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Bad Medicine: Good-Faith FDA Approval as a Recommended Bar to Punitive Damages in Pharmaceutical Products Liability Cases

Joan E. Shreffler

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Bad Medicine: Good-Faith FDA Approval as a Recommended Bar to Punitive Damages in Pharmaceutical Products Liability Cases

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INTRODUCTION

On September 30, 2004, pharmaceutical giant Merck & Co. (“Merck”) announced that it would immediately withdraw revolutionary painkiller Vioxx from the global market.¹ The swift action came six days after Merck’s CEO, Raymond Gilmartin, received a call from the company’s chief researcher informing him that an outside panel had abruptly halted a post-market Vioxx trial due to concerns that the drug may increase the risk of heart attack or stroke.² The financial impact on the drugmaker will be substantial. Doctors wrote an estimated 100 million prescriptions for Vioxx from its launch in 1999 until 2004, and the drug accounted for 11% of Merck’s global sales in 2003.³ Its loss is expected to reduce the company’s profit by 20%.⁴

1. Barbara Martinez et al., *Expiration Date: Merck Pulls Vioxx from Market After Link to Heart Problems*, WALL ST. J., Oct. 1, 2004, at A1.

2. *Id.*

3. *Id.*

4. *Id.*

Former Vioxx users began filing suits against the pharmaceutical giant less than a week after Merck's announcement.⁵ On August 19, 2005, a jury in a Texas state court returned a verdict against Merck in the first of the Vioxx trials, rendering a staggering \$253.45 million judgment.⁶ As of October 2005, over 5,000 suits related to the painkiller still awaited adjudication in state and federal courts nationwide,⁷ and analysts estimate Merck's potential liability at as much as \$20 billion.⁸

Months after Merck's initial announcement, as thousands of cases began consolidating, each side started jockeying for position. In the world of pharmaceutical litigation, this means fighting, and fighting hard, for the ideal federal court venue. Merck wanted the U.S. District Court for the District of Maryland to hear all federal Vioxx cases.⁹ Plaintiffs' attorneys preferred trying the cases in the District Court for the Southern District of Texas located in Houston.¹⁰ In January 2005, a multidistrict litigation panel of federal judges selected District Judge Eldon E. Fallon of the Eastern District of Louisiana to oversee the thousands of federal claims.¹¹ The venue decision is a clear victory for the plaintiffs' attorneys.¹²

5. Barnaby J. Feder, *Vioxx Recall May Bring Flood of Suits to Merck*, N.Y. TIMES, Oct. 5, 2004, at C2.

6. Richard Stewart & Ruth Rendon, *Vioxx Jury Awards Widow \$253 Million*, HOUS. CHRON., Aug. 20, 2005, at C1 (noting that because of Texas' statutory cap on punitive damages, the court will likely remit the award to \$26.1 million).

7. See Barbara Martinez, *Vioxx Plaintiffs Want to Fight on New Front*, WALL ST. J., Oct. 24, 2005, at B1 (stating that as of the date of the article there were 3,400 state and 2,300 federal Vioxx cases pending across the country).

8. Barbara Martinez, *Lawyer Outlines Attack on Merck for Vioxx Trial*, WALL ST. J., June 24, 2005, at B1. In fact, \$20 billion could be a rather conservative figure. As Professor Richard Epstein notes in an open letter to the jurors from the first trial, "[r]ight now there are over 4,000 law suits against Merck for Vioxx. If each clocks in at \$25 million, then your verdict is that the social harm from Vioxx exceeds \$100 billion, before thousands more join in the treasure hunt." Richard A. Epstein, Editorial, *Ambush in Angleton*, WALL ST. J., Aug. 22, 2005, at A10.

9. Barbara Martinez, *Preparing for Vioxx Suits, Both Sides Seek Friendly Venues*, WALL ST. J., Nov. 17, 2004, at B1. Merck's pleadings contend that Maryland is the ideal location for the trials because of the court's experience in past consolidated products liability cases and because of the courthouse's location near major airports and large hotels. *Id.* Of course, Maryland is also a part of the Fourth Circuit, often considered the most conservative federal circuit in the country. *Id.*

10. *Id.* South Texas is known for large jury awards, most prominently a \$1 billion verdict against drugmaker Wyeth in April 2004. *Id.*

11. Michael Perlstein, *All Vioxx Lawsuits to Be Heard in New Orleans*, TIMES-PICAYUNE (New Orleans), Feb. 17, 2005, at 1, available at LEXIS, News & Business File. In the wake of Hurricane Katrina, the multidistrict litigation oversight was temporarily moved to Houston. See Martinez, *supra* note 7.

12. Perlstein, *supra* note 11.

It is natural that both the plaintiff and defendant in any personal injury case will want the case heard in a location where the judge and jury will be most sympathetic to his or her plight.¹³ In recent years, however, the stakes in these battles over pharmaceutical litigation venue have risen significantly for one key reason: the relative ease with which a plaintiff may establish his or her right to an award for punitive damages.¹⁴ Punitive damage award amounts are also increasing: the average award doubled from \$3.3 million to \$7.6 million between the mid-1980s and the mid-1990s.¹⁵ As a result, punitive damages, historically a common law doctrine, are increasingly fodder for legislative debate.¹⁶ Some states, with varying degrees of strictness, are adopting provisions limiting either the amount that a plaintiff may receive in punitive damages or the burden a plaintiff must meet in demonstrating his or her entitlement to such an award.¹⁷

Among the states enacting legislation regarding punitive damages, some have singled out litigation over an injury caused by an allegedly defective product,¹⁸ or even pharmaceutical litigation

13. In fact, plaintiffs' attorneys commonly seek out specific south Texas counties as venues where judges are considered more sympathetic and juries are considered more generous. See Kevin M. Clermont & Theodore Eisenberg, *Exorcising the Evil of Forum-Shopping*, 80 CORNELL L. REV. 1507, 1508 n.1 (1995) (citing impoverished, predominantly Hispanic, and largely uneducated Duval and Maverick counties as particularly popular among the plaintiffs' bar).

14. See Briggs L. Tobin, Comment, *The "Limited Generosity" Class Action and a Uniform Choice of Law Rule: An Approach to Fair and Effective Mass-Tort Punitive Damage Adjudication in the Federal Courts*, 38 EMORY L.J. 457, 480 (1989) ("[A] plaintiff class has an incentive to shop for the forum where most members of the class may take advantage of the most liberal punitive damage rule.").

15. Sandra Torrey, *Juries in 1990s Reluctant To Make Punitive Awards; Average Award Has Doubled, Study Finds*, WASH. POST, June 17, 1997, at A3.

16. See, e.g., James Bradshaw, *Ohio Tort Reform Unlikely To Solve Pain-vs.-Gain Judgment Dilemma*, COLUMBUS DISPATCH (Ohio), Jan. 23, 1997, at 7A, available at LEXIS, News & Business File (criticizing Ohio's newly passed tort reform bill which, among other provisions, limits punitive damage awards); Sue Anne Pressley, *Texans Draw Line in Sand on Lawsuits; New Gov. Bush Declares Emergency on the Tort Reform Issue Due on Hill Soon*, WASH. POST, Feb. 23, 1995, at A3 (citing new Texas bill capping punitive damages that passed the state Senate after heated debate); Eckert Sager, *Punitive Damages Bill Faces Maryland Vote*, J. OF COM., Mar. 24, 1992, at 9A, available at LEXIS (explaining a proposed state punitive damages reform statute).

17. See *infra* notes 29–33, 37 and accompanying text (citing statutes in force in Alabama, Alaska, California, Colorado, Connecticut, Illinois, Iowa, Kansas, Kentucky, Minnesota, Mississippi, Montana, Nevada, North Carolina, South Carolina, South Dakota, Texas, and Virginia).

18. See *infra* notes 48–49 (referencing legislation passed in Arizona, Illinois, Indiana, New Jersey, North Dakota, Ohio, Oregon, and Utah).

specifically,¹⁹ as deserving special treatment. These states recognize these types of products liability cases as a unique breed of litigation, partly due to a plaintiff's ability to assert a claim on a theory of strict liability.²⁰ In an ordinary personal injury case, such as a claim arising from an automobile accident, proving entitlement to punitive damages requires some showing of fault on behalf of the defendant.²¹ Only nine jurisdictions, however, have enacted legislation specifically tying the availability of punitive damages against a pharmaceutical manufacturer to the process the pharmaceutical manufacturer undergoes to gain the required Food and Drug Administration ("FDA") approval to market its drug in the United States.²²

This Comment argues that because the standards required by the FDA are stringent enough to preempt even the most liberal statement of punitive damages entitlement, states should not subject pharmaceutical manufacturers to large punitive awards if they have obtained FDA approval in good faith.²³ Following a survey of state punitive damages law, federal constitutional constraints, the purposes of punitive damage awards, and the steps a pharmaceutical manufacturer must take to achieve FDA approval, this Comment concludes that punitive damages are irrational in pharmaceutical cases premised on defective design or failure-to-warn theories when the drug at issue achieved good-faith FDA approval.

19. See *infra* note 49 (citing the laws of Arizona, Illinois, New Jersey, North Dakota, Ohio, Oregon, and Utah).

20. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998) (stating that any entity "who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect," regardless of intent or knowledge).

21. See generally Ellen Wertheimer, *Punitive Damages and Strict Products Liability: An Essay in Oxymoron*, 39 VILL. L. REV. 505, 508-10 (1994) (noting that the law developed the strict liability doctrine to ensure that injured persons would be compensated without making out a prima facie case of negligence because of lack of access to pertinent information regarding the manufacture of the product). This Comment argues that strict liability should cut against allowing a plaintiff suing under the doctrine to seek punitive damages, which are ordinarily appropriate only if a plaintiff can show more than ordinary negligence. See, e.g., RESTATEMENT (SECOND) OF TORTS § 908(2) cmt. b (1965) (asserting that punitive damages are inappropriate when a defendant's conduct constitutes nothing more than "ordinary negligence," such as "mere inadvertence, mistake, [or] errors of judgment").

22. See *infra* notes 48-49 and accompanying text (outlining the laws enacted in Arizona, Illinois, Indiana, New Jersey, North Dakota, Ohio, Oregon, and Utah, all of which adhere to this approach, with varying standards of the presumptive nature of FDA approval to the manufacturer's level of culpability).

23. "Good faith" in this context means compliance with all FDA requirements regarding testing, monitoring, and disclosure, as well as the absence of knowing misstatements, fraud, or material omissions on the part of the pharmaceutical manufacturer.

I. SURVEY OF PUNITIVE DAMAGES LAW AMONG JURISDICTIONS

The availability of punitive damages to plaintiffs injured by defective products varies significantly from state to state. Four states erect an absolute bar to punitive damages through either constitutional provision²⁴ or legislative enactment.²⁵ At the other end of the spectrum, a number of states leave it to the courts to approve an award of punitive damages according to common law standards. The courts in a majority of these states award punitive damages only upon the plaintiff's proving the defendant acted maliciously or intentionally.²⁶ The courts in the remainder of these states award

24. Punitive damages are constitutionally prohibited by article I, section 3 and article VII, section 5 of the Nebraska Constitution. *See, e.g., Abel v. Conover*, 104 N.W.2d 684, 688 (Neb. 1960) ("It has been a fundamental rule of law in [Nebraska] that punitive, vindictive, or exemplary damages will not be allowed, and that the measure of recovery in all civil cases is compensation for the injury sustained."); *see also id.* at 693 (Wenke, J., concurring) ("[T]he Constitution of Nebraska does not permit the recovery of punitive, vindictive, or exemplary damages by individuals in civil cases.").

25. The states barring punitive damages by statute are Louisiana, Massachusetts, and New Hampshire. LA. CIV. CODE ANN. art. 2315(B) (2004) (prohibiting the award of punitive damages unless specifically authorized by statute); *id.* ("Damages do not include costs . . . unless such treatment, services, surveillance, or procedures of any kind are directly related to a manifest physical or mental injury or disease."); *id.* art. 2545 (making product sellers liable for return price with interest, reasonable expenses occasioned by sale, and attorneys fees, but not for deterrence or retribution); MASS. GEN. LAWS ANN. ch. 106, § 1-106 (West 2005) ("[N]either consequential or special nor penal damages may be had except as specifically provided."); N.H. REV. STAT. ANN. § 507:16 (Lexis 2004) (prohibiting punitive damages unless expressly prescribed by statute).

26. *See Nat'l Bank of Commerce v. McNeill Trucking Co.*, 828 S.W.2d 584, 587 (Ark. 1992) (affirming the trial court's denial of punitive damages and stating that "negligence, however gross, will not justify an award of punitive damages"); *Arrow Int'l v. Sparks*, 98 S.W.3d 48, 57 (Ark. Ct. App. 2003) (affirming \$4 million punitive damage award against a manufacturer where the evidence showed the manufacturer was aware of reported injuries and deaths involving its product but continued to manufacture and sell the product without providing adequate or timely warnings); *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1277-78 (Haw. 1992) (affirming dismissal of a claim for punitive damages based upon the pacemaker manufacturer's bad-faith conduct during the course of settlement negotiations, holding that the malicious conduct must be connected with the manufacture and marketing of the injury-causing product); *Masaki v. Gen. Motors Corp.*, 780 P.2d 566, 573-74 (Haw. 1989) (remanding case for a reevaluation of a proper punitive damage award after the trial judge erroneously instructed the jury that an award could be justified based on a preponderance of the evidence, rather than by clear and convincing evidence); *Tuttle v. Raymond*, 494 A.2d 1353, 1360-62 (Me. 1985) (vacating award of punitive damages because defendant's reckless actions were not accompanied by the requisite malicious conduct); *Hanover Ins. Co. v. Hayward*, 464 A.2d 156, 158-59 (Me. 1983) (affirming a denial of punitive damages because such an award would not provide a deterrent effect over and above the three-year prison sentence received by defendant on related criminal charges); *Bowden v. Caldor, Inc.*, 710 A.2d 267, 276-77 (Md. 1998) (requiring actual knowledge on the part of a manufacturer of a defect in its product to justify punitive damages); *Owens-Corning Fiberglas Corp. v. Garrett*, 682 A.2d 1143, 1162-63 (Md. 1996) (reversing punitive damage award in asbestos case where there was

punitive damages under common law standards ranging from a defendant's knowledge and disregard of a conscious risk²⁷ to conduct indicating a reckless indifference to the interests of others.²⁸

insufficient evidence of defendant's malice under a clear and convincing evidentiary standard); *Gonzales v. Surgidev Corp.*, 899 P.2d 576, 589-91 (N.M. 1995) (affirming award of punitive damages against a medical device manufacturer where evidence showed the manufacturer had actual notice of injuries involving its devices yet continued promoting the use of its product without providing any warnings to the medical community); *Zarella v. Minn. Mut. Life Ins. Co.*, 824 A.2d 1249, 1262 (R.I. 2003) (affirming dismissal of claim for punitive damages upon jury finding that defendant did not act willfully, recklessly, or wickedly); *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992) (remanding for reconsideration of punitive damages consistent with state common-law rule requiring a finding by clear and convincing evidence that the defendant acted intentionally, fraudulently, maliciously, or recklessly); *Huckeby v. Spangler*, 563 S.W.2d 555, 558-59 (Tenn. 1978) (affirming court of appeal's ruling vacating a punitive damages award upon concluding the award would not have a deterrent effect); *Bolsta v. Johnson*, 848 A.2d 306, 308 (Vt. 2004) (affirming the trial court's refusal to grant punitive damages against a drunk driver and stating that "willful violation of the law is insufficient evidence of malice"); *Mead v. W. Slate, Inc.*, 848 A.2d 257, 264 (Vt. 2004) (holding that punitive damages are improper where the evidence fails to demonstrate a "knowing and willful disregard of risks that made injury to plaintiff a substantial certainty"); *Pion v. Bean*, 833 A.2d 1248, 1259 (Vt. 2003) (affirming an award of punitive damages based on "'overwhelming' evidence that plaintiffs acted with malice"); *Davis v. Celotex Corp.*, 420 S.E.2d 557, 560-61 (W. Va. 1992) (affirming punitive damages award against asbestos manufacturer acting with actual knowledge of the serious health risks of asbestos and refusing to follow suggested guidelines to ameliorate the risks to workers and consumers); *Garnes v. Fleming Landfill, Inc.*, 413 S.E.2d 897, 904-05 (W. Va. 1991) (remanding the issue of punitive damages to the trial court with the instruction that any such award "should bear a reasonable relationship to the potential of harm caused by defendant's actions").

Michigan common law prohibits punitive damages as a means to sanction defendants, but "exemplary" damages are proper for compensation purposes when a plaintiff suffers humiliation, outrage, or indignity as a result of a defendant's malicious or reckless actions. Michigan courts, however, construe this standard strictly. *See, e.g., Jackovich v. Gen. Adjustment Bureau, Inc.*, 326 N.W.2d 458, 464 (Mich. Ct. App. 1982) (holding that the trial court properly refrained from giving a jury instruction on plaintiff's request for punitive damages to punish the defendant because such an instruction was not recognized in the state); *Birkenshaw v. City of Detroit*, 313 N.W.2d 334, 339 (Mich. Ct. App. 1981) (reversing an exemplary damage award upon concluding that the award actually constituted punitive damages intending to punish the defendant).

27. *See Cloroben Chem. Corp. v. Comegys*, 464 A.2d 887, 891-92 (Del. 1983) (affirming an award of punitive damages based upon evidence that defendant manufacturer was "aware that its product and package were unsafe yet continued to package it in the same manner"); *Sliman v. Aluminum Co. of Am.*, 731 P.2d 1267, 1275-76 (Idaho 1986) (affirming an award of punitive damages against a bottle manufacturer upon finding evidence that the defendant corporation's conduct was an "extreme deviation" from the norm, and that it knew of many accidents similar to plaintiff's but nonetheless failed to warn consumers); *Morrison v. Quality Produce, Inc.*, 444 P.2d 409, 411 (Idaho 1968) (holding that it was error to submit an instruction on punitive damages to the jury when the evidence did not show that the distributor "acted maliciously, fraudulently or with gross negligence").

28. *See Chambers v. Montgomery*, 192 A.2d 355, 358 (Pa. 1963) (holding that "punitive damages are awarded only for outrageous conduct, that is, for acts done with a

Other states have codified statutory standards for the level of culpability that can expose a defendant to punitive damages. The overwhelming majority of states adopting this legislative approach award punitive damages only when a defendant's conduct is either malicious²⁹ or willful and wanton.³⁰ The courts in these states place no strict cap on the amount of punitive damages available to a plaintiff (though they may require that punitive damages bear a "reasonable relationship" to compensatory damages) and do not, as a matter of law, hold that a manufacturer's approval from any federal

bad motive or with a reckless indifference to the interests of others"); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 448 (Pa. Super. Ct. 1987) (holding that the trial court erred in denying claims for punitive damages against a drug manufacturer when the plaintiff demonstrated defendant's culpable state of mind in failing to notify the medical community of a serious risk of its marketed antibiotic); *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 54 (Wis. 1984) (holding that plaintiff could not seek punitive damages from a DES manufacturer when plaintiff's own physician testified that he did not rely on any of defendant's allegedly fraudulent statements in prescribing the drug); *Wangen v. Ford Motor Co.*, 294 N.W.2d 437, 442 (Wis. 1980) (rejecting Ford Motor Company's contention that a plaintiff seeking punitive damages must demonstrate the defendant's intentional desire to injure). Other standards do not lend themselves to generalization. *New York*, for example, awards punitive damages in only those products liability cases involving either a willful failure to warn or a strict liability action. *See, e.g., Lugo v. LJN Toys, Ltd.*, 146 A.D.2d 168, 171 (N.Y. App. Div. 1989) (reversing an award of punitive damages against a toy manufacturer absent evidence of the manufacturer's wrongful motive, willful intent to injure, or reckless indifference); *Anderson v. Fortune Brands, Inc.*, 723 N.Y.S.2d 304, 307-08 (N.Y. Sup. Ct. 2000) (holding that a cause of action premised upon the willful failure of the manufacturer to warn consumers of product dangers is an appropriate vehicle for the assessment of punitive damages). Wyoming permits punitive damages only when the defendant's conduct involves "some element of outrage similar to that usually found in crime." *Sheridan Commercial Park, Inc. v. Briggs*, 848 P.2d 811, 817 (Wyo. 1993); *see also Alexander v. Meduna*, 47 P.3d 206, 219-20 (Wyo. 2002) (affirming an award of punitive damages based on the level of profitability enjoyed by the defendant as a result of its fraud and deceit); *Farmers Ins. Exch. v. Shirley*, 958 P.2d 1040, 1052 (Wyo. 1998) (reversing an award of punitive damages as disproportionate to defendant's level of reprehensibility).

29. *See* ALASKA STAT. § 09.17.020(b) (2004) (outrageous conduct exemplified by malice, bad motive, or reckless indifference to the safety of others); CAL. CIV. CODE § 3294(a) (West 2005) (oppression, fraud, or malice); COLO. REV. STAT. ANN. § 13-21-102(1)(a) (West 2004) (fraud, malice, or willful and wanton conduct); NEV. REV. STAT. ANN. § 42.005(1) (West 2003) (oppression, fraud, or malice); N.C. GEN. STAT. ANN. § 1D-15(a) (West 2005) (fraud, malice, or willful and wanton conduct); S.D. CODIFIED LAWS § 21-1-4.1 (2004) (malicious or willful and wanton conduct).

30. *See* IOWA CODE ANN. § 668A.1(1)(a) (West 2005); S.C. CODE ANN. § 15-33-135 (2004). Note, however, that in products liability cases in South Carolina punitive damages are unavailable when the cause of action is based solely upon a theory of strict liability. *Barnwell v. Barber-Colman Co.*, 393 S.E.2d 162, 163-64 (S.C. 1989) (*per curiam*). The remaining states whose legislatures adopted statutory standards utilize slight variations on the level of culpability required before punitive damages are recoverable. *See* KY. REV. STAT. ANN. § 411.184(2) (West 2004) (oppression, fraud, or malice); MINN. STAT. ANN. § 549.20(1)(a)-(b) (West 2005) (deliberate disregard for the rights and safety of others).

agency or compliance with statutory law shields the manufacturer from punitive damage liability.

A. Statutory Standards

While punitive damages are traditionally a creature of the common law, an increasing number of states are opting to statutorily restrain such awards through a variety of mechanisms. These mechanisms either curtail the amount a court may award or limit the amount the plaintiff, the plaintiff's attorney, or both may collect. States employ different types of statutes that cap punitive damages with each type of statute reflecting different concerns. The traditional cap limits an award to a fixed monetary sum and is now seldom employed.³¹ The majority of states using cap legislation today employ statutes linking the upper limit of punitive damages directly to the compensatory damages award in the case, allowing a punitive award equal to either double³² or triple³³ the award of actual damages. This approach, endorsed by the American Law Institute³⁴ and the

31. Virginia is now the only state currently using this strict statutory scheme, capping any one plaintiff's non-compensatory damages at \$350,000. VA. CODE ANN. § 8.01-38.1 (West 2004).

32. See CONN. GEN. STAT. § 52-240b (2003) (limiting punitive damage awards in products liability cases to two times an award of actual damages). The Texas legislature recently enacted a statutory cap on punitive damage awards, limiting them to the greater of \$200,000 or two times the compensatory damages plus noneconomic damages, up to \$750,000. TEX. CIV. PRAC. & REM. CODE ANN. § 41.008 (Vernon 2004). Note, however, that in Texas, the extremely low standard of gross negligence can justify an award of punitive damages so long as the purpose of the award is to punish the defendant's morally culpable conduct and not to enrich the plaintiff. See generally *Owens-Corning Fiberglas Corp. v. Malone*, 972 S.W.2d 35 (Tex. 1998); *Mobil Oil Corp. v. Ellender*, 934 S.W.2d 439 (Tex. App. 1996). This cap did not apply in the groundbreaking April 27, 2004 verdict against pharmaceutical giant Wyeth because the jury found that the conduct of the drugmaker violated the Texas Penal Code. Brenda Sapino Jeffreys, *Record-Setting \$1 Billion Verdict Returned in Fen-Phen Suit*, May 3, 2004, <http://www.law.com/jsp/article.jsp?id=1083328797998>.

33. See ALA. CODE § 6-11-21(2) (2004) (excepting actions for wrongful death and class actions, punitive damage awards in personal injury actions are limited to the greater of three times the compensatory damage award or \$1.5 million); 735 ILL. COMP. STAT. 5/2-1115.05(a) (2003) (limiting punitive damage awards to three times the compensatory damage award); N.C. GEN. STAT. § 1D-25(b) (2004) (limiting punitive damage awards to \$250,000 or three times compensatory damages, whichever is larger; if a jury returns a verdict for punitive damages in excess of the statutory cap, the trial judge has the obligation to reduce the award to comply with the law).

34. AMERICAN LAW INSTITUTE, 2 ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY: REPORTERS' STUDY 256-59 (1991) (proposing that state legislatures and courts establish a required numerical ratio between compensatory and punitive damages, but declining to recommend a specific ratio).

American College of Trial Lawyers,³⁵ provides courts and juries clear guidance by which to assess a proper award. Both the American Law Institute and the American College of Trial Lawyers suggest limiting damages to the greater of either a multiple of the compensatory damages awarded or a fixed sum, reasoning that such an approach provides consistency while equipping “the trier of fact with great flexibility to do justice in the rare situation where a defendant has engaged in heinous conduct with a huge potential for harm, but which resulted in little actual harm.”³⁶

As the name suggests, punitive damages are indeed intended to punish defendants. A number of states capping punitive damages recognize this fact while realizing that the monetary amount of any particular award will affect different defendants in different ways. A handful of states therefore tie statutory caps to a defendant’s wealth, often limiting damages to a percentage of the individual defendant’s net worth or annual income.³⁷ Commentators have long suggested that this approach to punitive caps most aptly accomplishes the primary goals of punitive damages—punishment and deterrence—in a way that traditional caps do not.³⁸ Other states seeking to achieve these goals without necessarily considering the solvency of a defendant choose not to adopt general caps applicable in all cases, but

35. AMERICAN COLLEGE OF TRIAL LAWYERS, REPORT ON PUNITIVE DAMAGES OF THE COMMITTEE ON SPECIAL PROBLEMS IN THE ADMINISTRATION OF JUSTICE 15 (1989) (recommending that any statutory punitive damages limit be restricted by relationship to compensatory damages).

36. Victor E. Schwartz & Mark A. Behrens, *Punitive Damages Reform: State Legislatures Can and Should Meet the Challenge Issued by the Supreme Court of the United States*, in Haslip, 42 AM. U. L. REV. 1365, 1379 (1993).

37. See KAN. STAT. ANN. § 60-3701 (1994) (limiting punitive damage awards to defendant’s annual gross income or \$5 million, whichever is less); MISS. CODE ANN. § 11-1-65 (West 1999) (limiting punitive damage awards according to the net worth of the defendant); MONT. CODE ANN. § 27-1-220 (2003) (limiting punitive damage awards in products liability cases to \$10 million or 3% of the defendant’s net worth, whichever is less).

38. See, e.g., Debra Dison Hall, *Pretrial Discovery of Net Worth in Punitive Damages Cases*, 54 S. CAL. L. REV. 1141, 1144-45 (1981) (“[A]n award of punitive damages must take into account two factors: the outrageousness or maliciousness of the defendant’s conduct, and his ability to pay.”); Walter Lucas, *Punitive Cap Makes Injury a Cost of Doing Business*, 138 N.J. L.J., 789, 804 (1994) (arguing that the “best yardstick” for accomplishing the deterrent goal of punitive damages is consideration of the net worth of the defendant, and that a generally applicable cap on punitive damages limits courts’ abilities to accomplish this goal); Clarence Morris, *Punitive Damages in Tort Cases*, 44 HARV. L. REV. 1173, 1191 (1931) (“[A] penalty which would be sufficient to reform a poor man is likely to make little impression on a rich one; and therefore the richer the defendant is the larger the punitive damage award should be.”).

instead have enacted statutes varying the quantitative cap in relation to the reprehensibility of the defendant's conduct.³⁹

The small number of states opting to limit punitive damages through statutory caps reflects the divergent opinions and ongoing debate about these caps' fairness and efficacy. Proponents argue that strict limits are beneficial because they place defendants on notice as to the extent of their potential liability.⁴⁰ Critics respond that these caps are superficial and arbitrary.⁴¹ These critics argue further that since any cap must be high enough to effectively deter wrongful conduct, regardless of the defendant's wealth, a meaningful cap would need to be virtually limitless anyway.⁴²

Other states pursuing the punishment and deterrence goals of punitive damages limit the portion of the award that any one plaintiff or plaintiff's attorney may receive rather than implementing a general cap on such awards. Legislatures in at least four of the states adopting this approach limit the plaintiff's recovery to a percentage of any punitive award, and several have established a fund into which the balance of the award must be paid.⁴³ Oregon actually limits the

39. See FLA. STAT. ANN. § 768.73 (West 2005); OKLA. STAT. ANN. tit. 23, § 9.1 (West 2004); see also *Graham v. Keuchel*, 847 P.2d 342, 363 n.114 (Okla. 1993) (stating that before beginning the inquiry into the amount of appropriate damages the plaintiff must show by clear and convincing evidence that the defendant has acted with intent, with malice, or with reckless disregard for the rights of others). A final approach to a statutory cap, currently in force only in the state of Washington, places an upper limit on punitive damages according to a formula that takes into account the injured plaintiff's average annual wage and life expectancy. WASH. REV. CODE ANN. § 4.56.250 (West 2004). While the Supreme Court of Washington held that an application of this provision may be unconstitutional, see *Sofie v. Fibreboard Corp.*, 771 P.2d 711, 723 (Wash. 1989), the statute remains on the books.

40. See *infra* notes 70–80 and accompanying text (discussing *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996)). In *BMW*, the United States Supreme Court noted that statutory caps were critical to providing defendants “fair notice” as to the type of conduct that may give rise to punitive damages awards and the extent of any potential punishment. See *BMW*, 517 U.S. at 574 (“Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose.”).

41. Kimberly A. Pace, *Recalibrating the Scales of Justice Through National Punitive Damage Reform*, 46 AM. U. L. REV. 1573, 1622–23 (1997).

42. *Id.* at 1623–24.

43. These states include Georgia, Indiana, Missouri, and Oregon. See GA. CODE ANN. § 51-12-5.1(e)(2) (2000) (requiring 75% of the recovery of any punitive damages award be paid into the state treasury account instead of to the plaintiff); IND. CODE ANN. § 34-51-3-6 (West 1998) (entitling plaintiff to the full amount of compensatory damages awarded but requiring any punitive damages to be paid by the defendant to the clerk of court, who then pays 25% of the recovered amount to the plaintiff and deposits the other 75% with the state treasurer's violent crime victim compensation fund); MO. ANN. STAT. § 537.675 (West 2000) (requiring 50% of any punitive damage award to be deposited into

portion of the award a plaintiff's attorney may receive.⁴⁴ Moreover, some of these states allow a defendant to credit the amount paid in punitive damages in previous cases regarding the same conduct towards new awards against the defendant.⁴⁵ The theory underlying this scheme is the familiar adage that punitive damages are meant to punish the defendant, not enrich any plaintiff.⁴⁶ The constitutionality of statutory caps has been repeatedly attacked and upheld, based on the reasoning that because a legislature has the power to abolish punitive damages entirely, as the legislatures in some states have done, then the legislature necessarily has the power to limit non-compensatory damages.⁴⁷

A few state statutes codify the idea that a manufacturer complying with federal statutory or regulatory standards cannot be held liable for punitive damages, absent a showing of bad faith or fraudulent misrepresentation by the manufacturer to the regulatory body. In the context of the pharmaceutical industry, these statutory provisions range materially in breadth and significance. A relatively favorable plaintiff's forum may have a rebuttable presumption against a drug's defectiveness and the manufacturer's bad-faith conduct or negligence if the injury-causing drug received FDA approval.⁴⁸ States

the Tort Victims' Compensation Fund instead of being paid to the plaintiff); OR. REV. STAT. § 18.540(1) (1997) (permitting Oregon plaintiffs to recover only 40% of any punitive damage award).

44. Out of the 40% of an award available to the plaintiff in Oregon, *see supra* note 43, the plaintiff's attorney may not receive more than 50% of the plaintiff's award or 20% of the entire award. OR. REV. STAT. ANN. § 18.540(1) (West 2003).

45. *See* GA. CODE ANN. § 51-12-5.1(e)(2) (granting only one award of punitive damages for any single act or omission regardless of how many causes of action arise thereunder or how many plaintiffs sustain injury thereby); MO. ANN. STAT. § 510.263 (West 2004) (crediting defendants with amounts previously paid for punitive damages in other cases arising out of the same conduct).

46. *See* *Newport v. Fact Concerts, Inc.*, 453 U.S. 247, 266-67 (1981) ("Punitive damages by definition are not intended to compensate the injured party, but rather to punish the tortfeasor whose wrongful action was intentional or malicious . . .").

47. *See, e.g.,* *Hemmings v. Tydyman's Inc.*, 285 F.3d 1174, 1200 (9th Cir. 2002) (reversing determination that plaintiffs were not entitled to punitive damages but upholding the constitutional validity of the federal statutory cap applying to actions brought under 42 U.S.C. § 1981); *Phillips v. Mirac, Inc.*, 651 N.W.2d, 437, 442 (Mich. Ct. App. 2002) (reversing entry of a judgment in excess of the statutory cap); *Rhyne v. K-Mart Corp.*, 149 N.C. App. 672, 675, 562 S.E.2d 82, 86 (2002) (affirming the trial court's reduction of a punitive damage award to \$250,000 per plaintiff from a jury verdict of \$11.5 million pursuant to state statutory cap).

48. For instance, Indiana places a presumption against punitive damages in products liability cases where the injury-causing product complied with governmental standards. IND. CODE ANN. § 34-20-5-1 (LexisNexis 1998) (stating that upon a showing of compliance, there is "a rebuttable presumption that the product that caused the physical

more sympathetic to drug manufacturers have adopted outright rules against such awards unless the plaintiff shows that the manufacturer knowingly withheld information from or misled the FDA in gaining approval to market the drug.⁴⁹ The legislatures in these states recognize the time and expertise involved in the FDA approval process and appreciate that the public interest in the availability of affordable prescription drugs is best served by limiting the extent of manufacturer liability when injury results from an approved pharmaceutical.⁵⁰ This approach represents a state legislature's determination that courts should not ignore the expert regulatory process and continually reevaluate a drug's risks based on a judge or jury's own lay standards.⁵¹

B. Constitutional Constraints

State statutory and case law are significant sources of the increasing number of limits on the availability of punitive damages, but they are not the only sources. Punitive awards also invoke constitutional considerations. Defendants argue that if punitive damages truly aim to serve the purpose of punishment, constitutional due process protections ensure certain procedural and substantive safeguards.⁵² Given that punishment is traditionally a remedy of criminal law, not the civil tort system, defendants may contend that simple civil process is inadequate to protect the interests at stake.⁵³ Most of these arguments have been unsuccessful. For example, the Supreme Court held in *United States v. Halper*⁵⁴ that the Fifth Amendment's prohibition on double jeopardy⁵⁵ does not prevent a single defendant from incurring liability for punitive damages in more

harm was not defective and that the manufacturer or seller of the product was not negligent").

49. See ARIZ. REV. STAT. ANN. § 12-701(A)(1), (B) (2003); 735 ILL. COMP. STAT. ANN. 5/2-2107 (West 2003); N.J. STAT. ANN. § 2A:58C-5(c) (West 2000); N.D. CENT. CODE § 32-03.2-11(6) (1996); OHIO REV. CODE ANN. § 2307.80(C)(1)(a) (West 2005); OR. REV. STAT. § 30.927(1)(a) (1997); UTAH CODE ANN. § 78-18-2 (2002).

50. See, e.g., *Grundberg v. Upjohn Co.*, 813 P.2d 89, 97 (Utah 1991) (evaluating the Utah legislature's reasons for adopting its statute).

51. *Id.*

52. See John Calvin Jeffries, Jr., *A Comment on the Constitutionality of Punitive Damages*, 72 VA. L. REV. 139, 139 (1986).

53. See John C. Coffee, Jr., *Does "Unlawful" Mean "Criminal"?: Reflections on the Disappearing Tort/Crime Distinction in American Law*, 71 B.U. L. REV. 193, 194 (1991) ("Characteristically, tort law prices, while criminal law prohibits.").

54. 490 U.S. 435 (1989).

55. U.S. CONST. amend. V (declaring that no person may "be subject for the same offense to be twice put in jeopardy of life and limb").

than one case arising out of the same conduct.⁵⁶ Furthermore, in *Browning-Ferris Industries of Vermont, Inc. v. Kelco Disposal, Inc.*,⁵⁷ the Court held that the Excessive Fines Clause of the Eighth Amendment⁵⁸ does not apply to punitive damages awarded in civil cases between private parties.⁵⁹

While refusing to find outright constitutional prohibitions on punitive damages, the Court has nonetheless articulated some governing limitation principles.⁶⁰ Procedural due process limitations, for example, may restrict a state's ability to impose its own punitive damages law upon a defendant. In *Honda Motor Company Ltd. v. Oberg*,⁶¹ the Court struck down an Oregon state court punitive damages award based on constitutional concerns.⁶² Oregon law precluded an appellate court from reviewing the *amount* of a punitive damages award, permitting the court to only consider whether *any* punitive award was appropriate.⁶³ Once the appellate court found evidence supporting a punitive award, generally, state law required the reviewing court to uphold the jury's award in its entirety.⁶⁴ The United States Supreme Court held that Oregon's law failed to

56. *Halper*, 490 U.S. at 450 (rejecting a double jeopardy argument and affirming \$6 million jury verdict for the plaintiff in an antitrust suit).

57. 492 U.S. 257 (1989).

58. U.S. CONST. amend. VIII ("Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.").

59. *Browning-Ferris*, 492 U.S. at 260 (holding that the clause likely applies only to criminal cases, and certainly does not apply to civil cases between private parties in which no governmental interests are implicated). The Court left open, however, the "materially different" question of whether the Eighth Amendment is implicated in *qui tam* actions, "in which a private party brings suit in the name of the United States and shares in any award of damages." *Id.* at 275 n.21. The Court also chose not to address the constitutionality of state statutes requiring a portion of punitive damage awards to be paid into a state fund rather than being awarded to the plaintiff. *See, e.g.*, statutes of Georgia, Indiana, Missouri, and Oregon, *supra* note 43 and accompanying text. There may be a corollary to the "materially different" *qui tam* argument that Eighth Amendment limitations should apply because these state governments benefit from the imposition of punitive damage awards. To date, the Court has not addressed this question.

60. *See* Thomas C. Galligan, Jr., *Disaggregating More-Than-Whole Damages in Personal Injury Law: Deterrence and Punishment*, 71 TENN. L. REV. 117, 118 (2003) ("[I]n recent years the United States Supreme Court has twice held that awards of punitive damages were so grossly excessive that they violated the defendant's substantive due process rights, and has twice held that the procedure under which punitive damages were awarded violated the defendant's procedural due process rights.").

61. 512 U.S. 415 (1994).

62. The state court jury awarded \$5 million in punitive damages against Honda in a products liability action. *Id.* at 418.

63. *Id.* at 426-27 ("[I]f the defendant's only basis for relief is the *amount* of punitive damages the jury awarded, Oregon provides no procedure for reducing or setting aside that award.").

64. *Id.*

provide adequate appellate review under the Federal Constitution's procedural due process requirements.⁶⁵

While compensatory damages generally serve to redress the loss caused to a plaintiff by a defendant's actions, "punitive damages serve a broader function; they are aimed at deterrence and retribution."⁶⁶ In evaluating the appropriateness of a punitive damage award, then, the question of reasonableness must be directly correlated with the degree of reprehensibility of the defendant's conduct.⁶⁷ The Supreme Court thus recognizes that substantive due process concerns are also implicated when punitive damages are imposed upon a defendant and, as a result, holds that such awards may not be "grossly excessive."⁶⁸ To aid lower courts in complying with this requirement, the Court developed a three-prong test for use in determining whether a given award comports with substantive due process standards. The criteria requiring consideration include "(1) the degree or reprehensibility of the defendant's misconduct, (2) the disparity between the harm . . . suffered by the plaintiff and the punitive damages award, and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases."⁶⁹ The test is premised on the

65. *Id.* at 432. ("Oregon's denial of judicial review of the size of the punitive damage awards violates the Due Process Clause of the Fourteenth Amendment.").

66. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003).

67. *See id.* at 419 ("[P]unitive damages should only be awarded if the defendant's culpability, after having paid compensatory damages, is so reprehensible as to warrant the imposition of further sanctions to achieve punishment or deterrence."); *see also* *Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 17-18 (1991) (holding that the Federal Constitution imposes a substantive limit on the size of punitive damages awards).

68. *Cooper Indus. v. Leatherman Tool Group*, 532 U.S. 424, 434 (2001). The Court articulated a similarly critical principle in *Cooper Industries*: A federal appellate court reviewing a punitive damage award from a district court should evaluate the excessiveness of the award de novo, granting no presumption of appropriateness to the district court's assessment. *Id.* at 436. The Court reasoned that because the "excessiveness inquiry" requires evaluation of constitutional standards, an appellate court is reviewing a question of law rather than a question of fact making de novo review appropriate. *Id.* at 435-36.

69. *Id.* at 440 (citing *BMW of N. Am. v. Gore*, 517 U.S. 559, 574-75 (1996)). The Court recently expanded the definition of "reprehensibility," stating that analysis of this first prong requires consideration of whether

the harm caused was physical as opposed to economic; the tortious conduct evinced an indifference to or a reckless disregard of the health or safety of others; the target of the conduct had financial vulnerability; the conduct involved repeated actions or was an isolated incident; and the harm was the result of intentional malice, trickery, or deceit, or mere accident.

State Farm, 538 U.S. at 419. The absence of any one of these factors, the Court concluded, may not necessitate reversing a punitive damage award, but a judgment resting on less than all three would be "suspect." *Id.*

requirement of the Due Process Clause that a state provide a defendant adequate notice not only of the types of conduct that might subject him to liability for punitive damages, but also the possible severity of the penalty that may be imposed for that conduct.⁷⁰

The substantive due process consideration figured prominently in the Court's decision to strike down a multimillion dollar state court award in *BMW of North America v. Gore*.⁷¹ The plaintiff discovered that his new car had been damaged and repainted at the defendant's out-of-state factory prior to its delivery to the Alabama dealership at which the plaintiff purchased the vehicle.⁷² The plaintiff contended that BMW's failure to disclose the repair constituted a material omission for which he deserved compensation.⁷³ The jury agreed and awarded the plaintiff \$4,000 in compensatory damages and \$4 million in punitive damages.⁷⁴ The Supreme Court of Alabama remitted the punitive damages award to \$2 million,⁷⁵ but the United States Supreme Court concluded that the sum was still impermissibly high under the Fourteenth Amendment.⁷⁶ Justice Stevens, writing for the majority, explained the constitutional significance of the state court's punitive award: "Alabama does not have the power . . . to punish BMW for conduct that was lawful where it occurred and that had no impact on Alabama or its residents."⁷⁷

Applying the first prong of the test articulated in *Cooper Industries*, the *BMW* Court held that because the repair and subsequent nondisclosure were lawful in the state in which the car was manufactured and repainted, and because the injury to the plaintiff was purely economic, the defendant's conduct could not be considered particularly reprehensible.⁷⁸ The Court then noted the significant 500:1 ratio of punitive damages to compensatory damages awarded by the trial court as enough to "raise a suspicious judicial eyebrow" under the second prong of its analysis.⁷⁹ Finally, applying

70. *BMW*, 517 U.S. at 574.

71. *See id.* at 559.

72. *Id.* at 562 & n.1.

73. *Id.* at 563.

74. *Id.* at 565.

75. *Id.* at 567.

76. *Id.*

77. *Id.* at 572-73.

78. *Id.* at 575-80.

79. *Id.* at 583. The Court declined to specify a ratio that may have been appropriate. Later, however, the Court cited *BMW* in striking down a \$145 million state court punitive award in *State Farm Mutual Insurance Company v. Campbell*, 538 U.S. 408 (2003). In *State Farm*, the Utah Supreme Court had remitted a compensatory damage award for fraud and intentional infliction of emotional distress from \$2.6 million to \$1 million but sustained the

the third prong of its test, the Court reasoned that in other states, awards against defendants based on similar conduct had not exceeded several thousand dollars, so BMW could not have been on adequate notice that it could be subject to a multi-million dollar verdict.⁸⁰

Underlying this constitutional framework is the twofold purpose of punitive damages: punishment and deterrence.⁸¹ These stated objectives suggest an inherent requirement that defendants deserve punishment for knowingly wrongful conduct and that the imposition of a punitive award will deter the defendant from engaging in similar wrongful conduct in the future. Against this backdrop, an examination of the FDA's approval and regulatory practices will be helpful in examining whether punitive damages assessed against a pharmaceutical manufacturer that followed FDA guidelines, but nevertheless produced an allegedly harmful drug, are warranted by either of these goals.

II. ACHIEVING FDA APPROVAL

Congress passed the Federal Food, Drug and Cosmetic Act ("FDCA") in 1938.⁸² Congress enacted the FDCA in response to a public call for greater federal oversight of pharmaceuticals following a number of deaths caused by Elixir-Sulfanilamide, a liquid form of a drug used to treat streptococcal infections.⁸³ The FDCA authorizes the Food and Drug Administration ("FDA") to require pre-market testing of drugs and to oversee post-marketing conduct by

trial court's punitive damages figure. *Id.* at 415. The United States Supreme Court struck down the 145:1 ratio of punitive damages to compensatory damages. *Id.* at 425. In doing so, the Court "decline[d] again to impose a bright-line ratio which a punitive damages award cannot exceed," but noted that "few awards exceeding a single-digit ratio between punitive and compensatory damages . . . will satisfy due process." *Id.* The Court further hinted that a 4:1 ratio may be the limit of constitutionality as far as substantive due process is concerned. *Id.*

80. *BMW*, 517 U.S. at 584.

81. *Id.* at 568; *see also* *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 19 (1991) ("[U]nder the law of most States, punitive damages are imposed for purposes of retribution and deterrence."); RESTATEMENT (SECOND) OF TORTS § 908 (1965) (stating that the purpose of punitive damages is "to punish [a defendant] for his outrageous conduct and to deter him and others like him from similar conduct in the future").

82. Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-394 (2000)).

83. H.A. WALLACE, DEPT. OF AGRICULTURE, REPORT OF THE SECRETARY OF AGRICULTURE ON DEATHS DUE TO ELIXIR-SULFANILAMIDE-MASSENGILL, S. DOC. NO. 124, at 2 (1937); *see also* Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG., June 1981, available at <http://www.fda.gov/oc/history/elixir.html>.

manufacturers.⁸⁴ The FDA has since adopted thousands of federal regulations to accomplish these directives.⁸⁵ Today, despite the adoption of these regulations, the FDCA still provides the basic framework for the steps a manufacturer must take to distribute a pharmaceutical in the United States.⁸⁶ FDA regulations, in turn, predicate the drug's introduction into interstate commerce on the agency's approval of the manufacturer's New Drug Application ("NDA").⁸⁷ Thus, while the FDCA's language still outlines the steps a manufacturer must take to market a drug in the United States, FDA regulations essentially dictate whether it may be introduced in the first place.

The long, arduous, and expensive process a pharmaceutical manufacturer undergoes to receive FDA approval should raise serious doubts about the ability of the manufacturer of an allegedly harmful drug to act maliciously or even recklessly in making the drug available to the public once the company submits all required information to the FDA. The application process alone typically takes two years to complete, and the testing that must take place before the application process begins can take many times longer.⁸⁸ In fact, the regulations imposed by the United States Food and Drug Administration are generally considered the world's most demanding.⁸⁹

A new drug cannot be marketed in the United States without receiving approval from the FDA's Center for Drug Evaluation and Research ("CDER"), which certifies not only that the drug is safe, but that it is effective for its advertised intended use.⁹⁰ Before even

84. 21 U.S.C. § 360e; *id.* § 360l; *see also* H.R. REP. NO. 94-853, at 1 (1976) (authorizing the FDA to require pre-market testing of pharmaceuticals and oversight of pre-market conduct of drug companies).

85. *See* 21 C.F.R. §§ 200–300 (2005).

86. The Food and Drug Administration "shall promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products," 21 U.S.C. § 393(b)(1), and specifically shall "protect the public health by ensuring that human and veterinary drugs are safe and effective." *Id.* § 393(b)(2).

87. *See* MARK MATHIEU, *NEW DRUG DEVELOPMENT: A REGULATORY OVERVIEW*, 186 (5th ed. 2000).

88. *See* CHI-JEN LEE, *DEVELOPMENT AND EVALUATION OF DRUGS: FROM LABORATORY THROUGH LICENSURE TO MARKET* 25 (1993) (describing public misconception of the FDA's role in drug approval).

89. *See* MATHIEU, *supra* note 87, at 1.

90. *See* ELAINE WHITMORE, *DEVELOPMENT OF FDA-REGULATED MEDICAL PRODUCTS: PRESCRIPTION DRUGS, BIOLOGICS, AND MEDICAL DEVICES* 44 (2004) (discussing the pre-marketing approval process). More on the CDER can be found on its official website. *See* <http://www.fda.gov/cder/index.html>.

submitting an application for approval, however, a pharmaceutical manufacturer must produce evidence of safety and effectiveness through both preclinical research, in which the drug is tested in Petri dishes and in animals, and three phases of clinical research involving studies of the drug in humans.⁹¹ The FDA does not become involved in the process until all preclinical testing is complete and the drug company wishes to test the drug's safety and effectiveness in humans.⁹²

A drug manufacturer undertakes years of preliminary testing before ever presenting a new drug to the FDA. Once a researcher identifies a compound that may be effective in treating some condition, a pharmaceutical company may decide to take on preclinical in vitro and in vivo testing, representing the first major step toward regulatory approval.⁹³ Although the FDA does not dictate the types of tests that must be conducted, extensive regulation governs even these initial stages of the process.⁹⁴ For example, a nonclinical research laboratory—a laboratory that uses test subjects other than humans—must have, among other attributes, educated and experienced personnel,⁹⁵ an independent quality assurance unit⁹⁶ staffed independently from this personnel,⁹⁷ specific protocols,⁹⁸ and health and welfare standards for tested animals.⁹⁹ Through testing, researchers often find that tested compounds are unsafe, not readily

91. See RICHARD A. GUARINO, *NEW DRUG APPROVAL PROCESS*, at xix (1993).

92. Jeffrey P. Cohn, *The Beginnings: Laboratory and Animal Studies*, FDA CONSUMER SPECIAL REPORT 4 (Jan. 1995), available at <http://www.fda.gov/cder/about/whatwedo/testtube-3.pdf>.

93. See MATHIEU, *supra* note 87, at 7–8. Preclinical testing includes any testing that does not involve human test subjects. *Id.* at 5. In vitro testing involves observations of how the compound reacts with other compounds in various non-living environments. See RICK NG, *DRUGS: FROM DISCOVERY TO APPROVAL* 3 (2004). In vivo testing examines the safety and efficacy of the compound on animal test subjects. *Id.*

94. See Cohn, *supra* note 92, at 4.

95. 21 C.F.R. § 58.29(a) (2005) (“Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.”).

96. *Id.* § 58.35(a) (“A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part.”).

97. *Id.* (“For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.”).

98. See *id.* § 58.120–130 (regulating protocol and conduct of a nonclinical laboratory study).

99. See *id.* § 58.90 (outlining required standard operating procedures for the housing, feeding, handling, and care of animal test subjects).

absorbed or metabolized, or contain some other defect that makes them ineligible for further development.¹⁰⁰ In fact, those close to the process estimate that only 1 out of every 1,000 drugs that enters the nonclinical testing process ever progresses beyond this phase.¹⁰¹ Of the drugs qualifying for further testing, only 1 in 5 will ever be marketed as a new product—1 in every 5,000 compounds that enters initial nonclinical testing.¹⁰² Conducting a thorough nonclinical study that adheres to FDA regulations represents a phase of research often lasting over 6 years.¹⁰³

For the approximately 0.1% of compounds that move from the nonclinical phase to testing involving human subjects, FDA oversight grows progressively more intense. Prior to beginning the three phases of clinical studies involving humans, the FDA requires a manufacturer to file an Investigational New Drug application (“IND”).¹⁰⁴ The IND must contain information regarding the chemical formulation of the new drug, results of in vivo animal studies, the proposed design of the human study, a description of the types of patients to be studied, an outline of risk-minimizing procedures, details involving how the drug will be administered, and dosing information, among other data.¹⁰⁵ Unlike a New Drug Application, which requests FDA approval to market the drug to the public, there is no formal approval process; a drug manufacturer may initiate clinical trials as proposed in an IND 30 days after the FDA receives the application, so long as the FDA does not contact the manufacturer within this 30-day period to tell the manufacturer otherwise.¹⁰⁶ The IND, then, is essentially a notice to the FDA that the drug company intends to ship the yet-unapproved drug in interstate commerce to test sites and proceed with clinical trials in humans.¹⁰⁷

Expensive and time consuming, pre-market clinical trials are divided into three phases, with submission of a new IND required for each phase.¹⁰⁸ At any stage of any phase, the FDA may step in and

100. MATHIEU, *supra* note 87, at 19.

101. *Id.*

102. WHITMORE, *supra* note 90, at 88.

103. *Id.* at 95.

104. MATHIEU, *supra* note 87, at 49.

105. 21 C.F.R. § 312.23 (2005) (outlining the suggested contents of the Investigator’s Brochure that must be submitted with the IND).

106. MATHIEU, *supra* note 87, at 50. For more on the specific requirements of an NDA, see *infra* notes 126–29 and accompanying text.

107. MATHIEU, *supra* note 87, at 49.

108. See GUARINO, *supra* note 91, at 41–42.

halt a trial should any concerns over safety or protocol arise.¹⁰⁹ Phase I examines the general safety of the new drug and watches for potential side effects on a very small scale, normally in trials involving between 10 and 100 people.¹¹⁰ Participants in Phase I trials may be healthy volunteers or may be terminally ill patients who have opted to try the new drug.¹¹¹ Even though Phase I clinical trials involve comparatively small numbers of test subjects, such trials average a year in length and commonly cost upwards of \$10 million.¹¹²

Phase II trials involve larger-scale testing of the drug on patients who have the specific condition the drug is designed to treat.¹¹³ Normally, somewhere between 50 and 500 patients participate in Phase II trials, which involve double-blind studies intended to determine the effective dose of the drug and the ideal drug regimen, in terms of both frequency and duration.¹¹⁴ Phase II clinical trials, due to their complexity and purpose, are even more costly and time-consuming than Phase I trials, generally taking one to two years to complete and costing the manufacturer about \$20 million.¹¹⁵ At the end of Phase II testing, representatives from the pharmaceutical manufacturer must meet with agents of the FDA to discuss any plans to move on to Phase III trials.¹¹⁶ Only about 30% of the drugs that enter clinical trials progress past Phase I and II testing.¹¹⁷

Phase III trials test a drug's safety and efficacy on a large patient group and at a variety of sites, essentially representing a geographically and numerically expanded version of a successful Phase II trial.¹¹⁸ Thousands of patients typically participate in Phase III trials, and their treatment is followed for years in order to gauge

109. NG, *supra* note 93, at 181.

110. *Id.* at 144; *see also* § 312.21(a) ("These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.").

111. NG, *supra* note 93, at 144.

112. *Id.*

113. WHITMORE, *supra* note 90, at 94; *see also* § 312.21(b) (stating that the purpose of this phase is "to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug").

114. NG, *supra* note 93, at 145.

115. *Id.*

116. LEE, *supra* note 88, at 67.

117. NG, *supra* note 93, at 145.

118. *Id.* at 146; *see also* § 312.21(c) (stating that Phase III testing is "intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling").

long-term side effects and safety.¹¹⁹ The studies are double-blind and randomized,¹²⁰ designed to provide detailed insights into the effectiveness of the new drug as opposed to either placebos or the most effective current treatment, or both.¹²¹ Phase III trials last from three to five years and cost up to \$100 million due to their magnitude.¹²²

All of the above steps—preclinical testing and Phase I through III of clinical trials—may easily last fifteen years and cost a drug company hundreds of millions of dollars.¹²³ The result is that only one out of thousands of investigational compounds shows itself to be safe and effective enough to justify submitting an application for FDA approval to market the drug to the public.¹²⁴ Even then, of course, not all applications are approved.¹²⁵

A new drug's entrance into the formal FDA approval process begins with a manufacturer submitting an NDA.¹²⁶ A proper NDA must contain detailed technical information including the chemistry of the compound, all components used in its manufacture, the environmental impact of manufacturing procedures, toxicity indicators, effects of the drug on reproduction or fetal development, absorption and metabolic tendencies, methods used in all animal and human studies and the results of such studies, any observed side effects, summaries of risks and benefits, a statistical evaluation of clinical data, and any other information related to the evaluated safety and effectiveness of the drug.¹²⁷ A typical NDA can easily be thousands of pages in length and must comply with dozens of FDA guidelines.¹²⁸ In evaluating an NDA, the FDA seeks to resolve three

119. WHITMORE, *supra* note 90, at 94.

120. See § 314.126(b)(2)(i) ("A placebo-controlled study ... usually includes randomization and blinding of patients or investigators, or both.").

121. WHITMORE, *supra* note 90, at 94.

122. NG, *supra* note 93, at 147.

123. For example, in 2004 alone, Pfizer's research and development expenses were estimated at \$7.68 billion. This figure does not account for the drugmaker's general and administrative expenses, totalling almost \$17 billion. Scott Hensley, *Pfizer Plans \$2 Billion in Cost Cuts*, WALL ST. J., Feb. 11, 2005, at A3.

124. Only about 1 out of every 1,000 compounds progresses past preclinical testing. See *supra* note 102 and accompanying text. Then, for every 100 drugs that enter clinical testing, 70% progress from Phase I to Phase II, 33% from Phase II to Phase III, and only 25%–30% successfully complete Phase III. Ken Flieger, *Testing Drugs in People*, FDA CONSUMER SPECIAL REPORT 4 tbl.1 (Jan. 1995), available at <http://www.fda.gov/cder/about/whatwedo/testtube-3a.pdf>.

125. Flieger, *supra* note 124.

126. 21 U.S.C. § 355(a)–(b) (2000).

127. 21 C.F.R. § 314.50 (2005); see also LEE, *supra* note 88, at 71–74.

128. MATHIEU, *supra* note 87, at 185, 196–97.

key considerations: (1) whether the drug is safe and effective for its proposed use(s) and whether the benefits of the drug outweigh the risks; (2) whether the drug's proposed labeling (package insert) is appropriate and what additional information, if any, it should contain; and (3) whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.¹²⁹

To evaluate these three considerations, the FDA compiles a review team of chemists, pharmacologists, physicians, microbiologists, and statisticians to evaluate each properly presented NDA, and often consults with one of seventeen standing advisory committees on drugs and biologics for advice.¹³⁰ From the time an NDA is submitted, it takes an average of fifteen to twenty months for the FDA to make an ultimate decision on whether to approve a new drug for marketing in the United States.¹³¹ A grant of approval from the FDA affirms the agency's view that the benefits of the drug outweigh any foreseeable risk. It does not, however, ensure that a drug will have no adverse side effects—in fact, “[t]here is no such thing as absolute safety in drugs.”¹³² With side effects for some drug users an inevitable part of even the most beneficial pharmaceuticals, the current standards for reaping large punitive awards could apply to any manufacturer, for any drug. Under the regime in some jurisdictions, then, all pharmaceutical manufacturers are supposedly engaging in abhorrent behavior.

In 1979, the FDA further strengthened its approval process beyond the requirements imposed for submission of an NDA by dictating the format of a drug's warning label and package insert with the goal of ensuring proper use by consumers.¹³³ The labeling regulations reflect the FDA's experience with the purposes and effects of labeling, as well as the agency's recognition of its own responsibility to ensure that each drug's label meets scientific and regulatory requirements.¹³⁴ Drafting a prescription drug's package insert begins with the pharmacology, toxicology, and safety data included in the IND and NDA, as well as the data supplied by

129. Outline of the NDA Process, <http://www.fda.gov/cder/regulatory/applications/NDA.htm> (last visited Oct. 20, 2005).

130. LEE, *supra* note 88, at 76.

131. WHITMORE, *supra* note 90, at 47. The fifteen-to-twenty-month wait, as of 2002, is down from a high of thirty months in 1992. *Id.*

132. *Drug Safety (Part I): Hearings Before the Subcomm. on Intergovernmental Relations*, 88th Cong. 147 (1964).

133. 21 C.F.R. § 201.56–57 (2005).

134. GUARINO, *supra* note 91, at 362.

premarket clinical and nonclinical trials.¹³⁵ In general, the label of an FDA-regulated drug must “contain a summary of the essential scientific information needed for the safe and effective use of the drug, . . . be informative and accurate and neither promotional in tone nor false or misleading in any particular . . . [and] be based whenever possible on data derived from human experience.”¹³⁶ Although the manufacturer will suggest the bulk of a label’s substantive information, the FDA has the final say on the contents of the warning—most significantly, on which of the adverse indications are included and how they are worded.¹³⁷ In fact, the FDA itself “has stated clearly that its labeling decisions reflect conscious policy choices not only about what information should be included in drug labels, but also what information should *not* be included.”¹³⁸

The FDA also conducts extensive post-approval monitoring of any drug that hits the U.S. market to ensure continuing safety and efficacy. Pharmaceutical companies must closely monitor their drugs and report to the FDA any adverse drug information they receive from any source, through mandatory continuing research studies or through reports from users and physicians.¹³⁹ The FDCA reinforces these reporting requirements with the threat of civil and criminal penalties for any manufacturer who does not comply fully or who is found to have deliberately concealed knowledge of adverse drug reactions.¹⁴⁰ Significantly, the FDA itself feels its requirements are stringent enough to mitigate the need for punitive liability. FDA spokesman Jeff Pruitt, commenting on a recent House of Representatives bill proposing limiting punitive damage awards against manufacturers of FDA-approved drugs, stated the agency’s position clearly: “We believe that punitive damages should be

135. *Id.* The text of each prescription drug’s package insert is also published in the Physician’s Desk Reference, the compendium of drug information relied upon by prescribing medical professionals. PHYSICIAN’S DESK REFERENCE (59th ed. 2005), available at <http://www.PDR.net>.

136. § 201.56(a)–(c).

137. See Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD & DRUG L.J. 233, 236 (1986) (stating that the FDA “retains, as a practical matter, complete control over package inserts”). Mr. Cooper is a former FDA Chief Counsel. *Id.* at 233.

138. David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 418 (1996).

139. LEE, *supra* note 88, at 78.

140. 21 U.S.C. §§ 332–334 (2000).

allowed only if it can be proven that companies did not comply with all the rules during the approval process.”¹⁴¹

Imposing punitive damages against a drug manufacturer constitutes a finding that the manufacturer *deserves* punishment for making the drug available to consumers because its conduct in doing so was “grossly negligent, intentional, willful, wanton, malicious, reckless, outrageous” or “exhibited a flagrant disregard for others.”¹⁴² However, it is ultimately the FDA’s choice, not that of the manufacturer, to permit the drug to be marketed in the United States. Therefore, if the manufacturer acted in one of the aforementioned reprehensible ways, it must have been in its conscious failure to adhere to FDA testing and reporting requirements and in violation of federal law.¹⁴³ This Comment argues that punitive damages should be available against a drug manufacturer for an injury allegedly caused by an FDA-approved pharmaceutical only when the plaintiff can prove a violation of federal law by the manufacturer during the pre- or post-market approval process.

III. PHARMACEUTICAL MANUFACTURERS SHOULD NOT BE SUBJECT TO PUNITIVE DAMAGES IF FDA REGULATIONS HAVE BEEN FOLLOWED

Pharmaceutical manufacturers can be held liable for injuries to drug users under three general doctrines: manufacturing defect, design defect, and failure to warn.¹⁴⁴ Manufacturing defect theories are rarely raised in pharmaceutical cases and are thus not considered in this discussion.¹⁴⁵ Plaintiffs seeking punitive damages in

141. See Anne C. Mulkern, *Medical Liability Cap Sought: House Bill Limits Awards from Doctors, Drugmakers*, DENVER POST, July 26, 2005, at A-01 (citing claims that “the bill provides equity for companies that have followed the rules while going through the 10- to 15-year Food and Drug Administration approval process for their medications”).

142. Pace, *supra* note 41, at 1618–19 (outlining the varying standards for punitive damage entitlement in different states).

143. See *supra* note 140 and accompanying text.

144. North Carolina, see *Smith v. Fiber Controls Corp.*, 300 N.C. 669, 678, 268 S.E.2d 504, 509–10 (1980), and Virginia, see *Sensenbrenner v. Rust, Orling & Neale, Architects, Inc.*, 374 S.E.2d 55, 58 (Va. 1988), still do not recognize a cause of action in strict liability for personal injury caused by a product.

145. A product “contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.” RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(a) (1998). When a manufacturing defect is found to be the cause of injury, strict liability is imposed upon the manufacturer, and, therefore, there is no specific finding of fault. Fault is assumed simply by the fact that the individual product deviates from its intended design. MARGARET C. JASPER, *THE LAW OF PRODUCT LIABILITY* 7 (2d ed. 2001). Because pharmaceutical products liability cases rarely allege such a defect, this

pharmaceutical litigation more typically rely on design defect and failure-to-warn theories.¹⁴⁶ A closer examination of each theory indicates that neither supports the award of punitive damages in the pharmaceutical context.

A. Design Defect

A “design defect” can take one of two forms, depending on whether a jurisdiction classifies claims of injury from pharmaceuticals as general products liability actions or as their own separate category.¹⁴⁷ Under the former view, a prescription drug “is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe.”¹⁴⁸ Generally, a successful design defect claim requires a finding of negligence, though strict liability may be imposed in the case of an unreasonably dangerous design.¹⁴⁹ However, the design defect theory of liability, as worded by the *Restatement (Third) of Torts*, does not imply that the manufacturer knew of the design defect or concealed any indications of a defect from consumers. In fact, the strict liability doctrine allows a plaintiff to recover even if a reasonable manufacturer could not have discovered the product’s danger until *after* the drug had been marketed to the plaintiff.¹⁵⁰ This standard therefore deems a product “not reasonably safe” if hindsight demonstrates a safer alternative existed, even though the manufacturer acted reasonably in testing and

Comment only notes the apparent lack of logic in imposing damages that are, by definition, based upon a malicious act or extreme recklessness, when the plaintiff has not been required to show any specific state of mind in proving general liability. See Wertheimer, *supra* note 21, at 508–10.

146. See Michael Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data*, 78 IOWA L. REV. 1, 18 n.85 (1992) (citing JAMES A. HENDERSON, JR. & AARON D. TWERSKI, *PRODUCTS LIABILITY: PROBLEMS AND PRACTICE* 298 (1st ed. 1987)) (“Courts have almost exclusively imposed punitive damages in design defect and failure-to-warn cases. The inadvertent product defect case that occurs because of imperfect quality control rarely, if ever, involves the kind of reckless conduct that would support punitive damages.”).

147. States treat the issue differently. See *supra* Part I (surveying the treatment of punitive damages among state jurisdictions).

148. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998). The recitation of Restatement provisions in this Comment is intended to show the general or prevailing view; some states have adopted statutes regarding products liability doctrines that may differ slightly.

149. JASPER, *supra* note 145, at 7.

150. See Aaron D. Twerski, *A Moderate and Restrained Federal Product Liability Bill: Targeting the Crisis Areas for Resolution*, 18 U. MICH. J.L. REFORM 575, 591 (1985).

designing the product.¹⁵¹ Just because the adverse side effects of the drug “could have been reduced or avoided,” then, the stated standard does not even contemplate that the manufacturer was aware or should have been aware of the potential adverse side effect at the time of FDA approval.¹⁵² In fact, due to the FDA’s requirements that even the Phase III clinical trials involve only a few thousand patients, such trials will inevitably miss the occasional rare adverse side effect that may affect only 1 in 10,000 people.¹⁵³ Because the definition of liability premised on design defect does not require an injured plaintiff to show that the manufacturer possessed the knowledge of a potential injury that could have led to a better design—but only that a better design was possible—a plaintiff does not bear the burden of showing that the pharmaceutical company acted intentionally, maliciously, recklessly, or even negligently with regard to the drug design in order to prove himself entitled to compensatory damages.¹⁵⁴ Indeed, a plaintiff in a pharmaceutical case will commonly not even have to present evidence that a manufacturer had actual information available during the design of the drug that would have allowed it to alter a drug’s composition in a way that would render the drug safer.¹⁵⁵

The fact that the generally-accepted design defect standard imposes upon plaintiffs the burden of demonstrating that the risk of harm through not adopting a “reasonable” alternative design was

151. *Id.*

152. As a matter of course, strict liability is widely recognized in design defect claims against pharmaceutical manufacturers. See, e.g., *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1195 (Alaska 1992); *Bryant v. Hoffmann-LaRoche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003); *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 834 (Neb. 2000). But see *Brown v. Superior Court*, 751 P.3d 470, 475–83 (Cal. 1988) (holding that strict liability may not apply so long as a drug was properly prepared and labeled with warnings of possible dangers that were known or reasonably knowable at the time of distribution).

153. LEE, *supra* note 88, at 77. If this number is unacceptably risky the proper course of action, this Comment argues, is to pressure the FDA to require expanded clinical trials, not to punish drug companies for the FDA’s perceived shortcomings.

154. Whether this should be so is outside the scope of this Comment. However, for a good discussion, see generally Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167 (2000) (arguing that compliance with FDA regulations should have a preclusive effect on a plaintiff’s ability to be compensated for injuries allegedly caused by an approved drug).

155. A defendant drug manufacturer will occasionally prevail on such a claim if the plaintiff fails to show the existence of an alternative design and the court finds that, as a matter of law, the drug was an “unavoidably unsafe product.” See, e.g., *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 399–403 (6th Cir. 1990) (affirming summary judgment for defendant on a strict liability claim for injuries allegedly caused by defendant’s DTP vaccine). The manufacturer prevailed when the court held that DTP was unavoidably unsafe and that no alternative design was available that was safer yet still as effective. *Id.*

“foreseeable”¹⁵⁶ provides little relief to drug manufacturers. This standard of recovery implies that the plaintiff can prevail by demonstrating that the manufacturer could have produced a safer drug and that the difference in harm between this hypothetical pharmaceutical and the one actually produced justified its costs.¹⁵⁷ Yet in approving the pharmaceutical’s NDA, the FDA undertook a similar cost-benefit analysis and found that the efficacy benefits of the drug outweighed any safety risks.¹⁵⁸ Allowing plaintiffs to recover from a good-faith manufacturer under these circumstances implies either that the FDA erred in its cost-benefit analysis or that the lip service given to foreseeability has no real viability in the products liability context.

Jurisdictions treating design defect cases as general products liability actions, therefore, do not require plaintiffs to demonstrate that a drug manufacturer continued to market an allegedly harmful drug while aware of a risk created by the product’s design. This leaves one to wonder upon what grounds a plaintiff’s claim for punitive damages in such a case is premised. Courts awarding punitive damages in design defect cases considered under the general products liability rubric thus struggle to articulate their logic when addressing this issue. For example, in *Masaki v. General Motors Corp.*,¹⁵⁹ the Supreme Court of Hawaii assumed the availability of punitive damages against the defendant manufacturer even though the plaintiff premised his case on strict liability.¹⁶⁰ That court defended its position by reasoning that “[a]lthough strict liability dispenses with the need to prove fault in order to find the defendant liable, it does not preclude consideration of the defendant’s aggravating conduct for the purpose of assessing punitive damages.”¹⁶¹ However, if a plaintiff can show both the existence of a design defect and aggravating conduct on the part of the defendant,

156. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998); *supra* note 148 and accompanying text.

157. See Jeffrey J. Rachlinski, *Regulating in Foresight Versus Liability in Hindsight: The Case of Tobacco*, 33 GA. L. REV. 813, 818 (1999) (arguing that the stated rule is more a negligence standard, though plaintiffs continue to recover under the strict liability regime).

158. See *supra* notes 130–32 and accompanying text.

159. 780 P.2d 566 (Haw. 1989).

160. *Id.* at 573 (“[W]e find no logical or conceptual difficulty in allowing a claim for punitive damages in a products liability action based on strict liability.”). Although the state supreme court vacated the lower court’s punitive award with this decision, it remanded the case for reconsideration with instructions that the plaintiff must show entitlement to punitive damages by a “clear and convincing standard of proof.” *Id.* at 575.

161. *Id.*

as contended by the *Masaki* court, his claim would not need to be premised on strict liability in the first place.

Permitting punitive damages in design defect cases when plaintiffs cannot show that a defendant consciously committed a reprehensible act essentially imposes a presumption of knowledge of all "qualities and characteristics" of a drug onto manufacturers and implies that a defendant *deserves* punishment.¹⁶² This presumption certainly eases the plaintiff's burden, but it does so on the basis of a judge-made assumption, not on solid evidence of knowledge or intent on the part of the manufacturer. Equally troubling is that the use of such a presumption to punish a drug manufacturer who neither knew nor should have known of a drug's dangers eliminates the deterrent function that punitive damages are designed to serve. A manufacturer cannot change present behavior based on a threat that it will be imputed with knowledge in the future that it does not have, and possibly cannot obtain, at present.

The *Restatement (Third) of Torts* treats pharmaceuticals differently than other products, stating that a prescription drug

is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug . . . are 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.¹⁶³

Unlike the aforementioned general definition of design defect,¹⁶⁴ the use of the word "foreseeable" occurs not once, but three times in the formulation specific to prescription drugs. This implies that drugmakers are charged with actual or constructive knowledge of the possibilities of an injury occurring to the pharmaceutical's users, at a frequency and intensity making the drug's risks outweigh its benefits. Therefore, at trial under the design defect rubric, plaintiffs can potentially collect punitive damages based on a finding of a foreseeable defect and absent any actual knowledge of the defect by the manufacturer.

This approach is problematic, however, because it attempts to duplicate the inquiry undertaken by a team of experts at the FDA

162. See *Montgomery Elevator Co. v. McCulloch*, 676 S.W.2d 776, 780-81 (Ky. 1984) (articulating the precise facts a manufacturer is presumed to know).

163. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(b) (1998) (emphasis added).

164. See *id.* § 2(b).

over a period of years, placing that inquiry into the hands of lay jurors and condensing the time period for consideration into days or weeks. Awarding punitive damages through this approach—upon a finding that known risks outweighed known benefits—requires one of two conclusions. The first is that the informed determination of the FDA in approving the drug was incorrect. The second is that the FDA did not have all the information necessary to make its determination, presumably because this information was withheld by the drug manufacturer. The prior view assumes an inadequacy with the FDA procedures. There is no logical rationale for imposing punitive damages against the manufacturer in this instance, because the manufacturer neither “deserves” the punishment nor can it change its behavior to remedy what the jury has determined to be a shortcoming. In the latter situation—in which there is credible evidence that FDA approval was obtained through unlawful grounds—the presumption against punitive damages may be rebutted. However, considering the extensive FDA procedures, it should require an egregious omission that is directly related to the plaintiff’s injury for the jury to be allowed to consider punitive damages—indeed, it is only in this case that wrongful behavior need be punished and deterred, and the wrongful behavior cited must be the misrepresentation to the FDA, not the alleged design defect itself.

B. Failure to Warn

The generally articulated standards imposing liability based upon failure to warn, like those based upon defective design,¹⁶⁵ vary depending upon whether a jurisdiction classifies injuries allegedly caused by pharmaceuticals as general products liability actions or as a special class of products litigation. Jurisdictions treating the claims as general products liability actions often state that a product “is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings . . . and the omission of the instructions or warnings renders the product not reasonably safe.”¹⁶⁶ This standard, once again employing the word “foreseeable,” implies that to some degree the manufacturer must have purposely or knowingly failed to include in the product warning some danger of which the manufacturer was or reasonably should have been aware. What this standard ignores,

165. See *supra* notes 147–48, 163 and accompanying text.

166. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (1998).

when applied in the realm of prescription drugs, is that the FDA may prohibit a manufacturer from warning of certain adverse reactions, possibly due to a disagreement among experts as to the degree of danger.¹⁶⁷ The FDA has determined that when the risk of an adverse reaction is either too unclear or too remote, it should not be included in a drug's label due to the danger that the most important sections of the label will be buried in superfluous text.¹⁶⁸

This issue is present in the pending Vioxx lawsuits, where one major allegation driving plaintiffs' cases is that a panel conducting post-market clinical trials for Merck had early data indicating the higher risks of heart problems in patients using Vioxx as opposed to a placebo.¹⁶⁹ Merck argues that indications that the risk was statistically significant were not conclusive until the end of the clinical trial, after which the drug was promptly removed from the market.¹⁷⁰ Therefore, each time this claim goes to a jury, twelve laypersons essentially will be determining one of two things: whether Merck violated FDA regulations and, if not, whether those FDA regulations are adequate to ensure public safety.

A standard more tailored to pharmaceuticals states that a prescription drug "is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: prescribing and other health-care providers . . . or the patient."¹⁷¹ The problem with this standard is that the FDA states exactly what warnings are provided to health care providers¹⁷² and to patients.¹⁷³ In fact, there have been a number of situations in which a pharmaceutical manufacturer has been subject to liability under a failure-to-warn

167. See 21 C.F.R. § 1.21(c)(1) (2005) (prohibiting labels from including risks of hazards about which there are differing opinions); *id.* § 201.57(d) (stating that contraindication labeling should include only known, not theoretical, hazards); see also Failure to Reveal Material Facts, 39 Fed. Reg. 33,229, 33,231–32 (Sept. 16, 1974) (codified as amended at 21 C.F.R. pt. 1) (reflecting the FDA's refusal to approve a warning on a drug label unless there is significant medical evidence of the risk).

168. See Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,446–47 (June 26, 1979).

169. Barbara Martinez, *Merck Documents Shed Light on Vioxx Legal Battles*, WALL ST. J., Feb. 7, 2005, at A1.

170. *Id.*

171. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

172. Physicians receive a compilation of warning labels for all FDA-approved drugs in the Physician's Desk Reference. PHYSICIAN'S DESK REFERENCE, *supra* note 135.

173. A package insert containing a drug's indications, dosing instructions, and warnings must accompany each FDA-approved drug available to the public. See 21 C.F.R. § 201.56–.57 (2005) (detailing general and specific requirements for content and format of prescription drug labels).

theory for not employing a warning that was in fact proposed by the manufacturer and expressly rejected by the FDA.¹⁷⁴ For example, in *Wooderson v. Ortho Pharmaceutical Corp.*,¹⁷⁵ the Supreme Court of Kansas upheld an award of punitive damages against a manufacturer of oral contraceptives based on the plaintiff's contention that the package insert did not warn of the risk of renal failure.¹⁷⁶ Incredibly, the court dismissed a letter introduced at trial from the FDA to the manufacturer that stated the FDA's disagreement with the company that a warning of the injury eventually suffered by plaintiff needed to be added to the drug's package insert.¹⁷⁷ Without explaining its rationale, the court concluded that the manufacturer's argument that it could not be held liable for failure to warn "ha[d] no merit" because the "letter [could not] be construed as a clear determination by the FDA that [the drug did] not merit warnings."¹⁷⁸ Given the FDA's authority to make the final determination on warnings promulgated for prescribing doctors and the consuming public,¹⁷⁹ it seems reasonable that the company would rely on even an informal expression of the FDA's opinion regarding a particular warning when formulating its drug label.

Similarly, in *Feldman v. Lederle Laboratories*,¹⁸⁰ the Supreme Court of New Jersey reversed a judgment in favor of a defendant drug company and reinstated the plaintiff's claims for both compensatory and punitive damages, dismissing the FDA's involvement in the contents of the allegedly harmful drug's label, which did not warn of the possibility of plaintiff's injury.¹⁸¹ In *Feldman*, an official at the FDA had specifically advised the defendant against publicizing the warning because the FDA was still studying the matter.¹⁸²

Aside from placing drug manufacturers in an impossible position between plaintiffs who demand increased warnings and an FDA that often rejects those warnings, the imposition of punitive damages on a

174. See Geiger & Rosen, *supra* note 138, at 420–21.

175. 681 P.2d 1038 (Kan. 1984), *cert denied*, 469 U.S. 965 (1984).

176. *Id.* at 1062–64.

177. *Id.* at 1057.

178. *Id.*

179. See W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1446 n.38 (1994) (explaining that the FDA reserves the ability to determine whether there is a sufficient basis for including a given warning because adverse effects to test subjects may prove to be coincidental or erroneous).

180. 479 A.2d 374 (N.J. 1984).

181. *Id.* at 378–80, 393.

182. *Id.* at 379.

failure-to-warn theory also fails to serve the deterrence and punishment goals for which punitive awards are designed. If a manufacturer is found liable based upon failure to warn, the jury has essentially decided that the warning approved and, in fact mandated by the FDA was incomplete or inadequate. Imputing fault on the drug manufacturer for such a perceived oversight cannot encourage the company to provide "better" warnings without simultaneously encouraging the manufacturer to defy the FDA by rejecting the warnings approved by the agency.¹⁸³

The five general types of behavior giving rise to awards of punitive damages in products liability cases are: inadequate testing and manufacturing procedures, failure to warn of known dangers before marketing, post-marketing failure to remedy known dangers, fraudulent misconduct, and knowing violations of safety standards.¹⁸⁴ The safeguards provided by the FDA process sufficiently seek out and eliminate these behaviors,¹⁸⁵ making the imposition of punitive damages necessary only in those instances where a manufacturer commits an actual violation of an FDA requirement. This means that unless the drug manufacturer's actions subject it to criminal or civil penalties by the government, punitive damages are inappropriate.

Two examples illustrate the way the award of punitive damages should center on FDA requirements and a manufacturer's good-faith compliance with them. The FDA describes and requires compliance

183. Consider *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (Or. 1974). In that case, the state supreme court affirmed a large jury verdict based upon the plaintiff's allegation that the label on the defendant's oral contraceptives failed to warn of the risk of injury that allegedly led to plaintiff's blindness. *Id.* at 537-44. The manufacturer argued that the warnings on its package were written by the FDA and required by federal law. *Id.* at 534. The court rejected this argument, holding that "the warnings given by an ethical drug manufacturer may be found inadequate, '[a]lthough all of the government regulations and requirements have been satisfactorily met in the production and marketing of [the drug], and in the changes made in the literature.'" *Id.* (quoting *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 162 (D.S.D. 1967)). Given this holding, one wonders how the manufacturer could have absolved itself of liability without violating the regulations promulgated by the FDA. See Viscusi et al., *supra* note 179, at 1469 ("Once the FDA has made a determination about proposed pharmaceutical labeling, it would be a violation of federal law for the manufacturer to attempt to deviate from that judgment.").

184. David G. Owen, *Punitive Damages in Products Liability Litigation*, 74 MICH. L. REV. 1257, 1329 (1974) (arguing that strong public policy rationales mandate allowing punitive damage awards in products liability cases).

185. See, e.g., Viscusi et al., *supra* note 179, at 1478 (arguing that "the requirements for an NDA are so extensive that, at the margin, the FDCA probably over-deters" a pharmaceutical manufacturer from trying to present the FDA with false or misleading information).

with what it believes are adequate testing and production practices.¹⁸⁶ A manufacturer that conducts FDA-mandated testing and still fails to detect an idiosyncratic response—such as one occurring in 1 out of every 10,000 patients¹⁸⁷—should not be liable for punitive damages. In this instance, the FDA determined that the increase in the cost of drugs resulting from further clinical trials involving thousands of additional people outweighed the benefit of identifying a rare reaction.¹⁸⁸ Having complied with the safeguards premised on this calculation, imposing punitive damages ignores the need for considering economic and medical efficiency. On the other hand, if the manufacturer makes some misrepresentation to the FDA about the amount of testing it has performed with regard to a new drug, and the FDA relies on this misrepresentation in approving the drug, the manufacturer has violated FDA regulations. In such a case, an affirmative statement from the FDA could properly form the basis for concluding that the manufacturer acted intentionally or maliciously in a private tort action.

The question comes down to whether lay jurors should preempt the determinations of teams of medical and statistical experts employed by the FDA. Approving only 1 out of every 5,000 investigated drugs, the FDA affirms on a daily basis—through the opinions of the agency's scientists and regulatory professionals—that pharmaceutical manufacturers are offering for sale the safest and most cost-effective drugs possible for the conditions they purport to treat. Courts and legislatures should defer to the FDA's extensive risk-benefit analysis and stop forcing manufacturers to choose between FDA compliance and self-preservation. Regrettably, courts continually eschew such deference even when drug manufacturers fully comply with FDA regulations.¹⁸⁹

IV. ABSOLVING MANUFACTURERS OF COMPENSATORY LIABILITY

This Comment argues that FDA regulations provide adequate protection to the consumers of prescription drugs, eliminating the justification for the award of punitive damages against drug

186. See *supra* notes 90–139 and accompanying text (detailing the FDA's extensive testing requirements).

187. See *supra* note 153 and accompanying text.

188. See Gregory C. Jackson, M.D., Comment, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 233 (1992).

189. See *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984) (stating that “the FDA's determination, even if it consisted of a risk-utility analysis, would not supplant the risk-utility balancing required in the judicial process”).

manufacturers.¹⁹⁰ This Comment also demonstrates how the award of punitive damages in the context of prescription drugs does not serve the punishment and deterrence objectives traditionally justifying such awards.¹⁹¹ This Comment therefore strongly supports the elimination of punitive damages against drug manufacturers, possibly through federal legislation preempting the jurisdiction of state courts, where verdicts can vary more dramatically. This position may appear radical, but others would go further still. Some members of Congress and a greater number of courts and legal scholars argue that—absent evidence of fraud, misrepresentation, or bribery—the makers of prescription drugs that receive FDA approval should be immune from all liability on claims against an approved product.¹⁹² These congressmen and scholars would include even compensatory damages in this prohibition.

Professor Richard B. Stewart, for instance, points to a report by the American Law Institute in support of his proposition that, with narrow exceptions, compliance with an administrative agency's regulatory requirements should preclude tort liability based on negligence.¹⁹³ Professor Stewart argues that the risk-benefit analysis undertaken by an agency like the FDA is discounted when a jury is confronted with an individual case of injury, and that juries in these cases often focus disproportionately on the injury suffered by the specific plaintiff rather than analyzing whether the product is socially beneficial to the general public.¹⁹⁴ Professor Margaret Gilhooley relies on a different rationale in her argument for a regulatory compliance defense, contending that the current uncertain liability standards and high costs of litigation may discourage the innovation

190. See *supra* Part II.

191. See *supra* Part III.

192. For example, several courts across the country articulate strong public policy rationales against all tort liability for drug manufacturers. See, e.g., *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 591, 595 (W.D. Tex. 2002) ("To 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."); *Brown v. Super. Ct.*, 751 P.2d 470, 477 (Cal. 1988) (citing the probable negative effects of strict liability on pharmaceutical manufacturers and concluding that they should not be strictly liable for injuries caused by their products so long as the drugs were properly prepared and labeled with sufficient warnings); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 90 (Utah 1991) (holding that prescription drugs approved by the FDA cannot, as a matter of law, be defective if "properly prepared, compounded, packaged, and distributed" in accordance with FDA regulations).

193. Stewart, *supra* note 154, at 2167. Professor Stewart relies on an ALI Reporter's Study from 1991, *Enterprise Responsibility for Personal Injury*, a project for which he was the Chief Reporter until 1989. *Id.* at 2167 n.1.

194. *Id.* at 2174–75.

of useful new drugs and that many pharmaceutical cases improperly premise liability on failure to warn, when the FDA has a large say in the content of drug warnings.¹⁹⁵ David R. Geiger and Mark D. Rosen argue that allowing any sort of tort liability subsequent to FDA approval amounts to the “retrospective jury nullification” of FDA regulations, fundamentally disadvantaging drug manufacturers relying on compliance with FDA regulations.¹⁹⁶ They argue that the FDCA should preempt state tort law and disallow any claims based on injury caused by an approved drug.¹⁹⁷

These contentions are problematic for two reasons. First, the fact that a drug was approved by the FDA does not make the plaintiff’s actual injuries any less the result of his use of the drug in question. Professor Stewart’s analysis, for example, suggests that the few people injured by a socially beneficial product are “unlucky losers in the risk-risk lottery.”¹⁹⁸ The premise of the American tort system, however, is that persons injured as a result of another’s actions deserve to be compensated by the party at fault.¹⁹⁹ “Fault” in this context does not imply intent or malice in the same way that “fault” gives rise to punitive damages. Instead, “fault” is synonymous with “causation” in the context of compensatory damages.²⁰⁰ If the

195. Margaret Gilhooley, *Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice*, 24 SETON HALL L. REV. 1481, 1483 (1994). Professor Gilhooley does caution, however, that more research into the adequacy and efficacy of current warnings should be pursued before casting aside the current tort standards entirely. *Id.* at 1506.

196. Geiger & Rosen, *supra* note 138, at 396–97. Mr. Geiger and Mr. Rosen are both practicing attorneys with significant experience in handling pharmaceutical litigation. *Id.* at 395.

197. *Id. passim*.

198. Stewart, *supra* note 154, at 2181. Professor Stewart suggests that to remedy this problem a system might be established whereby a tax is placed on all approved drugs, and that the unlucky few who are injured by an approved pharmaceutical be compensated for their out-of-pocket expenses from this fund. *Id.* at 2181–82. This insurance system, however, would pass costs onto consumers in the same way that pharmaceutical companies must now insure themselves for liability for compensatory damages, providing only negligible advantages over the tort system, particularly if an injured consumer unhappy with the administrative determination of his damages could seek judicial review.

199. See, e.g., *Thomas v. Barton Lodge II, Ltd.*, 174 F.3d 636, 648 (5th Cir. 1999) (“[T]he general principle of damages is compensation to plaintiff for his actual loss resulting from defendant’s wrong.”); *Plummer v. Abbott Labs.*, 568 F. Supp. 920, 922–23 (D.R.I. 1983) (“Tort damages are awarded in order fully and adequately to compensate an individual for injuries sustained. Thus, the underlying basis for such damages is the premise that the individual was injured in contemplation of law.” (internal citations omitted)); *Croley v. Republican Nat’l Comm.*, 759 A.2d 682, 689 (D.C. 2000) (“[T]he primary purpose of compensatory damages in personal injury cases is to make the plaintiff whole.”).

200. See, e.g., Ernest J. Weinrib, *Corrective Justice*, 77 IOWA L. REV. 403, 418 (1992) (“[C]ausation, fault, and compensatory damages . . . determine the victim’s entitlement

defendant or the defendant's product was the proximate cause of the plaintiff's injury, then the plaintiff is entitled to compensation for the monetary loss he actually suffered because of the injury.

Second, the preemption doctrine clearly does not apply in pharmaceutical cases. The Supreme Court has emphatically stated that federal law does not preempt a state law cause of action absent clear congressional intent that federal law govern.²⁰¹ The FDCA merely outlines the steps a manufacturer must take to market a drug in the United States. It does not create a cause of action.²⁰²

Furthermore, Congress had the opportunity to preempt state tort liability for faulty pharmaceuticals within the FDCA and specifically declined to do so. In 1976, Congress passed the Medical Devices Amendments ("MDAs") to the FDCA.²⁰³ The MDAs prohibit states from imposing on medical device manufacturers any standards or requirements that are "different from, or in addition to" those to which the manufacturers must adhere under federal law.²⁰⁴ The new provisions gave the FDA regulatory authority over a broad range of products including those deemed "class III medical devices."²⁰⁵ This classification includes heart valves, pacemakers, replacement joints, and other devices that are implanted into the body.²⁰⁶ In adopting the MDA, Congress recognized that "if a substantial number of differing requirements applicable to a medical device are imposed by

against the injurer by tracing the normative and physical sequence of wrongfulness from its origin in the defendant's action to its terminus in the plaintiff's suffering.").

201. See *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 9–11 (2003) (holding that even though the plaintiff's complaint articulated only state law claims for usury, removal was proper because the bank's defense was that it complied with federal interest rate limits and the National Bank Act purported to provide "an exclusive federal cause of action for usury against national banks"); *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 64–67 (1987) (holding that removal of employer's state-law breach of contract claim to federal court based on federal question jurisdiction was proper because Congress clearly intended that there be a cause of action under the ERISA section cited by plaintiff); *Hillborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713–16 (1985) (holding that when the FDA expressly stated that it did not intend its blood plasma collection regulations to be exclusive, local ordinances that provided additional restrictions and requirements did not run afoul of the Supremacy Clause).

202. See, e.g., *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994) (holding that the FDCA allows only the government a cause of action and does not afford a private right of action to individuals); *Rodriguez v. SK & F Co.*, 833 F.2d 8, 9 (1st Cir. 1987) (same).

203. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. § 360c–360k (2000)).

204. 21 U.S.C. § 360k(a).

205. Susan A. Allinger, *Federal Preemption of Products Liability Actions Against Medical Device Manufacturers*, 27 TEX. TRIAL L.F. 5, 5 (1993).

206. *Id.*

jurisdictions other than the Federal government, interstate commerce would be unduly burdened.”²⁰⁷ Therefore, Congress specifically understands the problems a manufacturer faces when confronted with conflicting standards from the FDA and the judicial system, yet declined to take steps to apply this protection to prescription drugs. It would be inappropriate to entirely exempt drugmakers from any sort of judicial inquiry whatsoever in the face of such clear congressional intent to the contrary.²⁰⁸ However, it is also inappropriate to allow punitive damage awards against manufacturers who are required to comply with federal regulations that sometimes frustrate the manufacturer’s efforts at full disclosure.

V. CLASS ACTION REFORM

On February 10, 2005, the United States Senate overwhelmingly passed a long-debated bill requiring that all class-action lawsuits against corporations be heard in federal rather than in state court.²⁰⁹ The bill sailed to victory in the House by a 279 to 149 vote, and President Bush signed it into law on February 18, 2005.²¹⁰ The law is designed to allow corporate defendants to remove many class action lawsuits from state to federal court where, on average, judgments prove less costly for corporate defendants.²¹¹ Then-House Majority Leader Tom DeLay (R-Tex.) focused on the bill’s impact on the consuming public and the effective function of the courts in lending his support to the legislation. Shortly after the House vote, he stated that “[c]onsumers and businesses alike have been victimized by lawsuit abuse. Court dockets are backed up, companies are paying lawyers instead of employees, and our economy is suffering for it all. Class action fairness is not just reform; it’s self-defense.”²¹²

207. H.R. REP. NO. 94-853, at 45–46 (1976).

208. This is not to suggest that legislation with a preemptive effect could not or should not be adopted. The calls for this type of legislation are mounting. See, e.g., Viscusi et al., *supra* note 179, at 1478 (arguing that preemptive legislation is needed to prohibit courts “from co-regulating pharmaceuticals through the award of tort damages” because “the FDCA does not [only] establish minimum standards for prescription drug products or their labeling”).

209. S. 5, 109th Cong., 119 Stat. 4 (2005).

210. Stephen Labaton, *Quick, Early Gains Embolden Business Lobby*, N.Y. TIMES, Feb. 18, 2005, at C1.

211. David Rogers, *Class-Action Bill Sails in Senate, and Heads Quickly to the House*, WALL ST. J., Feb. 11, 2005, at A2. Under the law, a corporate defendant may remove a class action suit to federal court when the aggregate of all plaintiffs’ claims exceeds \$5 million and when minimal diversity of citizenship requirements are met. *Id.*

212. DeLay: Decade-Long Fight Brings Class Action Fairness, House Sends Historic Class Action Measure to President (Feb. 17, 2005), <http://www.majorityleader.gov/news.asp?FormMode=Detail&ID=393>. DeLay claims that provisions in the law will prevent

Senator Arlen Specter (R-Pa.) stated that the purpose of the Class Action Fairness Act ("Act") is "to prevent judge shopping to States and even counties where courts and judges have a prejudicial predisposition on cases."²¹³ Specter expressed his sentiments that "[r]egrettably, the history has been that there are some States in the United States and even some counties where there is forum shopping, which means that lawyers will look to that particular State, that particular county to get an advantage."²¹⁴ The Act attempts to combat this problem by providing that defendants may remove most state-law class actions to federal court and by relaxing diversity of citizenship and other jurisdictional requirements.²¹⁵ Yet, the simple elimination of the "complete diversity rule" merely expands federal court jurisdiction over class actions to the extent that federal courts may now hear any cases where one named plaintiff or a requisite number of non-named class members live in a different state from the defendant.²¹⁶ Recent developments in the Vioxx litigation illustrate the potential inefficacy of the Act insofar as it promises to offer defendants the protections of a federal forum.²¹⁷ A group of plaintiffs' attorneys who claim to represent 20,000 former Vioxx users recently requested that Judge Eldon E. Fallon remand their cases from federal to state court.²¹⁸ This "breakaway group of lawyers" may succeed in exempting itself from the Act's more liberal diversity requirements by including as a defendant an individual or entity—such as a prescribing physician—that resides in the same state as one of their plaintiffs.²¹⁹

outcomes such as the Bridgestone/Firestone class action outcome, where plaintiffs' attorneys collected \$19 million while their clients received nothing, and the Microsoft antitrust cases, where attorneys claimed hundreds of millions of dollars while consumers received \$5–\$10 in voucher coupons. *Id.*

213. 151 CONG. REC. S999 (daily ed. Feb. 7, 2005) (statement of Sen. Specter).

214. *Id.*

215. See Class Action Fairness Act of 2005, Pub. L. No. 109-2, 119 Stat. 4 (codified in scattered sections of 28 U.S.C.).

216. *Id.*

217. Although a federal district court must apply the punitive damages law of the state in which it sits, *see infra* note 222 and accompanying text, corporate defendants nonetheless see federal forums as more favorable in part because the Federal Rules of Evidence impose greater restrictions on the amount and type of evidence a plaintiff may introduce. See Martinez, *supra* note 7.

218. Martinez, *supra* note 7.

219. See *id.* The admitted goal of these attorneys is to overwhelm Merck's lawyers with litigation on numerous fronts rather than allowing the drug company to focus solely on the federal multidistrict litigation. See *id.*

Furthermore, given the current jurisdictional variation in punitive damages law,²²⁰ even if loophole free, the Act alone is unlikely to remedy the quandary in which pharmaceutical manufacturers are often placed when courts essentially reevaluate FDA standards on a case-by-case basis. The court battle over venue in the Vioxx litigation provides an excellent example. Many of these cases are slated for hearing in federal courts,²²¹ yet both sides continue to fight for their preferred forum. Moreover, the lack of federal common law upon which a federal court may determine the reasonableness of a punitive damage award requires a federal district court to apply the law of the state in which it sits.²²² Therefore, the state survey of punitive damage law preceding this discussion remains relevant regardless of the purpose of the class action reform. Federal judges are still bound not only by any legislative mandates on the availability of punitive damages, but may also be guided by a state's case law in determining how large of an award has been deemed acceptable in that jurisdiction.

CONCLUSION

While the imposition of punitive damages against pharmaceutical companies has a material effect on the production of prescription drugs, the primary issue is whether such awards provide an effective benefit in terms of enhancing widespread drug safety. Many United States drug manufacturers currently spend more money on products liability insurance and litigation defense than on research and development efforts that could provide new and beneficial drugs to the public.²²³ Moreover, evidence from jurisdictions that do not allow punitive damages against pharmaceutical companies suggests that the deterrent effect of any litigation at all accomplishes what punitive damages purport to achieve because the stigma of a liability claim in the eyes of the public provides adequate incentives for drugmakers to refrain from "bad" conduct.²²⁴ The demonstrated effect of punitive damages, therefore, has been not to change drug companies' conduct during pharmaceutical development and manufacture, but instead to

220. See *supra* notes 24–51 and accompanying text.

221. As of October 2005, approximately 1,800 of the nearly 5,000 Vioxx suits were awaiting adjudication in federal court in New Orleans. Alex Berenson, *Maker of Vioxx Says Some Suits May Be Settled*, N.Y. TIMES, Aug. 26, 2005, at A1.

222. See *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938) ("Except in matters governed by the Federal Constitution or by Acts of Congress, the law to be applied in any case is the law of the State There is no federal general common law.").

223. S. REP. NO. 105-32, at 8–9 (1997).

224. *Id.* at 11–12.

deter these corporations from developing new drugs in the first place.²²⁵

Adding to the fact that the financial benefits of punitive damages benefit the few at the expense of the many is the unpredictable nature of such damages.²²⁶ The inconsistent jurisdictional approaches to punitive damages—both with regard to allowable award amounts and standards for entitlement—create massive disparities in the size of awards from state to state.²²⁷ This troubling variation is compounded by the fact that the instructions given by judges to juries regarding punitive damages are often extremely inadequate, leading to even more markedly varying and arbitrary results.²²⁸ Finally, the judicial system's inability to carefully evaluate the substantive scientific issues involved in drug reactions forces courts and juries to base their decisions to award damages on non-scientific factors, such as the appearance of the plaintiff and other witnesses, rather than on the underlying issues presented in expert testimony.²²⁹ Last summer's \$253 million verdict against Merck is illustrative. Jurors said that "much of the science sailed right over their heads" and they "focused

225. See Note, *A Question of Competence: The Judicial Role in the Regulations of Pharmaceuticals*, 103 HARV. L. REV. 773, 782 (1990) ("[T]he ex ante risks that the tort system imposes on pharmaceutical manufacturers can have marked adverse effects on the development, marketing, and pricing of medications."); see also Bruce N. Kuhlik & Richard F. Kingham, *The Adverse Effects of Standardless Punitive Damage Awards on Pharmaceutical Development and Availability*, 45 FOOD & DRUG L.J. 693, 699 (1990) (citing American Medical Association findings that liability concerns have a "profound negative impact on the development of new medical technologies" and that "new products are not being developed or are being withheld from the market because of liability concerns").

226. See Note, *supra* note 225, at 782-83 ("The threat of tort liability not only unnecessarily raises the costs of health care, but may also lead to an inappropriate decrease in the use of the medication, as the price will no longer reflect the relative risks and benefits of the drug.").

227. See U.S. GEN. ACCOUNTING OFFICE, *PRODUCT LIABILITY: VERDICTS AND CASE RESOLUTION IN FIVE STATES* 89-99, 25-31 (1989) (concluding that in the five states studied punitive damages varied a great deal in size and incidence).

228. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 588-92 (1996) (Breyer, J., concurring); see also *Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 46 (1991) (O'Connor, J., dissenting) (arguing that Alabama's jury instructions regarding punitive damages are unconstitutionally vague because juries are "offer[ed] no principled basis for distinguishing those tortfeasors who should be liable for punitive damages from those who should not be liable").

229. See, e.g., *Wells v. Ortho Pharm. Corp.*, 615 F. Supp. 262, 268-98 (N.D. Ga. 1986) (assessing over \$5 million in damages against a manufacturer of a contraceptive jelly which the plaintiff claimed caused birth defects in her child). While the overwhelming agreement in the scientific community was that there was no causal relationship between the jelly and the birth defects, the trial judge supplanted that consensus with his own determination that because plaintiff's experts were more "credible," causation was sufficiently established. *Id.*

instead on evidence they understood: that a big corporation allegedly covered up defects with its product."²³⁰ Predictable results under such a scheme are unlikely, if not impossible.

The Class Action Fairness Act of 2005 will also be ineffective to curb the problem in many cases due to the obligation of a federal district court to apply the law of the state in which it sits, including punitive damage precedents.²³¹ Short of a federal law mandating the preemptive effect regulations in the context of prescription drugs similar to the Medical Device Amendments of 1976, or a widespread recognition of the fact that it is not logical to punish drug manufacturers for a judicial determination of the inadequacy of the FDA's processes, drugmakers will continue to struggle with the same Catch-22, wrestling with the choice to obey the FDA or be "punished" and "deterred" from doing so through the imposition of punitive damages.

JOAN E. SHREFFLER*

230. Heather Won Tesoriero et al., *Merck Loss Jolts Drug Giant, Industry: In Landmark Vioxx Case, Jury Tuned Out Science, Explored Coverup Angle*, WALL ST. J., Aug. 22, 2005, at A1.

231. See *supra* note 222 and accompanying text.

* The author wishes to dedicate this piece to her parents, Drs. Jack and Carol Shreffler, for their unfailing support and encouragement over the past twenty-five years.

