$8-billion-dollar company by a fine? . . . [T]he management of a company like that doesn’t even care about what’s going on until you get to the named number ‘billion.’ ”). Over Wyeth’s objections, Plaintiffs’ counsel also asked the jury to send a message to the drug industry. 15RR58-59, 65-68; 26RR103, 120-21. But the desire to send a message to others is not a proper purpose of exemplary damages.³⁹ There was no legitimate basis under Texas law (or the Federal Constitution) to render such an award.

F. Under Federal and Texas constitutional standards, the \$900 million exemplary damages award is grossly excessive and must be reduced substantially as a matter of law.

The staggering amount of the jury’s exemplary damage award – *\$900 million* – is so

³⁸ The case was decided long before the United States Supreme Court handed down the rulings in *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996), and *State Farm* placing federal constitutional limits on punitive awards. It is unlikely that even the final, remitted award in *Texaco* would survive constitutional scrutiny today.

³⁹ *Compare* former CPRC § 41.001(3) (Vernon 1994 & Supp. 1995) (noting that punitive damages could be awarded as example to others), *with* CPRC §§ 41.001(5), 41.011 (Vernon 1997) (omitting this purpose); *see* William V. Dorsaneo III, 2 TEX. LITIG. GUIDE § 20.01[2][b] (2003) (“[T]his purpose is not recognized by later statutory definitions of exemplary damages.”).

excessive and extreme that it violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution, as well as the Due Course of Law⁴⁰ and Excessive Fines⁴¹ Clauses of the Texas Constitution. Accordingly, at a minimum, the award must be reduced substantially as a matter of law. *See Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 437 (2001) (as a matter of federal constitutional law, determination of exemplary damages amount is a question of law to be reviewed *de novo*, not a question of fact).

The Supreme Court has established three “guideposts” for evaluating the excessiveness of an exemplary damage award: (1) the “disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award” – the so-called “ratio” or proportionality test; (2) the difference between the exemplary damages awarded by the jury and the criminal or civil penalties authorized or imposed “in comparable cases” – the “analogous penalties” inquiry; and (3) the “degree of reprehensibility” of the defendant’s misconduct. *State Farm*, 538 U.S. at 418. Applied here, these constitutional guideposts demonstrate that the jury’s \$900 million exemplary damage award is unconstitutionally excessive.

1. *The ratio of exemplary to compensatory damages is excessive.*

In *State Farm*, the Supreme Court held that “an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety.”

⁴⁰ TEX. CONST. art. I, § 19. This “due course of law guarantee . . . has independent vitality, separate and distinct from the due process clause of the Fourteenth Amendment to the U.S. Constitution.” *In re J.W.T.*, 872 S.W.2d 189, 197 (Tex. 1994). The Texas Supreme Court also has recognized that “the Texas due course constitutional provision is different from, and arguably significantly broader than, the language of the corresponding federal provisions.” *Id.* at 197 n.23.

⁴¹ TEX. CONST. art. I, § 13. This clause applies not only to fines imposed by the government, but also to civil penalties such as punitive damages. *Pennington v. Singleton*, 606 S.W.2d 682, 690 (Tex. 1980); *State Farm Mut. Auto. Ins. Co. v. Zubiate*, 808 S.W.2d 590, 605 (Tex. App.—El Paso 1991, writ denied) (size of award must bear “a direct relationship to the purposes of the imposition of the fine”) Under *Pennington*, a penalty is unconstitutionally excessive “where it becomes so manifestly violative of the constitutional inhibition as to shock the sense of mankind.” 606 S.W.2d at 690.

Id. at 425. But “[w]hen compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee.” *Id.* (emphasis added).

As discussed in Part III, if any “compensatory” damages at all are allowed, the jury’s awards of such damages must be reduced to about \$1.5 million (because the awards above that amount are unrecoverable as a matter of law, improperly not segregated, and unsupported by sufficient evidence of their amount). As a result, the ratio of the jury’s \$900 million exemplary damages award to any remaining award of compensatory damages would be a breathtaking 600:1.

Yet even the 9:1 ratio between the exemplary award and the jury’s compensatory damage award offends constitutional limits. That ratio is more than double the 4:1 ratio found by *State Farm* to be “close to the line of constitutional impropriety” when a jury awards only modest compensatory damages. An award of over \$113 million in “compensatory” damages to the family of a woman with other pre-existing, life-threatening medical problems obviously qualifies as “substantial.” *Id.* at 426 (describing \$1 million compensatory award as substantial). Thus, as the Supreme Court of the United States has determined, a 1:1 ratio would be the “outermost” federal constitutional boundary. *Id.* at 425 (emphasis added).

Indeed, even a 1:1 ratio would be too high if this Court upholds a “compensatory” award above \$1.5 million in this case. Of the jury’s \$113 million compensatory award, some **\$79.13 million** was for “loss of companionship and society and mental anguish,” “loss of consortium,” and “loss of parental consortium.” It is realistic to assume that the vast bulk of this award represents the jury’s desire to “send a message” to Wyeth – as Plaintiffs’ counsel expressly urged them to do – rather than a true valuation of the losses

actually suffered by Mrs. Coffey and her family. As the *State Farm* Court explained, “compensatory damages” for non-economic injuries such as emotional distress “likely [are] based on a component which [is] duplicated in the punitive award . . . [because] ‘there is no clear line of demarcation between punishment and compensation [in such cases].’” 538 U.S. at 426 (quoting RESTATEMENT (SECOND) OF TORTS § 908, cmt. c at 466 (1979)). Because this huge award already includes a punitive element, even if it is reduced substantially for reasons already discussed, the maximum permissible ratio of exemplary to actual damages must be set much lower than 1:1 in order to avoid double punishment.

2. *The jury’s award is grossly disproportionate to analogous penalties and exemplary damage awards.*

The second guidepost required by the federal Due Process Clause directs courts to evaluate the disparity between the exemplary damage award at issue and the civil or criminal penalties authorized or imposed in comparable cases. *See State Farm*, 538 U.S. at 428. Here, the jury premised its cap-busting finding on Amy Myers’ overwriting of preliminary ADEs. But even if such conduct violated a federal duty to record and report ADEs – and the FDA review did not find any such unlawful conduct here – Congress has decided that the appropriate penalty for even a criminal violation is a fine of up to \$1,000 for a first offense or up to \$10,000 for a second offense. 21 U.S.C. §§ 331, 333(a). Under *State Farm* and *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), the United States Constitution prohibits a jury from deciding that it is appropriate to impose punishment that is *thousands of times* more severe than Congress itself has authorized for the alleged misconduct. *Cf. Lincoln v. Case*, 340 F.3d 283, 294 (5th Cir. 2003) (reducing award to maximum statutory civil penalty).

Moreover, even using a legislature’s prescription of pertinent *criminal* penalties as a guide to maximum punitive damages in a civil case must be done with “[g]reat care . . .

[because criminal penalties] can be imposed only after the heightened protections of a criminal trial have been observed.” *State Farm*, 538 U.S. at 428. Because Wyeth has not been afforded those protections here, including the protection of the reasonable-doubt standard, the Due Process Clause bars a state jury from “punishing” Wyeth at the level authorized following a criminal conviction.

Perhaps the most pertinent type of *civil* penalty in analogous cases is the pattern of exemplary awards in other tort cases that appellate courts are willing to sustain. A post-*BMW* survey of all product liability and wrongful death cases in which exemplary damages were considered on appeal graphically illustrates that the \$900 million award here is orders of magnitude greater than any other punitive award rendered or sustained. *See* 8AP1-2. For these reasons, the jury’s award falls well outside the outermost limits of “analogous” punishments.

3. *Wyeth’s level of culpability does not justify the award.*

Under *State Farm*, “reprehensibility” alone is not “sufficient to sustain [the] punitive damages award.” 538 U.S. at 419. Even when other reviewing courts have found that a defendant caused death through “reprehensible” conduct, they have reduced exemplary damage awards to a fraction of what the jury here awarded.⁴² In any event, Wyeth’s conduct in this case hardly rose to the level of “extremely reprehensible” conduct. Wyeth had issued a series of public warnings about the (low) potential risk of PPH associated with

⁴² *See, e.g., Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594 (8th Cir. 2005) (jury awarded \$4.025 million compensatory and \$15 million exemplary damages to smoker who died of lung cancer, but court reduced exemplary damages to \$5 million based on ratio guidepost even though company sold product for many years despite knowledge of extreme health risks, company misled consumers about risks, and risks related directly to decedent’s death); *Romo v. Ford Motor Co.*, 6 Cal. Rptr. 3d 793 (Cal. Ct. App. 2003) (jury awarded \$5 million compensatory and \$290 million exemplary damages for defect in Ford Bronco that killed three, but court held \$23.7 million was maximum constitutional exemplary award even though it found Ford’s conduct “extremely reprehensible”); *Advocat, Inc. v. Sauer*, 111 S.W.3d 346 (Ark.) (jury awarded \$15.3 million compensatory and \$63 million exemplary damages against nursing home for death of resident from severe malnutrition and dehydration, but court reduced exemplary award to \$21 million), *cert. denied*, 540 U.S. 1004 (2003). It is doubtful that even those reduced amounts on top of “substantial” compensatory damages satisfy the constitutional limits laid down in *State Farm*.

diet drugs, even if the jury in hindsight believed that those warnings should have been stronger. Moreover, even if this Court rejected all of Wyeth's arguments and concluded that a reasonable juror *might* have found that Wyeth's warnings were inadequate and that those inadequacies *somehow* caused Mrs. Coffey's death, such a determination would still reflect a liability case so close on the merits as to preclude the recoverability of punitive damages.

4. *The Federal Constitution prohibited the jury from using Wyeth's out-of-state conduct or wealth as a basis for its exemplary damage award.*

Also tainting the exemplary damage award are Plaintiffs' repeated invitations for the jury to punish Wyeth for conduct affecting Pondimin users outside the State of Texas.⁴³ Moreover, Plaintiffs' counsel encouraged the jury to punish Wyeth for Ms. Myers' conduct, which indisputably occurred outside Texas. *See supra* Part IV.C.1. As discussed in Part IV.B.2 above, *State Farm* establishes that a jury in one state has no lawful authority to award exemplary damages in order to punish a defendant for conduct occurring in another state. 538 U.S. at 421.

Finally, it is clear that Plaintiffs' counsel convinced the jury to render such a crushing award primarily because Wyeth is a large, out-of-state corporation with a deep pocket. In closing argument, Plaintiffs' counsel repeatedly referred to Wyeth as an "8-billion-dollar company" and twice implored the jury to set its punitive award on that basis.⁴⁴ The Supreme Court has held expressly, as a matter of federal constitutional law,

⁴³ *See* 26RR128 ("Cyndi Coffey, unknowingly – and many others – were taking the chance."); *id.* at 137 ("They're on the wrong path and they're killing people, and they killed Mrs. Coffey."); *id.* at 147 ("After six million Americans had put this into their bodies – six million Americans – it came off the market.").

⁴⁴ *See* 26RR132 ("[C]onsider the net worth of Wyeth. Wyeth is a company worth \$8 billion dollars. It is probably going to take some time and thought to figure out how do you get the attention of a company worth \$8 billion dollars."); *id.* at 134 ("[H]ow much punishment should be assessed on an \$8-billion-dollar company by a fine? . . . [T]he management of a company like that doesn't even care about what's going on until you get to the named number 'billion.'").

that a jury may not use a corporate defendant's "wealth" as a basis to render an exemplary damage award that exceeds the maximum level determined by applying the "ratio" and "analogous penalties" factors. See *State Farm*, 538 U.S. at 427 ("The wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award.").

Using a defendant's net worth as a basis for inflating punitive damage awards is constitutionally forbidden not only because it "bear[s] no relation to the award's reasonableness or proportionality to the harm," *id.*, but also because it gives courts and juries a vehicle for expressing biases against big non-local businesses and allows an individual State to impose undue burdens on interstate commerce. See *BMW*, 517 U.S. at 585; *Honda Motor Co. v. Oberg*, 512 U.S. 415, 432 (1994). Furthermore, it impermissibly allows courts and juries to shift wealth from corporate defendants to individual victims. See *Owens-Corning*, 972 S.W.2d at 39-40 ("Punitive damages are not designed or intended to . . . enrich individual victims.").

For these reasons, the Court must reduce the exemplary damages award *as a matter of law* to an amount that would comport with federal Due Process under *BMW* and *State Farm*, as well as with the Texas Due Course of Law and Excessive Fines Clauses.

SECTION THREE: TRIAL ERRORS

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

Reflecting the pattern of one-sided rulings, the trial court committed a variety of additional errors requiring a new trial.

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

At Plaintiffs' request, the court gave the jury the following spoliation instructions:

The Court instructs you that the deliberate alteration of the CDSSS [adverse event] records by Wyeth is spoliation or destruction of evidence relevant to this case. You may presume that the evidence in the CDSSS records which

were destroyed would have been unfavorable to Wyeth.

The Court instructs you that the deliberate destruction, by Wyeth, of the 14 files from the Mayo Clinic and Fargo, North Dakota is spoliation or destruction of evidence relevant to this case. You may presume that the information contained in the 14 files from the Mayo Clinic and Fargo, North Dakota, which were destroyed would have been unfavorable to Wyeth.

3AP2955. Plaintiffs requested these instructions based on Amy Myers' "overwriting" of the preliminary computer data regarding 14 heart valve cases, as well as on her inability to locate files that contained printed copies of the reports and her notes.

These instructions were erroneous. CR2575-81. As a threshold matter, before a party may properly request an instruction on the spoliation presumption, it must show that the allegedly destroyed evidence was relevant to a fact in issue. *State v. Gonzalez*, 82 S.W.3d 322, 330 (Tex. 2002); *Capital One Bank v. Rollins*, 106 S.W.3d 286, 297 (Tex. App.—Houston [1st Dist.] 2003, no pet.). Information suggesting heart-valve risks, however, is not relevant to Plaintiffs' claims that Pondimin caused Mrs. Coffey's lung disease or to their requests for exemplary damages and to bust the damages cap. *See* Parts II.B.2, IV.A.4, IV.B.1. Nor was any short delay in getting that information to the FDA shown to have affected the availability of Pondimin to Mrs. Coffey or the labeling promulgated by Wyeth. Therefore, a spoliation instruction was improper.

In addition, before giving the instructions, the trial court had to make preliminary findings that Plaintiffs had offered sufficient evidence to allow the jury to find three elements: (1) that Wyeth had a duty to preserve the evidence; (2) that Wyeth breached this duty by deliberately spoliating the evidence; and (3) that the spoliation prejudiced Plaintiffs' ability to present their case. *Offshore Pipelines, Inc. v. Schooley*, 984 S.W.2d 654, 666 (Tex. App.—Houston [1st Dist.] 1998, no pet.); *see also Trevino v. Ortega*, 969 S.W.2d 950, 954-55 (Tex. 1998) (Baker, J., concurring). Plaintiffs failed to offer legally or

factually sufficient evidence of these elements.

Regarding duty, for example, the FDA examined the same facts and did not find that Ms. Myers or Wyeth breached any regulatory duty by overwriting the initial internal computer entries or failing to retain Ms. Myers' duplicate hard copies of the intake information. DX1330. As to breach, all the testimony confirmed that the hard-copy files containing the information were not deliberately destroyed and that Ms. Myers did not overwrite the computer entries with an intent to conceal evidence.⁴⁵ See *Ordonez v. M.W. McCurdy & Co.*, 984 S.W.2d 264, 274 (Tex. App.—Houston [1st Dist.] 1998, no pet.) (trial court correctly refused spoliation instruction because no evidence was destroyed “for the purpose of concealing [it]”); *San Antonio Press, Inc. v. Custom Bilt Mach.*, 852 S.W.2d 64, 67 (Tex. App.—San Antonio 1993, no writ) (no spoliation remedy available if spoliation “done through mistake or misunderstanding and not with intent to hide or destroy evidence”). Instead, Wyeth officials intended to update those entries with complete and correct information, *as they did* a few weeks later. 19RR35.

Most importantly, Plaintiffs failed to show that they suffered any prejudice due to the process Wyeth followed in pursuing more complete, up-to-date information, entering it into the company's computer files, and submitting it to the FDA, a process that the overwriting of the initial computer entries did not affect. The undisputed evidence showed that Dr. Davis of Wyeth received the 14 preliminary reports of heart valve abnormalities from doctors at the Mayo Clinic and in Fargo. 16RR85, 87-88, 115-18; 19RR18-21; DX318-19. She memorialized the details of her conversations in telephone contact reports, *which were admitted into evidence*, and she then provided a summary of that information to

⁴⁵ 19RR59 (hard copy files were not destroyed); *id.* at 14, 29-30, 40 (Ms. Myers overwrote computer files because she believed the preliminary reports lacked sufficient information, not to conceal any information); *id.* at 33-36 (Ms. Myers was instructed to “cancel” – not “overwrite” – the computer files, which would have preserved a record of the files in the database).

Amy Myers, who used her notes from that conversation – and nothing else – to create the now-missing computer records and files regarding the 14 reports. *See supra* pp. 10-12. Thus, although Ms. Myers’ notes and the files containing 14 identical computer forms have been lost and the initial computer entries were overwritten, those were merely duplicates of the original source materials. Dr. Davis’s original materials containing the same information were retained *and offered into evidence*. Moreover, Wyeth preserved in its files a complete record of Wyeth’s in-person follow-up investigation on those reports (and five others). *See id.*⁴⁶ Thus, even *if* reports of heart valve cases were relevant to Plaintiffs’ claim that Pondimin caused Mrs. Coffey’s lung disease, those reports were not only available, but actually were put before the jury. In short, there was no legally or factually sufficient evidence that Ms. Myers’ overwriting resulted in the loss of any information. 16RR129-31; 19RR147-48, 156-59.

Significantly, there was no conceivable prejudice to Plaintiffs’ case. When source information is retained and introduced at trial but additional documents created using only that source information have been lost, a plaintiff is not entitled to a spoliation instruction.⁴⁷

Finally, even if the evidence could have established each of the elements of spoliation, the trial court’s instructions would be reversible error because, over Wyeth’s objection, the court told the jury that spoliation had been established as a matter of law. CR2575-81. The jury had to be allowed to decide whether the facts established spoliation when Wyeth’s evidence, if believed, negated such a finding. Proper spoliation instructions

⁴⁶ Consistently, although the FDA’s review of Wyeth’s ADE reporting system noted that the hard copies of Amy Myers’ 14 preliminary files were missing, the FDA did not conclude that any actual information had been lost. 19RR59-60, 149-50; PX1330 at 24-25; PX1173.

⁴⁷ *See Trevino*, 969 S.W.2d at 958 (Baker, J., concurring) (“[C]ourts should consider whether the destroyed evidence was cumulative of other competent evidence that a party can use in place of the destroyed evidence”); *Brumfield v. Exxon Corp.*, 63 S.W.3d 912, 920 (Tex. App.—Houston [14th Dist.] 2002, pet. denied) (if nonproducing party testifies as to substance or content of missing evidence, opposing party is not entitled to spoliation presumption); *Brewer v. Dowling*, 862 S.W.2d 156, 159 (Tex. App.—Fort Worth 1993, writ denied).

allow the jury to presume that missing evidence would be unfavorable only “if [they] find” that any disputed elements of spoliation were met. *E.g.*, *Wal-Mart Stores, Inc. v. Johnson*, 106 S.W.3d 718, 720-21 (Tex. 2003); *Cresthaven Nursing Residence v. Freeman*, 134 S.W.3d 214, 225 (Tex. App.—Amarillo 2003, no pet.); *Whiteside v. Watson*, 12 S.W.3d 614, 620 (Tex. App.—Eastland 2000, vacated by agr.). In this case, however, the trial court declared that “the deliberate destruction, by Wyeth, of the 14 files . . . is spoliation or destruction of evidence relevant to this case.” 3AP2955 (emphasis added). The trial court erred by resolving any factual disputes against Wyeth and instructing the jury as a matter of law that spoliation occurred⁴⁸ – an instruction that Plaintiffs’ counsel emphasized in closing argument. 26RR214 (“Judge Floyd says, bunk. They deliberately destroyed them.”). In addition, by instructing the jury to “presume” the overwritten data “would have been unfavorable to Wyeth,” the trial court made an impermissible comment on the weight of the evidence.

“[I]f a spoliation instruction should not have been given, the likelihood of harm from the erroneous instruction is substantial, particularly when the case is closely contested.” *Wal-Mart*, 106 S.W.3d at 724. Here, Plaintiffs’ counsel seized on the spoliation instructions during closing argument in an effort to tilt the jury, telling them that the Court itself had decided that Wyeth intentionally destroyed documents. 26RR213-14. Thus, the spoliation instructions unquestionably tainted the jury’s answer to the cap-busting question, thereby exposing Wyeth to hundreds of millions of dollars of additional damage liability. Wyeth is entitled to a new trial.

⁴⁸ See *Lively v. Blackwell*, 51 S.W.3d 637, 641 (Tex. App.—Tyler 2001, pet. denied) (“[S]poliation is not an issue exclusively reserved to the trial court as a question of law.”); *cf. Meek v. Bishop, Peterson & Sharp, P.C.*, 919 S.W.2d 805, 808 (Tex. App.—Houston [14th Dist.] 1996, writ denied) (court must submit fact questions to jury unless facts are undisputed or conclusively established).

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

1. *The trial court erroneously excluded evidence that Mrs. Coffey took other diet drugs with PPH warnings.*

Mr. Coffey assured the jury that his wife never would have taken Pondimin had she known it posed any risk of a potentially fatal illness like PPH. 14RR176. This was the only “proof” Plaintiffs offered in support of their claim that any alleged failure by Wyeth to warn Dr. Tyrrell of the PPH risks of Pondimin caused Mrs. Coffey’s death. Both Mrs. Coffey and Dr. Tyrrell were dead and their testimony had not been preserved.

Nevertheless, the trial judge barred Wyeth from presenting evidence that would have refuted Mr. Coffey’s testimony on this crucial issue. 15RR116-22. The two doctors who prescribed Tenuate and Meridia to Mrs. Coffey expressly counseled her about those drugs’ warnings of the potential risk of PPH and its associated risk of death, but she decided to take those drugs despite the stated risk of developing fatal PPH. 23OP20-30; 25OP187-92. This vital evidence would have contradicted Mr. Coffey’s speculation that his wife would not have taken a drug that posed a risk – however small – of a fatal illness. Because Wyeth’s proffered evidence went to the heart of Plaintiffs’ case on causation, the court’s improper exclusion requires a new trial.

2. *The trial court unfairly biased the jury on the issues of causation and safer alternative design by its rulings and instructions regarding the other diet drugs taken by Mrs. Coffey.*

Two of the other diet drugs Mrs. Coffey took (Tenuate and Meridia) warned of a potential risk of PPH as well as of the potentially fatal nature of that disease. CXNN, JJJ, TTT. In addition, individuals both within and outside the confines of the IPPHS have contracted PPH after taking Tenuate. 9OP60-62. Moreover, the IPPHS reached the same conclusions about Tenuate as it did about Pondimin when it reported that exposure to the diet drugs studied *as a group* was associated with a heightened risk of PPH. CXHH at 612-

13. If the IPPHS finding with respect to onset of symptoms could be ignored (as Plaintiffs contend it can with respect to Pondimin), then Tenuate would be at least as plausible a cause of Mrs. Coffey's PPH as Pondimin. Indeed, Tenuate may be a more plausible cause because she took it much closer in time to her onset of PPH symptoms.

Nevertheless, the trial court unfairly biased the jury in favor of finding that Pondimin was the cause of Mrs. Coffey's illness and that other diet drugs were safer. The court (1) prevented the jury from learning any of those facts about Tenuate and Ms. Coffey's use of that drug, and (2) instructed the jury during closing arguments that none of the "other un-named" diet drugs that Mrs. Coffey took causes PPH: "The jury will be instructed that the other diets drugs do not cause primary pulmonary hypertension." 26RR164-65; *see* 6RR5-16, 17-29; 14RR74-76; 15RR116-22; 15OP221-24; 18RR163-73; 23OP20-37; 25OP104-14, 187-95. In combination, these actions constituted an improper comment on the weight of the evidence that, at a minimum, unfairly biased the jury on the issues of causation and safer alternative design. A new trial is therefore required.

3. The trial court erroneously excluded evidence about Meridia.

In an effort to prove that Pondimin was "unreasonably dangerous," Plaintiffs contended that there were alternative diet drugs on the market available to Mrs. Coffey, one of which was Meridia. 20RR89-91; 24RR82-84. The Plaintiffs wanted the jury to infer that Meridia was a safer alternative, a key element of a defective design claim. 20RR89-91. Nevertheless, as part of the pattern of letting the jury hear only Plaintiffs' side of the story, the court excluded the evidence Wyeth offered to show that (1) Mrs. Coffey actually had taken Meridia after she took Pondimin; (2) like Pondimin and the other diet drugs she later took, the Meridia label and package insert warned of the potential risk of PPH, as well the potentially fatal nature of that disease; (3) Mrs. Coffey's doctor specifically warned her

of the risk; and (4) she chose to take the drug anyway. 20OP115-17; 23OP20-30; 25OP104-113, 187-92. This erroneous exclusion of evidence directly relevant to Plaintiffs' marketing and design defect claims was harmful and requires a new trial.

4. *The trial court repeatedly and erroneously instructed the jury that Dr. Tyrrell had not received Wyeth's "Dear Doctor" letters.*

The trial court repeatedly told the jury that Dr. Tyrrell had not received Wyeth's "Dear Doctor" letters for Pondimin and Redux, which contained updated PPH warnings based on the final IPPHS results. *See supra* at 7. This instruction was improper because there was some evidence that would have allowed a reasonable jury to find that he had received those letters. Although Dr. Tyrrell was a semi-retired doctor whose name did not appear on the address lists for Wyeth's letters, those letters were sent to a doctor in the same office where Dr. Tyrrell worked. *Id.* This at least would have permitted the jury to infer that Dr. Tyrrell saw those letters or learned of their contents during his work at the clinic or in discussions with his colleagues there.

In addition, the trial court gave this erroneous instruction no fewer than nineteen times across the testimony of a variety of witnesses. 9RR160-62, 165, 170, 175; 12RR193; 13RR22-26; 15RR14, 132, 135-36, 138, 141, 200; 17RR42, 70; 18RR37, 40, 42, 63-66; 19RR5-8, 167; 22RR34; 26RR178. This constant refrain created a high likelihood that the jury understood the instruction to mean either (i) that Dr. Tyrrell had not received updated Pondimin warnings from *any* source, even though Wyeth had shown that the Pondimin label and its various PDR entries had been updated to reflect the evolving results of the IPPHS before Dr. Tyrrell even wrote Mrs. Coffey's second and third prescriptions for Pondimin, or (ii) that the trial court believed "Dear Doctor" letters were the only effective means to communicate warnings to doctors, which they are not. Indeed, these understandings of the court's instruction are the only way to explain the jury's liability

finding on Plaintiffs' failure-to-warn claim. There was no evidence that Pondimin's label or the PDR should have reported any stronger warnings regarding PPH than those included at the time of Mrs. Coffey's third prescription.

The trial court's instructions thus constituted a direct, misleading, and erroneous comment on the weight of the evidence. These comments were harmful because they addressed crucial and contested issues under Plaintiffs' warnings, negligence, and exemplary damages claims, each of which was based in part on Wyeth's alleged failure to warn Dr. Tyrrell about the risks of PPH. *See Acord v. Gen. Motors Corp.*, 669 S.W.2d 111, 116 (Tex. 1984); *City of San Antonio*, 931 S.W.2d at 536; *Linden-Alimak*, 745 S.W.2d at 85; TEX. R. CIV. P. 277. Wyeth is therefore entitled to a new trial on all issues.

C. The trial court biased the venire by eliminating qualified jurors.

During jury selection, Plaintiffs' counsel requested that potential jurors be excluded "for cause" if they expressed any view that compensatory or exemplary damages awards should have some limits. 6RR132-33, 144-47, 150-51. Such a view accords with current law, however, as both state and federal law place substantive limits on the amounts of compensatory and exemplary damages that may be awarded in particular cases. *See supra* Parts III-IV. Nevertheless, over Wyeth's objections, the trial court struck five potential jurors on this basis alone.⁴⁹

As the massive awards later confirmed, the court systematically and improperly seated a jury that was biased in favor of limitless exactions. These strikes caused structural error because they deprived Wyeth of its right to a fair trial by jury by preventing selection of a jury from a representative cross-section of the community. *See Dempsey v. Beaumont Hosp., Inc.*, 38 S.W.3d 287, 289 (Tex. App.—Beaumont 2001, pet. disp'd by agr.) ("In

⁴⁹ 6RR132-33 (Venire Person No. 29), 144-46 (No. 42), 146-47 (No. 43), 150-51 (No. 48), 151 (No. 49).

cases involving juror disqualification the Complainant need not establish that probable injury resulted therefrom before a new trial may be granted.”) (internal quotations omitted); TEX. CONST. art. I, § 15; TEX. CONST. art. V, § 10.

D. It was error to allow Plaintiffs’ post-trial pleading amendment, which was surprising and prejudicial as a matter of law.

On the eve of trial, Plaintiffs represented in their Sixth Amended Petition that “in no event” would they seek more than \$50 million in compensatory damages and \$800 million in exemplary damages. 3AP2255. After trial, however, the trial court granted Plaintiffs’ motion to *increase* the compensatory limit by \$63,353,000 and the exemplary limit by \$100 million. 4AP5-6. But a party cannot amend its pleadings post-trial if “the amendment is on its face calculated to surprise” or prejudice the opposing party. *Greenhalgh v. Serv. Lloyds Ins. Co.*, 787 S.W.2d 938, 940 (Tex. 1990). Plaintiffs’ post-verdict motion to amend was surprising and prejudicial for three reasons.

First, Plaintiffs did not identify any trial evidence showing an additional \$63,353,000 in unpleaded compensatory damages or any new basis for an additional \$100 million in punitive damages. *See Nova Gulf Corp. v. Fidinam Res., Inc.*, 821 S.W.2d 729, 731 (Tex. App.—Houston [14th Dist.] 1991, writ denied). Second, the motion sought a massive increase in damages despite Plaintiffs’ prior representation, after completion of all discovery, that “in no event” would they seek greater recovery. *Cf. Greenhalgh*, 787 S.W.3d at 942 (Hecht, J., concurring) (noting potential for surprise and prejudice where damages amendment far exceeds original prayer). Finally, the retrospective increase in the amount of *compensatory* damages sought in the Petition threatens to increase Wyeth’s exposure to *exemplary* damages, because the constitutionality of a punitive award is

assessed in part by the ratio between it and any lawful compensatory award.⁵⁰ The trial court thus abused its discretion in granting Plaintiffs' motion. Plaintiffs' damage awards must be reduced, independently of all other objections, by at least \$63,353,000 in actual damages and \$100 million in punitive damages.

E. The jury's awards of non-economic and exemplary damages reflect a verdict based on unfair passion and prejudice.

Finally, the sheer size of the jury's unprecedented award of at least \$86,630,000 in non-economic damages reflects a verdict that "was the result of passion or prejudice or other improper motive or was in disregard of the evidence." *Dallas Ry. & Terminal Co. v. Farnsworth*, 227 S.W.2d 1017, 1022 (Tex. 1950). Counsel's inflammatory arguments fanned the flames of prejudice, increasing the chances for a verdict tainted by passion:

[Mrs. Coffey's] death was more inevitable than anybody sitting on death row in Huntsville. . . . That mother was on death row by a death warrant issued by this company because of their greed.

26RR230.

[A]re they going to get away with this by just paying some damages? Are they going to get away with it, or are they going to have to pay for their sins? Are they going to have to be punished? Which is what ought to happen for what they did. . . . If they can skip out of this keeping any of that profit, they have won. They have won. They got away with it. And they are going to do it again. God, I hope it's not one of us next time.

Id. at 226.

They marketed a drug that was defective and dangerous. It was killing people and they knew it, internally. . . . The warnings were wrong. They knew it internally and did not do anything about it. Finally, . . . the Mayo Clinic blew the whistle and it came off the market, begrudgingly. After six million Americans had put this into their bodies

Id. at 146-47.

⁵⁰ See *State Farm*, 538 U.S. at 418. In addition, this retroactive increase in Wyeth's potential exposure to punitive damages violated basic principles of due process with respect to the severity of potential penalties. See *BMW*, 517 U.S. at 574; TEX. CONST. art. I, § 19 (due course of law provision).

Contributing to the verdict were the following unfairly prejudicial events that occurred over Wyeth's objections:

- The trial court systematically excluded jurors who legitimately believed that damage awards should be subject to some substantive limitations. *See supra* Part V.C.
- The trial court improperly admitted lay and “expert” testimony that Wyeth destroyed documents, used Enron’s lawyers to stifle witnesses, and acted with malice. *See supra* pp. 13-14; Part IV.A.3.
- Plaintiffs introduced inadmissible and prejudicial documents. *See, e.g.*, PX752, 1319, 1332, 1392, 1397, 1417; 2RR140-43; 3RR70-71; 4RR76-79, 95-97; 8RR5-13; 11RR6-13; 26RR85.
- Both in questioning and in closing, Plaintiffs’ counsel implored the jury to send a message to the drug industry, an improper request under Texas and federal law. *See supra* Part IV.E.
- The sheer magnitude of the jury’s verdict demonstrates that the jury was highly inflamed and motivated by a desire to punish that was not confined to the exemplary damages award.
- Although Plaintiffs’ counsel told the jury that non-economic damages should total \$50 million (an excessive request in itself), 26RR227, the jury awarded \$86.63 million in non-economic damages and \$25.23 million in other compensatory damages unsupported by evidence, thus reflecting that its motive to punish rather than compensate spilled over to its actual damages award.

Because the jury’s massive award of non-economic damages and other record evidence reflect a compensatory damages award based on an improper motive to punish, it demands a new trial as a matter of law.⁵¹

Likewise, the jury’s award of \$900 million in exemplary damages was irretrievably tainted by unfair passion and prejudice as well as by all of the trial court’s erroneous rulings already described. Indeed, this is a case where the size of verdict alone establishes prejudice and passion as a matter of law because it is “so flagrantly excessive that it cannot

⁵¹ *See Ford Motor Co. v. Durrill*, 714 S.W.2d 329, 345 (Tex. App.—Corpus Christi 1986) (where decedent died from burns, court held that \$6.85 million in non-economic damages split among the estate and two beneficiaries must have been “motivated by other factors not found in the evidence”), *vacated by agr.*, 754 S.W.2d 646 (Tex. 1988); *see also Hernandez v. Braddock*, 641 S.W.2d 359 (Tex. App.—Corpus Christi 1982, no writ).

be accounted for on any other [lawful] ground.” *World Oil Co. v. Hicks*, 103 S.W.2d 962, 964 (Tex. 1937). As the Supreme Court of Texas has declared:

There are cases where a shockingly excessive verdict, and the record as a whole, leave no room for doubt that the minds of the 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. The remedy in such a case is to set the verdict aside and refuse remittitur.

*Id.*⁵² This is such a case. Therefore, at a minimum, a remittitur or new trial is required.

CONCLUSION AND PRAYER

The judgment should be reversed and judgment rendered for Wyeth. At a minimum, in view of the numerous errors singularly or taken together and in the interests of justice, Wyeth is entitled to a new, untainted trial on all issues of liability and damages. Alternatively, the judgment should be modified and the damages remitted. As a further alternative, the judgment must be modified, corrected, and/or reformed to address the errors above, to limit the actual and exemplary damages to the amount pleaded in Plaintiffs’ Sixth Amended Petition, and to cap the exemplary damages in accordance with CPRC § 41.008(b).

In no event may the awards of actual or exemplary damages stand at anything like the level contained in the judgment. Wyeth also requests recovery of its costs, including *ad litem* fees, and all other relief to which it may show itself justly entitled.

⁵² See also *Wells v. Dallas I.S.D.*, 793 F.2d 679, 683-84 (5th Cir. 1986) (reversing for new trial rather than remitting because of excessive damages); *cf. id.* at 684 (“[A]t some point on the scale an excessive award becomes so large that it can no longer be considered merely excessive. When an award is ‘so exaggerated as to indicate bias, passion, prejudice, corruption, or other improper motive,’ remittitur is inadequate and the only proper remedy is a new trial.” (citation omitted)).

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)

APRIL 14, 2005

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 April 14, 2005 a true and correct copy of **BRIEF FOR APPELLANT** was properly forwarded to all counsel of record for Appellees in accordance with Rule 9.5 of the Texas Rules of Appellate Procedure, by certified mail, return receipt requested, as follows:

Richard J. Clarkson
595 Orleans Street, Suite 500
Beaumont, Texas 77701

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

Joseph D. Deshotel
1310 Calvin Street
Beaumont, Texas 77701

Claudia Wilson Frost