



Texas Pharmaceutical Failure-to-Warn Claims: Alive and Well

BY AVRAM BLAIR AND G. ERICK ROSEMOND

Editor's note: This article was written in response to "The New Presumption of Adequate Warnings in Texas Pharmaceutical Litigation" (July, p. 612). The Texas Bar Journal Board of Editors strives to publish timely articles of import to the profession. The July article portrayed one side of a contentious issue. This article presents another perspective.

Last month, drug industry lawyers pronounced Texas pharmaceutical failure-to-warn claims DOA.¹ The culprit: preemption of Texas Civil Practices and Remedies Code's §82.007(b)(1).² The pronouncement erroneously presumes §82.007(b)(1) requires that plaintiffs prove fraud on the FDA as an essential element of their warning claims. Thus, the reports of such claims' death have been greatly exaggerated.

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First and foremost, §82.007(b)(1) does not require plaintiffs to prove a defendant committed fraud on any entity. Rather, §82.007(b)(1) is an ordinary “bursting bubble” presumption that disappears upon production of rebuttal evidence. A contrary interpretation assumes legislators intended to eliminate a valuable right both Texas and federal courts recognize has constitutionally coexisted with federal law for decades. The statute’s text, legislative history, analogous statutes, long-standing case law, and bedrock statutory construction rules require that courts construe §82.007 as constitutional and purposeful, preserving both legislative intent and Texans’ rights.

TEXAS CIVIL PRACTICES AND REMEDIES CODE §82.007(B)(1)

Section 82.007(a) provides a “rebut-

table presumption” that a defendant is not liable for warning claims if its drug’s accompanying warnings are FDA-approved. Plaintiffs may rebut this presumption by establishing that “the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to” the FDA “required information that was material and relevant to the performance of the product and was causally related to the claimant’s injury.”³

TEXAS AND FEDERAL RULES OF STATUTORY INTERPRETATION

Both Texas and federal law provide courts with a number of important rules to properly interpret statutes. Texas Government Code §311.021 mandates that courts “presume” the Legislature intends its laws be compliant with the U.S. and

Texas constitutions,⁴ effective in their entirety,⁵ and that public interest is favored over any private interest.⁶ This statute requires courts to avoid certain constructions if possible. Thus, even if a constitutional issue such as preemption looms, a court has no discretion simply to embrace and apply it to void the statute if reasonable and constitutional alternatives exist.

Additionally, once an alternative interpretation emerges, courts may also consider other interpretive aids, including: “(1) [o]bject sought to be attained; (2) circumstances under which the statute was enacted; (3) legislative history; (4) common law or former statutory provisions, including laws on the same or similar subjects; (5) consequences of a particular construction; [and] (6) administrative construction of the statute.”⁷ Texas courts are further compelled to avoid interpretations that eliminate or

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diminish common law rights if possible.⁸

In the unlikely event that a court ever reaches a constitutional issue, it must still follow black-letter rules and presumptions in construing a statute. Like the Texas Legislature, the U.S. Supreme Court mandates that a court interpreting a statute *begin* with a “presumption against the preemption” of state police power.¹⁰ Indeed, it has consistently reaffirmed “the historic primacy of state regulation of matters of health and safety,” which includes the power to enforce tort laws against drug companies. Thus, “a court should not find preemption” without “clear evidence of a conflict.”¹¹ Moreover, “any conflict *must be irreconcilable* or potential conflict is insufficient to warrant preemption of the state statute.”¹² Thus, if court engages in preemption analysis, it may find preemption only if there is no other interpretation. That is not the case with §82.007.

SECTION 82.007’S ELEMENTS

The primary concern expressed regarding state warning claims is the potential for conflict with FDA warning requirements.¹³ Even the FDA, however, has recognized that conflicts are not inevitable.¹⁴ This is true when the alleged failure to warn concerns a danger the FDA never had an opportunity to consider or when the FDA receives only partial or misleading risk information — which is the essence of a *failure to warn* claim.¹⁵ In these circumstances, no conflict is even possible. Section 82.007(b)(1) imposes four requirements: that information was (1) withheld from or misrepresented to the FDA; (2) required; (3) material and relevant to the performance of the product; and (4) causally related to the claimant’s injury.

The presumption first requires that a drug manufacturer withhold information from the FDA or misrepresent it — *intentionally or unintentionally*. This element can be met by evidence that the drug manufacturer was aware of the information but did not submit it to the FDA. The plaintiff could also show that

the defendant negligently misrepresented such information. Critically, §82.007’s plain text does *not* require that a plaintiff show that a defendant committed fraud on *anybody*, let alone the FDA. And it imposes no requirement that the FDA itself determine it has been defrauded. As §82.007’s Senate sponsor, Bill Ratliff, explained: “*But this, [§82.007] this doesn’t say that, this doesn’t say the agency has to find fraud, or has to find they were mis-*

led, what it says is that the information was relevant.”¹⁶

Under §82.007(b)(1), plaintiffs must also show that the defendant was required to produce to the FDA the information at issue. Myriad federal regulations impose such submission requirements.¹⁷ The terms in the phrase “material and relevant to the performance of the product” should be given their ordinary meaning.¹⁸ *Black’s Legal*

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Dictionary defines “material” as “important ... having influence or effect; or going to the merits.”¹⁹ “Relevant” ordinarily means “having significant and demonstrable bearing on the matter at hand.”²⁰ In the context of seeking damages for a particular injury from a drug, this phrase logically requires that the information withheld or misrepresented be something about the drug’s performance as it relates to the chain of events leading to injury.

As for §82.007(b)(1)’s “causally related” prong, Texas law has always required that the plaintiff show that the defendant’s defective warning was “causally related” to his or her injury. For example, the plaintiff could show the withheld information would have affected his or her doctor’s decision to prescribe the drug.²¹

Of note, §82.007 does *not* require that plaintiffs show that the FDA would not have approved the drug “but for”

defendant’s fraud or federal law violation.²² In fact, the statute clearly applies to information withheld or misrepresented *after* FDA approval.²³ Further, legislators expressly considered a “fraud on the FDA” requirement but rejected it.²⁴ And it is nonsensical to impose a requirement of federal law violation given that Texas long ago rejected FDA regulation violations as negligence *per se*.²⁵

THE NATURE OF §82.007’S PRESUMPTION

Under long-standing Texas law, rebuttable presumptions initially shift the burden to the opposing party to produce evidence countering the presumption. Once that is done, the presumption disappears — the so-called “bubble-bursting presumption.”²⁶

Such presumptions pervade pharmaceutical litigation. For example, “once a plaintiff proves that a manufacturer

failed to provide adequate instructions or warnings, his producing cause burden is aided by a presumption that he would have read and heeded adequate warnings or instructions had they been provided.”²⁷ Defendants can rebut it by offer[ing] evidence contrary to the presumption. The plaintiff must then “prove causation by a preponderance of the evidence, and the presumption has no further legal consequence.”²⁸ Likewise, Texas Civil Practice and Remedies Code §82.008, §82.007’s sister provision, provides a rebuttable presumption of no design defect when a manufacturer’s design complies “with mandatory safety standards or regulations adopted and promulgated by the federal government.” This presumption was recently ruled a “bursting-bubble” presumption.²⁹ The presumption created by §82.007, with its identical language, should be similarly interpreted.

Section 82.007(b)(1)’s legislative history confirms this interpretation. The provision’s original, and superceded, drafts required that plaintiffs prove by “clear and convincing evidence” that defendant’s (non)disclosures were intentional. Further, the Senate State Affairs Committee’s bill analysis notes the current language requires only the “establishing certain facts.”³⁰ And Sen. Ratliff observed that “if you can show that harm resulted from the product then it seems to me that it’s, that the presumption is not, is not all that big a hill to climb.”³¹

In short, §82.007’s plain language, legislative history, bedrock rules of statutory construction, and existing case law provide a reasonable interpretation that avoids constitutional concerns. This common sense interpretation requires neither the contrivances nor legalistic contortions one might employ to “interpret” the provision as preempted.³²

SECTION 82.007(B)(1) IS NOT AND CANNOT BE PREEMPTED

As demonstrated above, it is possible and reasonable to interpret §82.007(b)(1) to avoid any constitutional issues.³³ Similar-

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ly, it is possible and reasonable to assume that the Texas Legislature, when it enacted §82.007(b)(1), intended to afford Texas patients a real remedy, not an illusory one.³⁴ To the extent it takes away a patient's common law right, however, §82.007 must "be strictly construed and will not be extended beyond its plain meaning or applied to cases not clearly within its purview."³⁵

Assuming, however, that constitutional issues are reached, Texas courts should have little trouble finding pharmaceutical failure-to-warn claims viable. As discussed above, even the FDA has historically conceded there can be no preemption where the FDA never knew about or considered the information in question.³⁶ As one Texas federal court recently summarized, the "FDA's regulations do not conflict with Texas failure-to-warn law because they merely set minimum standards with which manufacturers must comply."³⁷ Indeed, the regulations expressly allow a manufacturer to "add[] or strengthen[] a contraindication, warning, precaution, or adverse reaction" without FDA intervention.³⁸ Thus, the court noted, "[w]ith little exception, courts that have considered this exact issue have concluded that state failure to warn claims are not preempted by the FDA and its attendant regulations."³⁹

The injection of evidence regarding defendants' communications with the FDA has never resulted in a finding of preemption.⁴⁰ For example, the U.S. Court of Appeals for the Third Circuit, applying Texas law in a pharmaceutical case, recently ruled evidence of defendants' FDA submissions admissible and "highly probative on issues of negligence and failure to warn."⁴¹ The court further wrote that the "failure to report adverse reactions to the FDA — whether accidental or intentional — would be probative of a failure to warn."⁴² Thus, any evidence that a defendant had misled the FDA was admitted because this "evidence certainly tended to prove that the defendant 'knows or should know of a potential risk of harm presented by a product but markets it without ade-

quately warning of the danger,' which is the definition of a 'marketing defect' under Texas tort law."⁴³

Finally, although drug manufacturers have seized upon recent pronouncements from the FDA about the alleged preemptive effect of its regulations,⁴⁴ there is a very open question as to whether the FDA's purported authority to void 50 states' tort law is itself constitutional and whether Congress could constitutionally delegate such authority if it so desired.

CONCLUSION

In the final analysis, §82.007 resembles nothing like the complicated, opaque legislation rife with hidden provisions and requirements that some would suggest.⁴⁵ It does not eliminate a cause of action and a right Texans have enjoyed for decades. Instead, interpreted under time-honored statutes and methods, it is a simple, rebuttable, evidentiary

presumption that operates just like others under Texas law — it disappears in the face of contrary evidence.

NOTES

1. See Travis J. Sales & Steven J. Mitby, *The New Presumption of Adequate Warnings in Texas Pharmaceutical Litigation*, 69 Tex. B. J. 612 (2006). The authors' firm represents Merck in Vioxx litigation.
2. See *Id.* at 614.
3. Tex. Civ. Prac. & Rem. Code Ann. §82.007(b)(1) (Vernon 1986).
4. *FSLIC v. Glen Ridge I Condominiums, Ltd.*, 750 S.W.2d 757, 759 (Tex. 1988) (citing *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833 (1986)) (courts have a "duty to construe statutes in a manner which avoids serious doubt of their constitutionality"); *Holmans v. Transource Polymers, Inc.*, 914 S.W.2d 189, 191 (Tex. App. — Fort Worth 1995, writ denied) ("[w]hen the statute lends itself to two interpretations, one which is reasonable and within the constitution and one which would render the statute unconstitutional, we must adopt the interpretation which protects the statute's constitutionality"); *Brady v. Fourteenth Court of Appeals*, 795 S.W.2d 712, 715

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- (Tex.1990) (“statutes are given a construction consistent with constitutional requirements, when possible, because the legislature is presumed to have intended compliance with [the constitution]”); *Williams v. Texas State Bd. of Orthotics & Prosthetics*, 150 S.W.3d 563, 571 (Tex. App. — Austin 2004, no pet.) (citing *General Servs. Comm’n v. Little-Tex Insulation Co., Inc.*, 39 S.W.3d 591, 598 (Tex. 2001)); *Texas Bldg. Owners & Managers Ass’n v. Public Util. Comm’n*, 110 S.W.3d 524, 536 (Tex. App. — Austin 2003, pet. denied).
5. See, e.g., *Casa Ford, Inc. v. Ford Motor Co.*, 951 S.W.2d 865, 870 (Tex. App. — Texarkana 1997, pet. denied). In interpreting the enabling clause of Tex. Civ. Prac. & Rem. Code §82, the court held, “[w]e should presume that the enabling clause is effective as to both Sections 82.002 and 82.004. The trial court’s interpretation impermissibly concludes that the Legislature enacted a statute with no effect on one of its expressly intended subjects.” See *id.* (citing Tex. Gov’t Code Ann. §311.021(2) (Vernon 1988)). A court is not, therefore, permitted to conclude the legislature intended to enact a statute that is a nullity absent some very clear expression of that intent.
 6. (Emphasis added).
 7. Tex. Gov’t Code Ann. §311.023 (Vernon 1988).
 8. *Holmans*, 914 S.W.2d at 191 (citing *Smith v. Sewell*, 858 S.W.2d 350, 354 (Tex.1993)).
 9. Preemption means a state statute is federally unconstitutional. *Hillsborough v. Automated Med. Labs*, 471 U.S. 707, 712-13 (1985).
 10. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (emphasis added); see also *Cartwright v. Pfizer, Inc.*, 369 F.Supp. 2d 876, 882 (E.D. Tex. 2005).
 11. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 885 (2000).
 12. See Sales & Mitby, *supra* note 2; *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 110 (1992) (J. Kennedy, concurring).
 13. See 71 Fed. Reg. 3933 (Jan. 24, 2006).
 14. *Id.* at 3936 (“FDA recognizes that FDA’s regulation of drug labeling will not preempt all state law actions”).
 15. *Id.* at 3935.
 16. Hearings on Tex. H.B. 4 before the Senate State Affairs Comm., 78 Leg., R.S. Tape 2 (April 14, 2003) (transcript available from Senate Staff Services Office).
 17. See 21 U.S.C. §§355(a), (b) (which requires submission of studies concerning the drug and its possible adverse side effects and “clinical studies concerning the safety and effectiveness of the drug”); 21 CFR §314.50(d)(2), (3), and (5) (listing information to be included in new drug applications).
 18. Tex. Gov’t Code Ann. §312.002(a); *Owens Corning v. Carter*, 997 S.W.2d 560, 577 (Tex. 1999).
 19. Joseph R. Nolan Et Al., *Black’s Law Dictionary* (6th ed. 1990). (emphasis added).
 20. See generally <http://www.m-w.com/dictionary> [Merriam-Webster Online Dictionary].
 21. Texas has adopted the “learned intermediary” doctrine, which imposes upon prescription drug manufacturers a duty adequately to warn a patient’s physician, not the patient himself. See *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 185 (Tex. 2004); *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986); *Khan v. Velsicol Chem. Corp.*, 711 S.W.2d 310, 313 (Tex. App. — Dallas 1986, writ ref’d n.r.e.) (refusing to apply doctrine to relieve pesticide manufacturer of duty to warn); *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App. — Corpus Christi 1973, writ ref’d n.r.e.).
 22. The few state statutes that have been held preempted have imposed such a requirement or a showing that FDA regulations were violated. For example, the Michigan statute at issue in *Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961 (6th Cir. 2004), provided that in order to overcome the presumption the plaintiff must show “(a) [the defendant] intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under

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- the federal food, drug, and cosmetic act..., and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.” (emphasis added). The statute in *Kobar v. Novartis Corp.*, 378 F.Supp. 2d 1166, 1168 (D.C. Ariz. 2005) provided that plaintiffs could overcome the presumption by proving, by clear and convincing evidence, violations of applicable federal food and drug administration regulations.
23. Hearings on Tex. H.B. 4 before the Senate State Affairs Comm., 78 Leg., R.S. Tape 2 (April 14, 2003) (transcript available from Senate Staff Services Office).
 24. Indeed, Sen. Harris proposed Committee Amendment 17 to §82.007. As Sen. Harris explained, it “requires that in order for exemplary damages to be awarded against a pharmaceutical company, in a products liability action involving a product approved by the FDA, the FDA must first find that there has been a fraud on the FDA.” Hearings on Tex. H.B. 4 before the Senate State Affairs Comm., 78 Leg., R.S. Tape 2 (May 13, 2003) (transcript available from Senate Staff Services Office). The amendment was rejected. *Id.*
 25. See *Baker v. Smith & Nephew Richards, Inc.*, 1999 WL 811334 *17 (Tex. Dist. 1999), *aff’d*, *McMabon v. Smith & Nephew Richards, Inc.*, 2000 WL 991697 (Tex. App. — Houston [14th Dist.] 2000, no pet.).
 26. See *General Motors v. Saenz*, 873 S.W.2d 353, 359 (Tex. 1993).
 27. See *Daimlerchrysler Corp. v. Hillhouse*, 161 S.W.3d 541, 550 (Tex. App. — San Antonio 2004, pet. granted, judgment vacated w.r.m.); *Magro v. Ragsdale Bros., Inc.*, 721 S.W.2d 832, 834 (Tex. 1986); *General Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex. 1993).
 28. *General Motors Corp.*, 873 S.W.2d at 359.
 29. *Bic Pen Corp. v. Carter*, 171 S.W.3d 657, 667 (Tex. App. — Corpus Christi 2005, pet. filed).
 30. Senate committee substitute, HB 4, Bill Analysis, 78 Leg., R.S. (2003).
 31. Hearings on Tex. H.B. 4 before the Senate State Affairs Comm., 78 Leg., R.S. Tape 2 (April 14, 2003) (transcript available from Senate Staff Services Office).
 32. See *Sales & Mitby*, *supra* note 2.
 33. See Tex. Gov’t Code Ann. §311.021(1) (Vernon 1988).
 34. See Tex. Gov’t Code Ann. §311.021(2) (Vernon 1988).
 35. *Holmans*, 914 S.W.2d at 191 (citing *Smith v. Sewell*, 858 S.W.2d 350, 354 (Tex. 1993)).
 36. See, e.g., *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 110 (1992) (J. Kennedy, concurring).
 37. *Cartwright v. Pfizer, Inc.*, 369 F.Supp. 2d 876, 882 (E.D. Tex. 2005).
 38. 21 C.F.R. §314.70(c)(6)(iii)(A) (2006).
 39. *Cartwright*, 369 F.Supp. 2d at 882 (emphasis added); see also *Hurley v. Lederle Labs.*, 863 F.2d 1173 (5th Cir. 1988) (noting the FDA

does not generally preempt state duty to warn laws); *Osburn v. Anchor Labs., Inc.*, 825 F.2d 908 (5th Cir. 1987) (providing examples where FDCA and FDA regulations of labeling did not preempt state tort law remedies).

40. See e.g., *Globetti v. Sandoz Pharm. Corp.*, 2001 U.S. Dist. LEXIS 2391, *8 (“While plaintiff may not offer evidence simply to show misrepresentations to or concealment from the FDA, such evidence may be relevant to showing the defendant’s knowledge relating to the adequacy of the warning or the truth of information represented to or concealed from plaintiff or her physician.”); see also *Bouchard v. Am. Home. Prod. Corp.*, 213 F.Supp.2d 802, 812 (N.D. Ohio 2002) (holding that if “as Bouchard has stated, her claims are based on direct fraud against her and her healthcare provider, rather than the FDA, then her claims are not preempted, and evidence concerning what information was and was not provided to the FDA might still be relevant”).
41. *In re Diet Drugs*, 369 F.3d 293, 312 (3rd Cir. 2004) (emphasis added).
42. *Id.* (emphasis added).
43. *Id.* at 313 (citing *Sims v. Washex Mach. Corp.*, 932 S.W.2d 559, 562 (Tex. App. — Houston [1st Dist.] 1995, no writ) & *Jackson v. Johns-Mannville Sales Corp.*, 750 F.2d 1314, 1318-20 & n. 8 (5th cir. 1985) (en banc) (Mississippi law)).
44. See, e.g., 71 Fed. Reg. 3933 (Jan. 24, 2006) (“Comments on the Products Liability Implications of the Proposed Rule”).
45. See *Sales & Mitby*, *supra* note 2.

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