

DID TEXAS GET IT WRONG? HOW CONSUMER PLAINTIFFS MAY SOON HAVE REDRESS AGAINST BIG PHARMA

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I. INTRODUCTION

The pharmaceutical industry affects nearly every American on a daily basis. Nearly seventy percent of Americans take prescription drugs daily and doctors across the country utilize products developed by pharmaceutical manufacturers in everyday medical procedures.¹ Fortunately, the United States government has agencies in place to regulate and approve the safety of such products and drugs in an effort to protect consumers.² In this age of growing dependence on the pharmaceutical industry, consumers have no choice but trust that the products they use are safe, and will not lead to harmful effects.

However, despite strict regulation of medical drugs and devices, the technology is not without imperfections, and consumers are sometimes subject to adverse reactions to products that have been approved as safe for public use.³ Undoubtedly, consumers can expect that some risk is involved with taking any medication, and the U.S. government makes efforts to warn the public about the risks ahead of time.⁴ Still, circumstances do arise when consumers experience life-changing and sometimes fatal effects of products previously approved by the government with no warning.⁵ An issue then arises regarding who the consumers may recover damages from for injuries

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¹*Study shows 70 percent of Americans take prescription drugs*, CBS NEWS, June 20, 2013, <http://www.cbsnews.com/news/study-shows-70-percent-of-americans-take-prescription-drugs/>.

²*About FDA: What We Do*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/aboutfda/whatwedo/> (last visited Mar. 17, 2015).

³See *infra* Part IV.A.

⁴U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 2.

⁵See *infra* Part IV.A.

sustained after using these products. As a part of tort reform in America, many states have enacted legislation providing pharmaceutical manufacturers a presumption of immunity from liability if the FDA had previously approved the warnings and labels on the products.⁶ Thus, thousands of claims by consumers against the manufacturers of these medical products and devices are denied every year, leaving consumers with little recourse for their damages. The purpose of this article is to explain the aforementioned movement in America in recent years and then suggest an argument that consumers may be able to use in order to recover for damages sustained from using certain drugs and devices.

First, this article will introduce examples of legislation from across the United States designed to protect pharmaceutical manufacturers from liability for damages incurred as a result of adverse reactions to medications. Further, it will explain the 2013 United States Supreme Court opinion in *Mutual Pharmaceutical Company v. Bartlett*, which expanded this protection to manufacturers of generic brand medications that more than eighty percent of Americans take daily.⁷ Second, this article will explain the controversial 2001 United States Supreme Court opinion in *Buckman Company v. Plaintiffs' Legal Committee*, which held that patients' state law "fraud on the FDA" claims were impliedly preempted by the Food, Drug, and Cosmetic Act.⁸ Third, this article will introduce the split among the circuit courts of appeals regarding the interpretation of *Buckman* and how it applies to various claims against medical manufacturers. Finally, the last part of this article will focus on a Fifth Circuit case that leaves unaddressed an argument that attorneys may be able to use in the future to overcome the hurdles associated with bringing claims against pharmaceutical manufacturers.⁹ The objective of this article is to give insight into tort reform's effect on the ability of consumers to recover damages caused by pharmaceutical products and suggest an argument that may potentially provide a remedy for consumer plaintiffs in the future.

⁶ E.g., MICH. COMP. LAWS SERV. § 600.2946(5) (LexisNexis 2004); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1) (West 2011).

⁷ 133 S. Ct. 2466, 2476–77 (2013).

⁸ 531 U.S. 341, 348 (2001).

⁹ *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 373 (5th Cir. 2012).

II. THE TREND TOWARDS SHIELDING PHARMACEUTICAL MANUFACTURERS FROM LIABILITY

A. *State Legislation Provides a Presumption of Immunity.*

In conjunction with the tort reform movement across the country, many states have enacted legislation giving pharmaceutical manufacturers protection from liability for damages resulting from their products. For example, a Michigan statute states that “in a product liability action against a manufacturer or seller . . . the manufacturer or seller is not liable . . . if the drug was approved for safety and efficacy by the [FDA].”¹⁰ This presumption is rebuttable, but only if the manufacturer intentionally withheld from or misrepresented to the FDA required information when seeking approval.¹¹ Texas has enacted a statute strikingly similar to the Michigan statute, providing drug manufacturers a presumption of immunity from liability if the warnings were approved by the FDA, unless the plaintiff proves that the manufacturer withheld from or misrepresented required information to the FDA.¹² Legislation resembling these two examples was clearly enacted in order to limit a manufacturer’s liability when it has complied with federal government requirements for the manufacturing and sale of pharmaceutical products. Understandably, this provides the manufacturer comfort in knowing that they will not be subject to liability so long as they comply with all requirements, places the burden of regulating pharmaceutical products on an agency created for that very purpose, and limits the number of frivolous lawsuits against drug companies. On the other hand, the statutes have sometimes created uncertainty for consumers who experience harmful, and sometimes fatal, effects of these products because the statutes limit whom the plaintiffs are able to recover from.

B. *Mutual Pharmaceutical Company v. Bartlett*

In 2013, the United States Supreme Court expanded the protections regarding failure-to-warn claims to the manufacturers of generic brand pharmaceuticals.¹³ In *Mutual Pharmaceutical Company v. Bartlett*, the

¹⁰ § 600.2946(5).

¹¹ *Id.*

¹² TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1), (b)(1).

¹³ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476–77 (2013).

plaintiff was prescribed a non-steroidal anti-inflammatory drug (“NSAID”) by her doctor for shoulder pain.¹⁴ Her pharmacist dispensed the generic version of this drug, Sulindac.¹⁵ The plaintiff then developed a very rare reaction to the drug, which caused about sixty percent of the outer layer of her skin to burn off or turn into an open wound, which rendered her permanently near-blind, among other injuries.¹⁶

The manufacturer of the generic version of the drug, Mutual Pharmaceutical Company, argued that Bartlett’s design defect claim was preempted by the Federal Food, Drug, and Cosmetic Act (“FDCA”).¹⁷ Prior to *Bartlett*, the Supreme Court had not decided whether and to what extent the FDCA preempted design defect claims against generic manufacturers.¹⁸

III. *BUCKMAN* FURTHER LIMITS ABILITY TO RECOVER FROM DRUG MANUFACTURERS

In 2001, the Supreme Court’s ruling in *Buckman v. Plaintiff’s Legal Committee* significantly limited plaintiffs’ ability to recover damages from a pharmaceutical manufacturer.¹⁹ There, plaintiffs sought damages under state tort law after they sustained injuries from the implantation of orthopedic bone screws in their spines.²⁰ Plaintiffs claimed that AcroMed Corporation, a consulting company that assisted the manufacturer of the screws in obtaining FDA approval on the devices, made fraudulent representations to the FDA in obtaining approval, which ultimately caused the injuries sustained by plaintiffs.²¹

Although roughly 2,300 civil actions had been brought in relation to these particular devices,²² the Supreme Court rejected plaintiffs’ claims.²³ The Court held that the federal statutory scheme gives the FDA ample power to deter and punish fraud against the Agency on its own,²⁴ and that

¹⁴ *Id.* at 2471–72.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *See id.* at 2470.

¹⁸ *See id.*

¹⁹ 531 U.S. 341, 348 (2001).

²⁰ *Id.* at 343.

²¹ *Id.*

²² *Id.* at 346.

²³ *Id.* at 347.

²⁴ *Id.* at 348.

policing fraud against federal agencies is hardly “a field which the States have traditionally occupied.”²⁵ Among the various disclosure requirements required by the FDA by manufacturers seeking approval of pharmaceutical devices, the Court noted that the FDA also has powers aimed at detecting, deterring, and punishing false statements made during the approval process.²⁶

The Court’s rationale in denying plaintiffs’ claims was that state-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Agency’s judgment and objectives.²⁷ Further, the Court feared that applicant manufacturers would be deterred from seeking certain types of approval from the FDA due to fear that their disclosures, although deemed appropriate by the Agency, would later be judged insufficient in a state court, subjecting the manufacturer to liability.²⁸ Consequently, manufacturers may have an incentive to submit a deluge of information that the Agency neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application.²⁹ The Court thought that this would delay the approval time of devices, which would in turn delay health care professionals’ ability to prescribe certain uses for devices.³⁰ In sum, the Court held that the plaintiffs’ state tort law fraud-on-the-FDA claims were preempted by federal law, and these sorts of claims would exert an extraneous pull on the scheme established by Congress.³¹

IV. THE COURTS OF APPEALS ARE SPLIT ON THE APPLICATION OF *BUCKMAN* TO STATE LEGISLATION

Since 2001, courts across the country have struggled with applying state legislation regarding pharmaceutical manufacturer liability in light of the Supreme Court’s opinion in *Buckman*. There is currently a circuit split regarding how to apply *Buckman*, and one particular case has left many unanswered questions for plaintiffs.

²⁵ *Id.* at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

²⁶ *Id.* at 349.

²⁷ *Id.* at 350.

²⁸ *Id.* at 351.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.* at 353.

A. The Sixth Circuit Dismissed Consumer's Claims Against Manufacturer Because the Fraud-on-the-FDA Claim Was Preempted by Federal Law in Garcia v. Wyeth-Ayerst Labs

In September of 1997, Plaintiff Garcia was prescribed Duract by her physician for neck and shoulder pain.³² The medication had been approved by the FDA earlier that year, however, it resulted in Garcia's liver failure, which required her to undergo a liver transplant in order to save her life.³³ Garcia sued defendant for making and selling an unsafe drug, among other causes of action.³⁴ However, the suit was dismissed on the basis of Michigan's products liability statute that immunizes drug manufacturers from liability under certain conditions.³⁵ In 2004, the Sixth Circuit analyzed the application of the statute under the holding of *Buckman*.³⁶

Section 600.2946(5) of a Michigan statute provides immunity from liability to pharmaceutical manufacturers if the pharmaceutical was approved for safety and efficacy by the FDA and the drug and labeling were in compliance with the FDA at the time of the approval and at the time it left the control of the manufacturer.³⁷ However, sections (a) and (b) of the statute provide exceptions to this immunity.³⁸ Sections (a) and (b) state that there is no presumption of immunity if the manufacturer intentionally withheld or misrepresented information to the FDA in seeking approval of the drug or if the manufacturer made an illegal payment to an employee of the FDA for the purpose of securing approval of the drug.³⁹

As previously discussed, the Supreme Court has already held in *Buckman* that state law fraud-on-the-FDA claims are preempted by federal law.⁴⁰ Thus, the Sixth Circuit found that sections (a) and (b) of the statute are unconstitutional under some circumstances but not others.⁴¹ However, the court in *Garcia* did not find that *Buckman* rendered the statute unconstitutional when the FDA, rather than a state court, has found that the

³² *Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961, 963 (6th Cir. 2004).

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* at 965–66.

³⁷ MICH. COMP. LAWS SERV. § 600.2946(5) (LexisNexis 2004).

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 353 (2001).

⁴¹ *Garcia*, 385 F.3d at 966.

manufacturer committed fraud or bribery.⁴² The Sixth Circuit found that severing the preemption exemptions will not give license to drug manufacturers to use bribery or fraud to obtain FDA approval, then rely on that approval as a shield from products liability: it will merely place responsibility for prosecuting bribery or fraud on the FDA rather than state courts.⁴³

B. The Second Circuit Held That Plaintiff's Fraud-on-the-FDA Claims Were Not Preempted by Federal Law in Desiano v. Warner-Lambert & Co.

In 2006, the Second Circuit Court of Appeals took a different approach than that of the Sixth Circuit.⁴⁴ Plaintiffs in this case asserted various common law tort claims against pharmaceutical manufacturer Warner-Lambert & Company after suffering serious liver problems after taking Rezulin, which is used in the treatment of Type-2 diabetes.⁴⁵ The facts involved the same Michigan statute as in *Garcia*, however, the Second Circuit reached its conclusion separately because *Garcia*'s conclusion as to preemption depended on its analysis of federal, as opposed to state, law.⁴⁶ While the pharmaceutical manufacturer here cited *Garcia* and *Buckman* and argued that there is no meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and plaintiffs' claims under Michigan tort law, the Second Circuit disagreed.⁴⁷

The Second Circuit found that there were three critical distinctions "between the nature of the claim which Michigan Compiled Laws § 2946(5) exempts from abolition and the claim in *Buckman*."⁴⁸ First, the court found that under the current facts, there is a presumption against preemption by federal law.⁴⁹ This is because the object of the Michigan statute was to regulate when victims could continue to recover under preexisting state products liability law, which "falls squarely within its

⁴² *See id.*

⁴³ *Id.* at 967.

⁴⁴ *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006).

⁴⁵ *Id.* at 88.

⁴⁶ *Id.* at 92.

⁴⁷ *Id.* at 93.

⁴⁸ *Id.*

⁴⁹ *Id.* at 93–94.

prerogative to ‘regulate matters of health and safety’⁵⁰ Thus, the cause of action cannot reasonably be characterized as a state’s attempt to police fraud against the FDA, so the holding of *Buckman* is distinguishable.⁵¹

Second, the court distinguished the facts of this case from *Buckman* by showing that the plaintiffs’ claims here were not dependent on any claim of fraud-on-the-FDA.⁵² Rather, all claims here were premised on traditional duties between a product manufacturer and Michigan consumers.⁵³ While the plaintiffs’ claims here did parallel safety requirements imposed by the FDA, they were not premised principally on the manufacturer’s failure to comply with federal disclosure requirements.⁵⁴ In *Buckman*, the plaintiffs’ did not claim that the bone screws were defective in any way or that there was any medical malpractice; they argued that their injuries were caused by the failure to disclose certain information to the FDA by the manufacturer of the screws.⁵⁵ Thus, the Second Circuit found this case distinguishable because the claims here were not solely based on fraud against the FDA; the claims were based on state common law tort liability.⁵⁶ The court said that finding that these claims were preempted would be the equivalent of finding that Congress, without any explicit expression of intent, overturned traditional state law duties between pharmaceutical companies and their consumers.⁵⁷

Finally, The Second Circuit pointed out that proof of fraud against the FDA is not even an element of a products liability claim like the one under these facts.⁵⁸ The Michigan statute only creates an affirmative defense for a drug manufacturer to assert if it so decides, and that the burden is not on the plaintiff to prove fraud as an element of the claim.⁵⁹ The court held that finding preemption of traditional common law claims where fraud is not even a required element would result in preemption of a scope that would go far beyond anything that has been applied in the past.⁶⁰ Thus, the Second

⁵⁰ *Id.* at 94.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.* at 95.

⁵⁵ *See id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.* at 96.

⁵⁹ *Id.*

⁶⁰ *Id.*

Circuit will start with a presumption against federal preemption unless that was the clear and manifest purpose of Congress.⁶¹

C. The Fifth Circuit Takes the Side of the Sixth Circuit Regarding the Application of Buckman in Lofton v. McNeil Consumer & Speciality Phamaceuticals

In 2012, the same issue reached the Fifth Circuit Court of Appeals in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*.⁶² In *Lofton*, plaintiffs brought suit against defendant manufacturers asserting that the medication Motrin caused a rare autoimmune reaction that resulted in the decedent's death and that the manufacturers had failed to warn consumers about the risk of severe autoimmune allergic reactions.⁶³ As explained earlier in this article, Texas enacted a statute in 2003 that provided manufacturers a presumption of immunity for failure to provide adequate warnings with regard to a pharmaceutical product if the warnings or information that accompanied the product were approved by the FDA.⁶⁴ However, the statute also provides an exception to this presumption if the claimant proves that the manufacturer made fraudulent representations to the FDA in order to obtain FDA approval of the product.⁶⁵

The Fifth Circuit went into a detailed discussion about the differing views of the Second and Sixth Circuits regarding the application of *Buckman* before concluding that it agreed with the Sixth Circuit.⁶⁶ The court found that section 82.007 is not an expression of traditional state common law.⁶⁷ Rather, it found that the statute presumptively insulates from liability for failure to warn defendants who made or sold drugs in accordance with FDA standards.⁶⁸ The court found that section 82.007(b)(1) of the statute eliminates protection for manufacturers only where they committed the same fraud that federal law “amply powers the FDA to punish and deter.”⁶⁹ Further, it explained that state tort claims are

⁶¹ *See id.*

⁶² 672 F.3d 372, 373 (5th Cir. 2012).

⁶³ *Id.*

⁶⁴ TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1) (West 2011).

⁶⁵ *Id.* § 82.007(b)(1).

⁶⁶ *Lofton*, 672 F.3d at 377–80.

⁶⁷ *Id.* at 379.

⁶⁸ *Id.*

⁶⁹ *Id.* (quoting *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001)).

impermissible if they ““exist solely by virtue of the FDCA disclosure requirements.””⁷⁰ Since, under the Texas statute, a plaintiff can only be successful if he established that a drug maker committed fraud-on-the-FDA, federal supremacy law is invoked under *Buckman*.⁷¹ Therefore, the Fifth Circuit found that where the FDA itself has not found fraud, section 82.001(b)(1) is preempted by federal law, and the plaintiffs are unable to recover on these types of claims.⁷²

V. THE *LOFTON* ARGUMENT: DID TEXAS GET IT WRONG?

While the plaintiffs in *Lofton* were unable to recover from the pharmaceutical manufacturer for the death of their family member, they did raise an interesting argument that may give some reprieve for victim consumers in similar situations in the future. For the first time on appeal in *Lofton*, appellant plaintiffs raised the argument that section 82.007(b)(1) is not severable from section 82.007(a) of the Texas Civil Practices and Remedies Code.⁷³ Thus, if the Fifth Circuit were to uphold its holding that section 82.007(b)(1) is preempted by federal law, it would have to preempt section 82.007(a), which provides manufacturers a presumption of immunity in the first place.⁷⁴

Appellant’s brief lays out the Lofton’s foundational argument that when the district court held that section 82.007(b)(1) was preempted by federal law, it inexplicably severed that section from section 82.007(a)(1)’s presumption without considering whether or not the statute, Texas, or federal law would permit it to do so.⁷⁵ The Loftons contended that this error by the court dramatically expanded the scope of section 82.007(a)(1) by re-writing the statute to allow even drug companies criminally convicted of fraud against the FDA in the approval of a drug, to use that approval to shield themselves from failure-to-warn claims for injuries caused by the dangers they hid from the FDA and the public.⁷⁶ By holding that section 82.007(b)(1) is preempted by federal law but that 82.007(a)(1) is not, the

⁷⁰ *Id.* (quoting *Buckman*, 531 U.S. at 353).

⁷¹ *Id.* at 380.

⁷² *See id.*

⁷³ Brief for Appellants at 13, *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372 (5th Cir. 2012) (No. 10-10956).

⁷⁴ *Id.* at 14.

⁷⁵ *Id.* at 13.

⁷⁶ *Id.* at 46.

district court effectively provided an irrefutable presumption that a drug manufacturer is immune from liability so long as the FDA approved its warning labels.⁷⁷ To support this argument, the Loftons relied on various U.S. and Texas Supreme Court cases involving the same issue of severability of statutes with a general rule and an exception.⁷⁸

First, the Loftons relied on the U.S. Supreme Court opinion in *Randall v. Sorrell* to support its argument against severability.⁷⁹ In that case, the Court held:

To sever provisions to avoid constitutional objection here would require us to write words into the statute . . . or to leave gaping loopholes . . . or to foresee which of many different possible ways the legislature might respond to the constitutional objections we have found. Given these difficulties, we believe the Vermont Legislature would have intended us to set aside the statute's contribution limits, leaving the legislature free to rewrite those provisions in light on the constitutional difficulties we have identified.⁸⁰

Further, the Loftons noted the Texas Supreme Court's contention that "a court may not write special exceptions into a statute so as to make it inapplicable under certain circumstances not mentioned in the statute."⁸¹ The Loftons argued that by finding section 82.007(b)(1) preempted but not section 82.007(a), the court essentially rendered the statute inapplicable under the facts of the case, a result not mentioned in the statute.⁸² The purpose of the statute was to provide a rebuttable defense to pharmaceutical manufacturers that they would not be liable unless they misled the FDA regarding the manufactured product.⁸³ The legislature did not intend to provide pharmaceutical manufacturers unlimited liability by having section 82.007(b)(1) completely disregarded.⁸⁴ In fact, the legislative history for the Act stated that provisions of the Act are severable only if "the invalidity

⁷⁷ *Id.*

⁷⁸ *Id.* at 44–51.

⁷⁹ *Id.* at 44.

⁸⁰ *Id.* (quoting *Randall v. Sorrell*, 548 U.S. 230, 262 (2006)).

⁸¹ *Id.* (quoting *Pub. Util. Comm'n of Tex. v. Cofer*, 754 S.W.2d 121, 124 (Tex. 1988)).

⁸² *See id.* at 44–46.

⁸³ *See* TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a), (b) (West 2011).

⁸⁴ *See id.*

does not affect other provisions or applications of this Act that can be given effect without the invalid provision or application”⁸⁵ The Loftons contended that severing 82.007(b)(1) from section 82.007(a) did exactly what the legislature intended to prevent: severing the exception from the general rule significantly expanded the applicability of section 82.007(a) to provide pharmaceutical manufacturers unlimited immunity, even if it had lied to the FDA to gain approval.⁸⁶

Finally, the Loftons cited another U.S. Supreme Court opinion holding that in such circumstances, statutes similar to the interaction of section 82.007(b)(1) and 82.007(a) must fall.⁸⁷ In *Davis v. Wallace*, the Court explained:

‘The meaning of the legislature must be gathered from all they have said, as well from that which is ineffectual for want of power, as from that which is authorized by law.’ Here the excepting provision was in the statute when it was enacted, and there can be no doubt that the legislature intended that the meaning of the other provisions should be taken as restricted accordingly. Only with that restricted meaning did they receive the legislative sanction which was essential to make them part of the statute law of the State; and no other authority is competent to give them a larger application.⁸⁸

The Texas Supreme Court has also held that where the scope of a statute is broadened by the invalidity of one of its exceptions, the whole statute must fall.⁸⁹ In *Anderson v. Wood*, the court held:

‘If, by striking out a void exception, proviso or other restrictive clause, the remainder, by reason of its generality, will have a broader scope as to subject or territory, its operation is not in accord with the legislative intent, and the

⁸⁵ Act of June 2, 2003, 78th Leg., R.S., ch. 204, § 23.03, 2003 Tex. Gen. Laws 847, 899.

⁸⁶ See Brief for Appellants at 46, *Lofton*, 672 F.3d 372 (No. 10-10956).

⁸⁷ *Id.* at 47.

⁸⁸ 257 U.S. 478, 484–85 (1922) (quoting *State ex rel McNeal v. Dombaugh*, 20 Ohio St. 167, 174 (Ohio 1870)).

⁸⁹ *Anderson v. Wood*, 152 S.W.2d 1084, 1087 (Tex. 1941).

whole would be affected and made void by the invalidity of such part.⁹⁰

In short, the Loftons argued that when part of a statute is unconstitutional, the remainder is only sustained if the result is consistent with the original legislative intent.⁹¹

For these reasons, the Loftons argued that if the Texas court finds failure-to-warn claims relying on section 82.007(b)(1) preempted, section 82.007(a)(1)'s rebuttable presumption must be preempted too because it cannot be severed from section 82.007(b)(1).⁹² In that event, Plaintiff's failure-to-warn claims should proceed to trial at which time Defendant would have no presumption of statutory "no liability" whatsoever and Plaintiff would be freed from any evidentiary obligations under section 92.007(b)(1) as well.⁹³

VI. CONCLUSION

The pharmaceutical industry clearly affects the life nearly every American on a daily basis. However, state legislation and recent court rulings have made it difficult for some innocent plaintiffs to recover for damages sustained by defective products or products that did not have adequate warnings to inform consumers about certain risks associated with such products. Recently, this has left consumer plaintiffs with little recourse. However, consumers may have found a way around such legislation that gives pharmaceutical companies a presumption of protection from liability so long as they complied with FDA requirements. Consumers, attorneys, and state legislators should be aware of this argument and how it could affect the liability of pharmaceutical manufacturers in the near future. Attorneys should become familiar with the arguments made on appeal by the Loftons in an effort to help consumer plaintiffs receive the justice they deserve.

⁹⁰ *Id.* (quoting J.G. SUTHERLAND, STATUTES AND STATUTORY CONSTRUCTION, § 306 (2d ed. 1904).

⁹¹ Brief for Appellants at 48, *Lofton*, 672 F.3d 372 (No. 10-10956).

⁹² *Id.* at 52.

⁹³ *See id.*