

## Preemption, tort reform, and pharmaceutical claims

### Part one: Who will become the pharmaceutical industry's insurers (or is it prescribing physicians and we do not know it?)

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In May, the Houston, Texas, judge overseeing the Texas Vioxx litigation ruled that unless the US Food and Drug Administration (FDA) has explicitly determined that a pharmaceutical manufacturer committed fraud in connection with the approval or marketing of an FDA-approved medication, Texas residents could not pursue a “failure-to-warn” claim against the medication’s manufacturer (1). While some praise rulings such as this as a step in favor of curbing baseless legal claims (2) and in favor of a more rational oversight of the pharmaceutical industry (3), what is the ultimate effect of this ruling on the others involved in the utilization of prescription medications, namely prescribing physicians and patients? In this and the next issue of *Proceedings*, we will look at the *Ledbetter* decision and its practical effect to see if we like the answers to these questions. In this issue, we analyze the decision itself and its effect on future legal disputes over prescription medications. In the next issue, we will look at where this leaves the citizens of Texas and where the underlying rationale for this and similar decisions leaves the American public.

#### THE LEDBETTER DECISION

In *Ledbetter v. Merck & Co.*, the plaintiff alleged numerous causes of action against Merck with respect to its pain relief medication Vioxx, including failure to adequately warn patients of the cardiovascular risks associated with use of the medication. In evaluation of Merck’s request for dismissal of the plaintiff’s failure-to-warn claims, the focus was on Section 82.007 of the *Texas Civil Practice and Remedies Code*, a statute passed as part of the 2003 Texas Tort Reform package (4). Statutes with the similar goal of insulating pharmaceutical manufacturers from liability have been passed by other states (5).

Section 82.007 applies to any “products liability action” involving medications and, more specifically, failure-to-warn claims involving medications (4). In such failure-to-warn claims, Section 82.007 creates a “rebuttable presumption” that the pharmaceutical company is “not liable with respect to allegations involving failure to provide adequate warnings or information” if the warnings with the medication (i.e., the package insert information) were approved by the FDA (4). Section 82.007 further provides that this presumption may be rebutted in one of five ways (4). The manner of rebuttal at issue in *Ledbetter* (and notably the manner of rebuttal that would generally be

at issue in any failure-to-warn claim against a pharmaceutical manufacturer) requires the claimant to show that the pharmaceutical manufacturer

before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant’s injury (4).

Merck argued that this method of rebuttal was unconstitutional since it represented state interference with the exclusive federal regulation of the pharmaceutical industry. Since this manner of rebuttal was unconstitutional, Merck argued that it was not a proper manner through which the claimant could rebut the underlying statutory “presumption” that Merck was not liable, given that the warnings that accompanied Vioxx (the information in the Vioxx package insert) were FDA approved. Since the presumption of no liability could not be legally rebutted, Merck submitted that it was entitled to dismissal of the plaintiff’s failure-to-warn claims (6). Specifically, Merck asserted that this manner of rebuttal under Section 82.007 was unconstitutional because it conflicted with exclusive federal regulation of the pharmaceutical industry as reflected in the Food, Drug, and Cosmetic Act (FDCA) (7) and recent FDA statements that accompanied its new 2006 medication labeling regulations (8).

Preemption is based on the Supremacy Clause of the US Constitution. The Supremacy Clause states:

This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding (9).

In essence, if there is a conflict between federal law and state law, the state law is unconstitutional (since it violates this clause

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of the Constitution), i.e., it is stricken/does not exist. Under the Supremacy Clause, federal law can preempt state law in several instances: 1) when Congress expressly enacts laws that preempt state laws; 2) when state law regulates conduct in areas Congress intended to be under exclusive federal government regulation; and 3) when state law actually conflicts with federal law (10). The preemption issue in *Ledbetter* focused on the second instance—whether or not the manner of rebuttal provided for in Section 82.007(b)(1) was unconstitutional because it was a state law that regulated conduct in an area where Congress intended exclusive federal government regulation.

To appreciate the impact and significance of preemption in the tort/products liability context, one needs to understand that an individual's right to legal redress for a tortiously inflicted injury is based on either common law or statutory law. Tort claims related to products such as pharmaceuticals are authorized by state law, either common law or statutory. Federal law has no statutory provisions authorizing similar causes of action, and there is no general common law (11). Thus, particularly in personal injury tort claims, the absence of a state law remedy means the absence of any remedy.

In *Ledbetter*, Merck's argument was in essence that the manner of rebuttal set forth in Section 82.007(b)(1) amounted to creation of a state "fraud-on-the-FDA" claim, meaning that such manner of "rebuttal" had to be based on Merck's failure to comply with FDA regulations in connection with the approval and marketing of Vioxx (6). Merck's position and request for dismissal of the plaintiff's failure-to-warn claims relied on interpretation of the 2001 US Supreme Court decision in *Buckman v. Plaintiffs' Legal Committee* (12).

*Buckman* involved a number of claims for injuries alleged to have resulted from the use of pedicle screws in connection with spinal surgery procedures. The claim at issue in *Buckman* was not a claim against the manufacturer of the orthopedic screws. Rather, the claim was against the Buckman Company, which assisted the screws' manufacturer (AcroMed) in securing FDA approval for the marketing of the screws. Specifically, the *Buckman* claimants alleged that FDA approval of the screws was the result of fraudulent representations made to the FDA by the Buckman Company on the intended use of the screws. The Supreme Court in *Buckman* held that plaintiffs' specific fraud-on-the-FDA claim against the Buckman Company was preempted (meaning that the plaintiffs could assert no such claim) because the state law claims that Buckman Company was liable because of its misrepresentations to the FDA in connection with the approval of the pedicle screws "inevitably conflict with the FDA's responsibility to police fraud." Accordingly, the state fraud-on-the-FDA claims were preempted and held unconstitutional because they represented an attempt to have state law govern an area in which Congress intended exclusive federal regulation (13).

In dismissing the failure-to-warn claims against Merck in *Ledbetter*, the judge noted that claimants could only use the manner of rebuttal set forth in Section 82.007(b)(1) "if the FDA determines that required information was withheld" (1). Thus, *Ledbetter* makes the FDA the arbiter of whether or not a

failure-to-warn claim exists in Texas. Unless the FDA has specifically found that it has been defrauded by a pharmaceutical manufacturer, no failure-to-warn claim can be asserted against the manufacturer. Recognizing the significance of this ruling and that the appellate courts in Texas would need to pass judgment on his ruling, the judge also ordered that appeal of his ruling be accelerated (1).

If this ruling is upheld on appeal, for all practical purposes claims for failure to warn against pharmaceutical manufacturers in Texas are a thing of the past. This may also have the practical effect of completely eliminating products liability claims against pharmaceutical manufacturers in Texas (14). Since federal law provides no individual a cause of action against a pharmaceutical manufacturer for failure to warn of the risks of pharmaceuticals, elimination of state failure-to-warn and products liability claims means that Texas citizens cannot assert such a claim against a pharmaceutical manufacturer (15). Further, even if one were to assume that the FDA proactively seeks out and tries to establish this manner of "fraud" on a routine and consistent basis, the likelihood that the FDA will determine that a manufacturer withheld required information from it within the applicable statute of limitations so that affected patients can timely assert a claim is remote (16).

#### IS LEDBETTER A CORRECT APPLICATION AND INTERPRETATION OF PREEMPTION LAW?

While *Ledbetter* is the first Texas state court opinion we are aware of that examines the constitutionality of Section 82.007(b)(1) under federal preemption, the general issue about whether failure-to-warn claims are preempted by federal law in some form has been evaluated by a number of courts over the past few years. To date, the preemption argument has generally been based on one (or more) of four contentions:

- A general contention that the FDCA preempts failure-to-warn claims
- A contention that the 2006 FDA Final Rule on the Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Labels requires preemption of state failure-to-warn claims
- A contention that *Buckman* generally requires a preemption of failure-to-warn claims
- A contention that application of *Buckman* to specific state statutory provision requires preemption

The general assertion that the FDCA requires preemption of failure-to-warn claims has not met with much success (17). Decisions rejecting preemption were based on the fact that FDA labeling regulations specifically state that they are only minimum standards of conduct (17). In fact, courts pointed out that FDA regulations specifically allowed for manufacturers to strengthen a label warning at any time (17).

The contention that the 2006 FDA final rule on labeling (8) mandates preemption is based on an assertion that these new regulations on medication labeling create a "floor and a ceiling" on manufacturer responsibility and are clear evidence that FDA regulations in this arena are meant to supersede state

warning requirements (18). Putting aside the specter that the FDA may have promulgated this position in direct violation of a US Presidential Executive Order (19), most courts faced with this contention declined to agree to this established preemption of state failure-to-warn claims (20). In declining to find preemption, courts relied on the fact that the recent FDA position in favor of preemption in the 2006 Preamble is contrary to prior FDA positions on the relation between the FDA and state law and is also contrary to the FDA's own regulations (21). Further, courts have ruled that the new FDA labeling regulations do not place a "ceiling" on manufacturer conduct, because FDA regulations still allow a manufacturer to provide warnings with medications beyond those required by the FDA (22). Thus, there is no preemption because FDA regulations are not the "final word" on the scope and substance of manufacturer warnings (20).

Following *Buckman*, another preemption argument has centered on whether or not state failure-to-warn claims based on inadequate label warnings were really fraud-on-the-FDA claims, since failure-to-warn claims have frequently included an assertion that the product label at issue was inadequate because the manufacturer misled or failed to provide important information to the FDA. If failure-to-warn claims can be characterized in this manner, *Buckman* mandates that such state failure-to-warn claims are preempted and are not viable causes of action (12). When the preemption question has focused on this issue, courts have still generally ruled against preemption (23). The bases for these decisions have been that failure-to-warn claims are not truly fraud-on-the-FDA claims because such causes of action are well based in traditional state common law (24) and because the FDA does not police whether or not manufacturers have complied with the duty to affirmatively provide stronger warnings than those warnings present in the FDA-approved label when indicated (25).

The significant split over whether or not state failure-to-warn claims are preempted by *Buckman* exists when courts have been faced with application of *Buckman* to specific state statutes somewhat similar in nature to Section 82.007. At this time, courts have addressed statutes of a similar nature in Arizona, Michigan, and New Jersey. These statutes provide pharmaceutical manufacturers with immunity from liability or exemplary/punitive damages in failure-to-warn claims if the warning with the product was FDA approved, unless product approval was obtained because the FDA was misled or not provided with adequate information. The Michigan statute provides immunity from failure-to-warn claims (26). The Arizona and New Jersey statutes provide immunity from exemplary/punitive damages (27).

The division of opinions depends on whether courts view *Buckman* expansively or narrowly. Courts finding preemption viewed *Buckman* expansively. These courts interpreted *Buckman* as holding that if a state claim involves in some manner improper manufacturer interaction with FDA, the state claim is preempted as a fraud-on-the-FDA claim (28). Cases finding no preemption viewed *Buckman* as narrowly applying only to circumstances in which there was no independent failure-to-

warn products liability claim. If there is a traditional state claim for failure to warn, the fact that a portion of the failure-to-warn claim might rely on evidence that the manufacturer misled and/or failed to provide proper information to the FDA did not mandate preemption of the failure-to-warn claim (29).

Prior to *Ledbetter*, the only reported case interpreting Section 82.007 in this context was *Ackerman v. Wyeth*, a federal court case out of the Eastern District of Texas (30). In *Ackerman*, the court addressed preemption in a very succinct and direct manner. The court held that because Section 82.007 created only a presumption, and because the manner of rebuttal at issue ("if the plaintiff comes forward with evidence that the FDA was somehow misled") rebuts only the presumption and does not establish liability or create a cause of action where none existed before, no preemption existed and the statutory manner of rebutting the presumption was constitutional (31).

In *Ledbetter*, the judge was obviously not persuaded by the federal court's brief evaluation of this issue in *Ackerman* and interpreted *Buckman* in an expansive manner. Instead of seeing that state failure-to-warn claims could be based on evidence above and beyond fraud on the FDA and that by enacting Section 82.007 the Texas legislature was not trying to create a state fraud-on-the-FDA cause of action, the judge instead appears to interpret Section 82.007 as providing an exclusive manner through which a claimant establishes liability, not just a manner to rebut the statutory presumption.

An issue that did not appear to be a focus of the *Ledbetter* decision, but which could be of significance, is the fact that *Buckman* dealt with FDA regulation of medical devices, not pharmaceutical products. Since issues related to the preemption and the federal regulation of medical devices addresses the scope of the Medical Device Amendments of the FDCA, provisions very different from those that pertain to pharmaceuticals, some courts do not believe this line of preemption cases to be relevant in this context (32). Review of two recent cases involving implantable defibrillators, however, is informative of recent judicial evaluation of the *Buckman* fraud-on-the-FDA issue in *Ledbetter*.

In late 2006, *In re Medtronic, Inc., Implantable Defibrillators Litigation* involved the sale of possibly defective devices, resulting in injury to the plaintiffs. One of the preemption issues addressed was Medtronic's assertion that the failure to advise patients and physicians about the device defect was preempted under *Buckman* (33). In finding no preemption of plaintiffs' claims, the court noted that the medical devices were used in a non-FDA-approved, "off-label" manner (33). Further, the court declined to read *Buckman* expansively, stating that the plaintiffs

may use evidence—if they are able to produce it—of Medtronic's efforts to manipulate the regulatory process in order to prove their negligence and strict liability claims, but they may not bring an independent claim for relief based on fraud-on-the-FDA. All plaintiffs' claims are based on state statutes or traditional tort causes of action; they seek no recovery for a fraud-on-the-FDA claim. For these reasons, the Court finds no basis in *Buckman* to find an implied preemption of plaintiffs' claims [citations omitted] (33).

In May 2007, a similar issue was addressed in *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation* (34). This opinion dealt with the claims of 73-year bellwether plaintiff Leopoldo Duron against Guidant in that multidistrict litigation. Guidant sought dismissal of the plaintiff's fraud and negligence-based claims against it on the basis of federal preemption because those claims

are incorrectly premised on the idea that Guidant withheld certain information from the FDA. Guidant asserted that the FDA, not Duron, is the only one that can regulate whether Guidant correctly supplied it with information and that Duron's allegations conflict with the FDA's responsibility to police itself. Guidant further contended Duron's fraud and negligence-based claims were merely "fraud-on-the-FDA" claims in disguise (35).

In holding that plaintiff's claims were not preempted, the court pointed out that Guidant's reliance on *Buckman* was "misplaced" because the claims before the US Supreme Court in *Buckman* "were actual 'fraud-on-the-FDA' claims. . . . There were no allegations that the products themselves were defective" (35). The court further held that the plaintiff's claims were not preempted because they did not seek to "usurp" the authority of the FDA but only asserted that Guidant's failure to comply with FDA regulations also violated state statutory and common law duties and that the plaintiff's claims were based on duties owed to him, not the FDA (35).

It is true that these two recent cases do not examine preemption issues specific to pharmaceuticals and do not involve interpretation of any statute similar to Section 82.007. It is interesting to note, however, the apparent continuing trend in evaluation of *Buckman* issues that the use of fraud-on-the-FDA evidence by claimants to support their state negligence and/or products liability claim does not dictate preemption of those state claims. This appears to be the rationale underlying the *Ackerman* evaluation of Section 82.007 (30). This was not the rationale followed by the judge in *Ledbetter* (1). Further, while the US Supreme Court does have a medical device preemption case on its docket for this fall (36), review of the circuit court opinion to be addressed does not reveal the presence of a *Buckman* preemption issue (37). As such, it appears that the next direction we will receive on this issue may very well come from the 14th District Houston Court of Appeals when it addresses *Ledbetter*.

## CONCLUSION

Does *Ledbetter* foretell that any failure-to-warn claim based on prescription medications is a thing of the past in Texas? While Section 82.007 states that it applies to health care providers and prescribers, the statute limits such application to "products liability" actions (4). Review of the statutory definition of a products liability action as set forth in the statute itself only references actions against a "manufacturer or seller" (38). In fact, some authors believe that Section 82.007 may be of no benefit to prescribing physicians (39). Under Texas case law existing prior to the passage of Section 82.007, a health care provider was subject to products liability laws only if the sale

or distribution of the product at issue was only "incidental" to the rendition of medical services (40). If the product got to the patient through the provision of professional medical services, products liability laws did not apply to the health care provider (41). Further, courts would need to address the fact that Section 82.007 conflicts with the provisions of another Texas statute that governs appropriate disclosures by health care providers to patients in connection with medical treatment (42).

Based on *Ledbetter*, the possibility exists that the prescribing physician could be exposed to a failure-to-warn claim, even if the pharmaceutical manufacturer was not. Further, counsel for Merck in the Texas Vioxx litigation (and for other pharmaceutical manufacturers) have advocated that under Texas law, even if claimants are able to utilize the manner of rebuttal set forth in Section 82.007(b)(1), application of the "learned intermediary" doctrine would still shield pharmaceutical manufacturers from liability (43). Under the learned intermediary doctrine, a pharmaceutical manufacturer avoids liability for failure to warn and attempts to place liability exposure solely on the prescribing physician by claiming that it provided the prescribing physician with an adequate warning (44).

The underlying policy issue here comes down to a matter of trust. Do we trust that if failure-to-warn claims involving pharmaceuticals follow the Texas Gray Wolf and Texas Red Wolf into extinction (45) the FDA and the pharmaceutical industry will provide the American public with uniform and quick access to reasonably priced safe medications? Do we trust the FDA to adequately police the pharmaceutical industry and prevent unreasonably dangerous medications from reaching the US market and/or remaining there? The FDA's record on proactively "policing" the pharmaceutical industry may leave much to be desired (46). Further, can and/or should any industry really police itself? These are questions that we will address in the next *Proceedings*.

One thing that we do know is that counsel representing pharmaceutical manufacturers tout the *Ledbetter* decision as providing pharmaceutical manufacturers with virtual complete immunity from products liability claims in Texas (14). Some authors are concerned that prescribing physicians may not have the same protections afforded the manufacturers (39). Thus, by virtue of *Ledbetter*, pharmaceutical manufacturers are essentially immune from liability while prescribing physicians may now be the only party exposed to liability for claims related to prescription medications, effectively making them the insurers for the pharmaceutical industry in Texas. Does tort reform, practically embodied as tort elimination in this context, best serve the interests of Texas citizens and the American public?

1. *Ruby Ledbetter v Merck & Co, Inc*, 2007 WL 1181991, \*1181991+(Trial Order) (Tex Dist Apr 19, 2007) Order Granting Defendant's Motion for Partial Summary Judgment and Granting Expedited Appeal (No 2005-59499).
2. Beck J, Herrmann M. *Why the Texas Vioxx Decision Matters*. Drug and Device Law Blogspot, April 22, 2007. Available at [http://druganddevicelaw.blogspot.com/2007\\_04\\_01\\_archive.html](http://druganddevicelaw.blogspot.com/2007_04_01_archive.html); accessed July 20, 2007.
3. See Troy DE. *State-Level Protection for Good-Faith Pharmaceutical Manufacturers*. Washington, DC: The Federalist Society, March 21, 2006.

4. Tex Civ Prac & Rem Code, §82.007 (Vernon's 2007).
5. See Mich Comp Laws, §600.2946(5) (immunizes manufacturers from products liability claims unless material information misrepresented or withheld from FDA); Ariz Rev Stat Ann, §12-701; NJ Stat Ann, §2A:58C-5(c); Ohio Rev Code Ann, §2307.80(C); Or Rev Stat, §30.927; Utah Code, §78-18-2 (immunizes manufacturers from punitive damages unless material information misrepresented or withheld from FDA); NC Gen Stat, §99B-6(b)(4) (compliance with FDA or other government standard a factor to be considered).
6. See *In re: Texas State Vioxx Litigation*, 2006 WL 4547728, \*4547728+(Trial Motion, Memorandum and Affidavit) (Tex Dist Aug 14, 2006) Merck's Motion for Partial Summary Judgment on Warnings Claims (No 2005-59499).
7. See 21 USC §301-392.
8. See *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed Reg 3922 (Jan 24, 2006).
9. See US Const art VI, cl 2.
10. See *English v General Electric Co*, 496 US 72, 78-79 (1990).
11. See *Erie v Tompkins*, 304 US 64 (1938).
12. *Buckman v Plaintiffs' Legal Committee*, 531 US 1012 (2001).
13. *Id* at 1020.
14. Beck J, Herrmann M. *Why Does Preemption Matter?* Drug and Device Law Blogspot, April 15, 2007. Available at [http://druganddeviceclaw.blogspot.com/2007\\_04\\_01\\_archive.html](http://druganddeviceclaw.blogspot.com/2007_04_01_archive.html); accessed July 20, 2007. ("In most pharma products cases, failure-to-warn is the whole ball game.")
15. See *In re: Vioxx Products Liability Litigation* — FSupp2d —, 2007 WL 1952964, \*10 (ED La July 7, 2007) (citing *Wack v Lederle Labs*, 666 FSupp 123, 128 (ND Ohio 1987) and Rabin RL. Poking holes in the fabric of tort: a comment. *DePaul Law Review* 2007;56:293).
16. See *Ruby Ledbetter v Merck & Co, Inc* (Tex Dist Apr 19, 2007) Plaintiffs' Steering Committee's Motion for New Trial, or, in the Alternative, Motion to Modify, Correct or Reform the Court's April 19 Judgment on Severed Warnings Claims (No 2005-59499).
17. See *Hill v Searle Laboratories*, 884 F2d 1064, 1068 (8th Cir 1989); *Osburn v Anchor Laboratories, Inc*, 825 F2d 908, 912-13 (5th Cir 1987); *Wells v Ortho Pharm Corp*, 788 F2d 741, 746 (11th Cir 1986).
18. See *Sykes v Glaxo-SmithKline*, 484 FSupp2d 289, 306-17 (ED Pa 2007); *Colacicco v Apotex, Inc*, 432 FSupp2d 523-38 (ED Pa 2006); *In re Bextra & Celebrex Marketing Sales Practices & Products Liability*, MDL 1699, WL 2374742 at \*5-12 (ND Cal Aug 2006).
19. Rauschenberger SJ. Re: Food and Drug Administration Final Rule on the Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Labels, Docket No 00N-1269 [letter to Mike Leavitt, Secretary, US Department of Health and Human Services], January 13, 2006. Available at <http://www.ncsl.org/programs/press/2006/060113Leavitt.htm>; accessed July 20, 2007.
20. See *In re: Vioxx Products Liability Litigation*, — FSupp2d —, 2007 WL 1952964, at \*8-9 (ED La July 7, 2007); *In re: Zyprexa Products Liability Litigation*, — FSupp2d —, 2007 WL 1678078 (EDNY June 11, 2007); *McNellis v Pfizer, Inc*, 2006 WL 2819046 (DNJ Sept 29, 2006); *Perry v Novartis*, 456 FSupp2d 678, 685-87 (ED Pa 2006); *Jackson v Pfizer, Inc*, 432 FSupp2d 964, 966-68 (D Neb 2006); *Witczak v Pfizer, Inc*, 377 FSupp2d 726, 730-31 (D Minn 2005); *Cartwright v Pfizer, Inc*, 369 FSupp2d 876, 885-86 (ED Tex 2005); *Levine v Wyeth*, — A2d —, 2006 WL 3041078 (Vt Oct 27, 2006). But see *Sykes v Glaxo-SmithKline*, 484 FSupp2d 289, 306-17 (ED Pa 2007); *Colacicco v Apotex, Inc*, 432 FSupp2d 523-38 (ED Pa 2006); *In re Bextra & Celebrex Marketing Sales Practices & Products Liability*, MDL 1699, WL 2374742 at \*5-12 (ND Cal Aug 2006); *Dusek v Pfizer*, 2004 WL 2191804, \*9 (SD Tex 2004); *Needleman v Pfizer*, 2004 WL 1773697, \*5 (ND Tex 2004).
21. See *In re Vioxx Products Liability Litigation*, — FSupp2d —, 2007 WL 1952964, at \*9 (ED La July 7, 2007); *In re Zyprexa Products Liability Litigation*, — FSupp2d —, 2007 WL 1678078, at \*36-37 (EDNY June 11, 2007); Fed Reg 66378, 66383-84 (Dec 1, 1998).
22. See *Perry v Novartis*, 456 FSupp2d 678, 681-82 (ED Pa 2006); *Witczak v Pfizer*, 377 FSupp2d 726, 730-31 (D Minn 2005).
23. See *Colacicco*, 432 FSupp2d at 538; *Caraker v Sandoz Pharmaceuticals Corp*, 172 FSupp2d 1018, 1040-41 (SD Ill 2001); *Levine*, — A2d —, 2006 WL 3041078 (Vt Oct 27, 2006). See also *Brown v DePuy Spine, Inc*, 22 MassLRptr 425, 2007 WL 1089337 (Mass Super Apr 9, 2007). But see *Dusek*, 2004 WL 2191804, at \*8 (SD Tex 2004).
24. *Caraker*, 172 FSupp2d at 1040-42; *Levine*, 2006 WL 3041078.
25. *Colacicco*, 432 FSupp2d at 538.
26. Mich Comp Laws, §600.2946(5).
27. NJ Stat Ann, §2A:58C-5(c); Ariz Rev Stat Ann, §12-701.
28. *Garcia v Wyeth-Ayerst Laboratories*, 385 F3d 961, 965-66 (6th Cir 2004); *Kobar v Novartis Corp*, 378 FSupp2d 1166, 1172-75 (D Ariz 2005).
29. *Desiano v Warner-Lambert & Co*, 467 F3d 85, 94-98 (2nd Cir 2007); *In re Vioxx Litigation*, Nos ATL-L-3553-05-MT & ATL-L-1296-05-MT, slip op (NJ Sup Ct June 8, 2007).
30. *Ackermann v Wyeth Pharmaceuticals*, 471 FSupp2d 739 (ED Tex 2006).
31. *Id* at 748-50.
32. See *In re Vioxx Products Liability Litigation*, — FSupp2d —, 2007 WL 1952964, at \*6, fn 6 (ED La July 7, 2007).
33. *In re Medtronic, Inc, Implantable Defibrillators Litigation*, 465 FSupp2d 886, 899-900 (D Minn 2006). But see *Baker v St Jude Medical, SC, Inc*, 178 SW3d 127, 138 (Tex App—Houston [1st Dist] 2005, pet denied). (In *Baker*, however, plaintiff specifically alleged that St. Jude's failure to provide FDA-required reports gave rise to a common law cause of action for fraud.)
34. *In re Guidant Corp Implantable Defibrillators Products Liability Litigation*, 2007 WL 1725289 (D Minn June 12, 2007). But see *Baker v St Jude Medical, SC, Inc*, 178 SW3d 127, 138 (Tex App—Houston [1st Dist] 2005, pet denied).
35. *Id* at \*10.
36. *Riegel v Medtronic, Inc*, — SCt —, 2007 WL 1802109 (US), 75 USLW 3065 (June 25, 2007).
37. *Riegel v Medtronic, Inc*, 451 FSupp2d 104 (2nd Cir 2006).
38. Tex Civ Prac & Rem Code, §82.001(2) (Vernon's 2007).
39. See Cooper RB, Faust DL. Products liability after House Bill 4. *South Texas Law Review* 2005;46:1159, 1175.
40. See *Thomas v St Joseph Hospital*, 618 SW2d 791, 796-97 (Tex Civ App—Houston [1st Dist] 1981, writ ref'd nre)
41. See *Barbee v Rogers*, 425 SW2d 342, 346 (Tex 1968); *Cobb v Dallas Fort Worth Medical Center—Grand Prairie*, 48 SW3d 820, 826-27 (Tex App—Waco 2001, nwh); *Easterly v HSP of Texas, Inc*, 772 SW2d 211, 213 (Tex App—Dallas 1989, no writ).
42. Tex Civ Prac & Rem Code, §74.101-74.106 (Vernon's 2007).
43. Sales TJ, Mitby S. The new presumption of adequate warnings in Texas pharmaceutical litigation. *Texas Bar Journal* 2006;69(7):612, 618.
44. See *Alm v Aluminum Co of America*, 717 SW2d 588, 591 (Tex 1986).
45. Wikipedia. *List of Extinct Animals of the United States*. Available at [http://en.wikipedia.org/wiki/List\\_of\\_extinct\\_animals\\_of\\_the\\_United\\_States](http://en.wikipedia.org/wiki/List_of_extinct_animals_of_the_United_States); accessed August 6, 2007.
46. See, e.g., Ross DB. The FDA and the case of Ketek. *N Engl J Med* 2007; 356(16):1601-1604; *FDA's Regulation of the New Drug Versed*, HR Rep No 1086, 100th Cong, 2nd Sess at 10 (1988); *FDA's Regulation of the New Drug Merital*, HR Rep No 206, 100th Cong, 1st Sess (1987); *FDA's Regulation of Zomax*, HR Rep No 584, 98th Cong, 1st Sess (1983); *Deficiencies in FDA's Regulation of the New Drug "Oraflex"*, HR Rep No 511, 98th Cong, 1st Sess (1983).