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Cover Page Footnote
J.D. Candidate, 2007, Fordham University School of Law; M.D., Mount Sinai School of Medicine, 1999; B.A., Emory University, 1994. I would like to thank my husband Mitch, my parents Lesly and Jay, my in-laws Harriet and Harold, and of course, Ralph and Solomon, for all their love, support, and encouragement. I would also like to thank Professor Benjamin Zipurksy for his thoughtful advice and guidance with this Note.
THE HEALTH ACT'S FDA DEFENSE TO PUNITIVE DAMAGES: A GIFT TO DRUG MAKERS OR TO THE PUBLIC?

Elissa Levy*

We thus come to the issue of punitive damages, an issue of extreme significance not only in monetary terms to this defendant in view of the hundreds of pending... actions and to the plaintiff as well, but from a longer range, to the entire pharmaceutical industry and to all present and potential users of drugs.1

INTRODUCTION

Despite rigorous regulation by the United States Food and Drug Administration ("FDA"), pharmaceuticals are indirectly co-regulated by the tort litigation system.2 While the FDA uses its scientific expertise to make public health determinations of whether therapeutic benefits outweigh the risks of individual drugs, lay judges and jurors are afforded the opportunity to second-guess these decisions and regulate through the imposition of compensatory and punitive damage awards.3 Concerned commentators contend that this dual regulation system has driven valuable drugs from the market and potentially keeps innovative drugs from reaching the market altogether.4 Moreover, they argue that the mere availability of a punitive damages claim in pharmaceutical litigation possibly increases litigation costs for manufacturers and leads to a greater likelihood of settlements.5 These commentators suggest that despite the general rule that regulatory

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1. Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832, 838 (2d Cir. 1967) (Friendly, J.). Although Judge Henry Friendly wrote this almost forty years ago, this statement remains relevant today.


4. Id. at 698-704 (describing the impact of liability and punitive damages awards on specific pharmaceuticals, including vaccines, contraceptives, and Bendectin).

5. Id. at 697.
compliance is not a defense to liability, compliance with FDA regulations should shield drug manufacturers from punitive damage awards.\(^6\)

Other commentators challenge these claims and state that FDA regulations merely establish minimum safety standards; FDA compliance, they argue, does not preclude liability.\(^7\) Concerned that the FDA fails to adequately protect the public from unacceptable risks, these commentators suggest that punitive damages are necessary to punish and deter manufacturer misconduct.\(^8\)

On July 28, 2005, the House of Representatives passed the Help Efficient, Accessible, Low-cost, Timely Healthcare ("HEALTH") Act of 2005, which includes an FDA regulatory compliance defense to punitive damages.\(^9\) This controversial provision has become a perennial, repeatedly included in legislation that passes in the House, but stalls in the Senate.\(^10\)

This Note argues that because of the unique societal importance of pharmaceuticals, and the comprehensiveness of FDA regulations, public policy weighs in favor of disallowing punitive damage awards in pharmaceutical litigation where the manufacturer complied with FDA regulations. In order to appreciate this issue fully, Part I of this Note will provide background, briefly discussing pharmaceutical products liability, punitive damages, and the tort reform movement. This part will also discuss the co-regulation of pharmaceuticals by the FDA and the tort system, including brief descriptions of the regulatory compliance defense and preemption.

Parts II.A and II.B explain the arguments for and against the FDA regulatory compliance defense to punitive damages in pharmaceutical products liability lawsuits.

Finally, Part III of this Note concludes that because of the strong public interest in the availability of life-sustaining and life-improving drugs, public policy favors federal legislation immunizing compliant manufacturers from punitive damages in the absence of an FDA determination of fraud. Part III suggests that, in order to ensure public health and safety, the enactment of this defense should be accompanied by the reworking of FDA regulations

and sanctions. This part also addresses possible consequences of the FDA regulatory compliance defense to punitive damages, such as the increase in economic damage awards.

I. BACKGROUND AND HISTORY OF THE CO-REGULATION OF PHARMACEUTICALS

This part provides the setting necessary for discussing the conflict in Part II over the appropriateness of the FDA regulatory compliance defense to punitive damages. Part I.A briefly discusses pharmaceutical products liability, punitive damages, and the tort reform movement. Part I.B examines the co-regulation of pharmaceuticals, including ex ante regulation by the FDA and ex post liability imposed by the tort system.

A. Pharmaceutical Products Liability, Punitive Damages, and the Tort Reform Movement

The current movement to reform the tort system was preceded by the 1960s and 1970s plaintiff-friendly expansion of tort rights and liabilities. After a couple of influential products liability opinions and the American Law Institute’s issuance of section 402A of the Restatement (Second) of Torts, plaintiffs’ barriers to recovery were reduced by courts holding manufacturers strictly liable for injuries caused by their products. The


13. Section 402A of the Restatement (Second) of Torts provides:
(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
(2) The rule stated in Subsection (1) applies although
(a) the seller has exercised all possible care in the preparation and sale of his product, and
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A (1965).

14. Justice Traynor’s concurrence in Escola, 150 P.2d at 440, and majority opinion in Greenman, 377 P.2d at 897, marked the emergence of strict liability for defective products. Just a couple of years after Greenman, the American Law Institute recommended the adoption of strict products liability in section 420A of the Restatement (Second) of Torts. See John C. P. Goldberg, Anthony J. Sebok & Benjamin C. Zipursky, Tort Law: Responsibilities and Redress 815-16 (2004). The overwhelming majority of states have since employed some fashion of strict products liability law. Id. at 815, 832. In general,
rationales cited for the shift from a negligence standard to a standard of strict liability include (1) obligation; (2) deterrence; (3) compensation insurance; (4) causation strict liability; (5) compensation equality; (6) litigation structure; and (7) judicial candor. In theory, strict liability deters manufacturers from marketing unsafe products and fairly compensates injured consumers.

Recognizing the risk of stifling the research and development of life-sustaining and life-improving drugs, and the inevitability of harm, in comment k to section 402A, the drafters of section 402A recommended against strict liability for design defects in "unavoidably unsafe" products, such as prescription drugs and vaccines. Although it is generally considered to be in the public's interest, in limited circumstances, to allow "unsafe" products to be marketed when there is a net positive effect on there is a tripartite classification for product defects: (1) manufacturing defects; (2) design defects; and (3) failure to warn or instruct. Id. at 846-47.

15. These justifications can be found in Justice Traynor's concurrence in Escola. See Goldberg, Sebok & Zipursky, supra note 14, at 823 (discussing Escola, 150 P.2d at 440 (Traynor, J., concurring)). For a further discussion of each of these rationales, see id.


17. Comment k to section 402A provides as follows:

   Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k. In addition to comment k, other liability-restrictive doctrines, such as the learned intermediary doctrine, and legislation, such as the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 (2000), have been crafted in response to concerns about tort law's impact on medical products and public health. See Goldberg, Sebok & Zipursky, supra note 14, at 900, 925, 937-38. In contrast to general consumer products where warnings must be conveyed directly to the consumer, tort law generally requires a drug manufacturer to provide instructions and warnings to the prescribing medical provider. Id. at 937-38. The treating or prescribing medical provider, known as the learned intermediary, is considered to be in the best position to make individualized medical decisions based on the risks and benefits of the drug, and the nature of the patient's condition. Id. Under this doctrine, it is the medical provider, not the manufacturer, who will incur liability for failing to adequately warn the patient. Id.
public health and safety, the interpretation of comment k varies among jurisdictions. The majority of jurisdictions apply comment k on a case-by-case basis, contending that societal interests can be served without providing manufacturers "blanket immunity" from strict liability for prescription drugs. Because of the protection afforded to manufacturers by comment k, few pharmaceutical products liability cases involve design defect claims—most involve the failure to warn of known or reasonably knowable risks, and the adequacy of warnings provided.

The expansion of tort liability is intertwined with the expansion of the punitive damages remedy against product manufacturers. No longer were punitive damage awards limited to malicious malfeasance; rather, the remedy became available to deter and punish product manufacturers for reckless indifference. While punitive damages have been a constant

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18. See Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 836 (Neb. 2000) (applying a case-by-case application of comment k of section 402A and rejecting section 6(c) of the Restatement (Third) of Torts). Section 6(c) of the Restatement (Third) of Torts, which specifically pertains to prescription drug and medical device design defect claims, has received much criticism for its tendency to favor defendants. See id. at 837-40.

19. See id. at 836. For a discussion of the appropriateness of the comment k defense, see Brown v. Superior Court, 751 P.2d 470, 476-77 (Cal. 1988).

20. See Michael D. Green, Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law, 42 St. Louis U. L.J. 163, 168 (1998). Most failure-to-warn claims concern adverse events that are not detected during clinical trials and are only identified after Food and Drug Administration ("FDA") approval. Id. at 169. Manufacturing defect claims are rare in pharmaceutical products liability litigation because of the FDA's strict manufacturing regulations and the technological capabilities of manufacturers. Id. at 168. Generally, in a cause of action for strict liability premised on failure to warn, a plaintiff only needs to prove that "the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." Carlin v. Superior Court, 920 P.2d 1347, 1351 (Cal. 1996). One commentator even claims that comment k itself "steered plaintiffs to the most prominent theory in pharmaceutical litigation: the inadequate warning or failure to warn claim." W. Kip Viscusi et al., Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense, 24 Seton Hall L. Rev. 1437, 1463 (1994). For cases permitting recovery for a strict liability claim based on the theory that the drug was defectively designed, see Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981), and Savina v. Sterling Drug, Inc., 795 P.2d 915 (Kan. 1990).

21. Thomas Koenig & Michael Rustad, His and Her Tort Reform: Gender Injustice in Disguise, 70 Wash. L. Rev. 1, 19-24 (1995). Punitive damages, also called "exemplary" or "vindictive" damages, are imposed to deter and punish wrongful conduct, and to compensate injured plaintiffs. Viscusi et al., supra note 20, at 1455-56. They have the potential to have an over-deterrent effect, and are often not needed to compensate a plaintiff who received compensatory damages. Id. In addition, commentators argue that the imposition of punitive damages against corporate entities provides neither punishment nor deterrence. See Lisa Litwiller, From Exxon to Engle: The Futility of Assessing Punitive Damages as Against Corporate Entities, 57 Rutgers L. Rev. 301, 301-02 (2004). For an overview of punitive damages and a discussion of the recent constitutional changes to punitive damages awards, see id. at 302-20.

22. See Koenig & Rustad, supra note 21, at 22. During the nineteenth century, punitive damages were primarily limited to intentional torts. Id. at 18. The Restatement (Second) states that the purpose of punitive damages is
to punish the person doing the wrongful act and to discourage him and others from similar conduct in the future. Although the purposes are the same, the effect of a
feature of American jurisprudence, their imposition against corporations has caused significant debate over their legitimacy.\textsuperscript{23} Despite numerous empirical studies concluding that punitive damage awards are infrequent,\textsuperscript{24} and recent judicial and legislative constraints on their recovery,\textsuperscript{25} concerns about punitive damages dominate contemporary tort reform debates.\textsuperscript{26}

Controversy surrounding such punitive damage awards in pharmaceutical litigation is best illustrated by two early, oft-cited cases: Roginsky \textit{v.} Richardson-Merrell, \textit{Inc.}\textsuperscript{27} and Toole \textit{v.} Richardson-Merrell \textit{Inc.}\textsuperscript{28} In Roginsky and Toole, plaintiffs sued the manufacturer of MER/29, a cholesterol lowering drug, for compensatory and punitive damages after developing cataracts allegedly caused by the drug.\textsuperscript{29} The plaintiffs alleged that the manufacturer disregarded animal studies showing the drug's cataractogenic effects, misrepresented the drug's safety profile to the FDA, and failed to issue appropriate warnings or to withdraw the drug from the market based on its known risks.\textsuperscript{30} In both cases, juries awarded the plaintiffs compensatory and punitive damages. On appeal, the punitive damages award was reversed by the U.S. Court of Appeals for the Second Circuit in Roginsky,\textsuperscript{31} but upheld by the California Court of Appeals in Toole.\textsuperscript{32}

civil judgment for punitive damages is not the same at [sic] that of a fine imposed after a conviction of a crime, since the successful plaintiff and not the state is entitled to the money required to be paid by the defendant.

Restatement (Second) of Torts § 908 cmt. a (1979).

23. See Goldberg, Sebok & Zipursky, supra note 14, at 470 (explaining that "contemporary critics argue that punitive awards threaten the vitality of the economy and empower undeserving plaintiffs and their lawyers to extract 'windfalls' from corporate defendants").

24. See, e.g., Theodore Eisenberg et al., \textit{Juries, Judges, and Punitive Damages: An Empirical Study,} 87 Cornell L. Rev. 743, 745 (2002). Although it is widely accepted that punitive damages awards are rare, punitive damages awards totaled approximately $150 million in 1993 and $30 billion in 2002. Litwiller, supra note 21, at 320. Moreover, commentators claim that their imposition is often unpredictable and arbitrary, potentially overdetering desirable activity. See Cass R. Sunstein, Daniel Kahneman & David Schkade, \textit{Assessing Punitive Damages (with Notes on Cognition and Valuation in Law),} 107 Yale L.J. 2071, 2084, 2111-14 (1998). In addition, fear of punitive damages awards may lead manufacturers to settle even weak claims. See Koenig & Rustad, supra note 21, at 46 ("The potential for future punitive damages awards by thousands of other claimants was undoubtedly a key motivator for firms to join the global settlement of breast implant claims.").

25. See Michael L. Rustad, \textit{The Closing of Punitive Damages' Iron Cage,} 38 Loy. L.A. L. Rev. 1297, 1300 (2005) (describing substantive and procedural tort reforms that constrain the punitive damages remedy, such as punitive damages caps, bifurcating the determination of the amount of punitive damages from the other portions of the trial, raising the burden of proof, designating a portion of the punitive damages award to the state, and restricting use of corporate wealth evidence).

26. See Eisenberg et al., supra note 24, at 744.
27. 378 F.2d 832 (2d Cir. 1967).
29. Roginsky, 378 F.2d at 832; Toole, 60 Cal. Rptr. at 403-04.
30. Roginsky, 378 F.2d at 832; Toole, 60 Cal. Rptr. at 403-08.
31. Roginsky, 378 F.2d at 835.
32. Toole, 60 Cal. Rptr. at 414-16.
In *Roginsky*, Judge Henry Friendly looked "to the entire pharmaceutical industry and to all present and potential users of drugs" and found that punitive damages were inappropriate in light of the hundreds of pending MER/29 actions.\(^3\) Acknowledging "the negligent—even highly negligent—manufacture and sale of [MER/29]," Judge Friendly held that the criminal penalties and compensatory damages recoverable would sufficiently meet the objectives of deterrence and social disapproval.\(^3\)

Punitive damages in such cases would have deleterious effects on manufacturers and the consuming public.\(^3\)\(^4\) Recognizing but failing to follow the *Roginsky* decision, the court in *Toole* held that a jury could have found that the manufacturer acted "recklessly and in wanton disregard of possible harm to others," supporting a finding of the malice necessary for the imposition of a punitive damages award.\(^3\)

Because of the uncertainty of this increased tort liability, as demonstrated by *Roginsky* and *Toole*, insurance premiums rose and pharmaceutical manufacturers were forced to reevaluate their businesses, either withdrawing drugs from the market or leaving the market altogether.\(^3\)\(^7\) For example, in 1983, Bendectin, the only drug approved to treat the nausea and vomiting associated with pregnancy, was voluntarily pulled from the market because multimillion dollar products liability claims resulted in skyrocketing insurance premiums.\(^3\)\(^8\) At the same time, ten of the thirteen manufacturers of childhood vaccines fled the American market because of rising insurance premiums and the cost associated with defending against lawsuits.\(^3\)

Concerned about the effect that increased liability with standardless punitive damage awards has on pharmaceutical manufacturers, and in turn, on the consuming public, courts, commentators, interest groups, and legislatures have attempted to alter the tort system for more than two decades.\(^3\)\(^9\) In 1986, Congress responded to the vaccine liability crisis by creating a no-fault compensation system for childhood vaccine-related injuries.\(^3\) The National Vaccine Injury Compensation Program removes vaccine injury claims out of the tort system and into a Vaccine Claims

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34. Id. at 840-41.
35. Id. at 841 (stating that the cost of large punitive damage awards will be passed onto consumers and may ultimately cause business to shut down).
36. *Toole*, 60 Cal. Rptr. at 416 & n.3. The court in *Toole* did not address the overall impact of punitive damages in pharmaceutical products liability actions.
38. See id. at 653.
39. See id. at 650.
Court, where the complainants’ burdens are eased in exchange for a limited compensation of up to $250,000.42

Although Congress responded to the negative effects of products liability litigation on the vaccine industry, there has been no similar federal legislation for prescription drugs. Seeking to provide greater certainty as to manufacturers’ responsibilities, encourage innovation, and ensure appropriate redress for injured parties, tort reform supporters call for a uniform, national standard in pharmaceutical products liability.43 Specifically, because the FDA’s regulation of pharmaceuticals is generally considered to be the most stringent of all government safety regulations,44 supporters of tort reform recommend a tort defense that would at least preclude punitive damages when manufacturers comply with FDA regulations.45 While several state legislatures have enacted such legislation,46 and the House of Representatives has repeatedly passed similar legislation, such efforts have consistently stalled in the Senate.

B. The Co-regulation of Pharmaceuticals

This part discusses the current dual-track system of ex ante regulation of pharmaceuticals by the FDA and ex post liability imposed by the tort system. It also outlines current state legislation that incorporates the FDA regulatory compliance defense, and describes the FDA regulatory compliance defense included in the HEALTH Act of 2005.

1. FDA Ex Ante Regulation

Before a manufacturer can market a new drug, the drug is scrutinized under the FDA’s comprehensive drug approval process.47 Pursuant to the Federal Food, Drug and Cosmetic Act of 1938 ("FDCA"), and its implementing regulations, the FDA ensures that each new drug that is introduced or delivered into interstate commerce meets the statutory standard for safety and efficacy, and that the benefits of the drug outweigh

43. See Kuhlkin & Kingham, supra note 3, at 707-08; Viscusi et al., supra note 20, at 1438-39.
44. See Green, supra note 20, at 163 ("To a greater degree than virtually any other consumer product, pharmaceuticals are subjected to rigorous regulatory control." (citation omitted)).
the risks for its intended use and intended population.\textsuperscript{48} Because it is impossible to anticipate all effects of a drug during pre-market trials, post-marketing surveillance, through clinical trials, observational studies, and spontaneous adverse event reports, is a critical aspect of the process.\textsuperscript{49}

The costly and time-consuming FDA evaluation process\textsuperscript{50} begins when the manufacturer submits an investigational new drug application ("IND").\textsuperscript{51} The IND process for a previously untested drug typically consists of three phases of clinical trials.\textsuperscript{52} During phase I studies, the drug is administered to patients or healthy volunteers to determine side effects and establish the dosage at which the drug can be taken without a high incidence of these adverse events.\textsuperscript{53} If phase I studies include patients with the condition that the drug is intended to treat, it may be possible to gain preliminary efficacy data.\textsuperscript{54} Phase II trials include well-controlled clinical studies to determine the drug's short-term side effects and the efficacy for its indicated use in patients with the condition or disease.\textsuperscript{55} Finally, after preliminary studies suggest that the drug is effective, phase III trials are conducted with a large number of patients to provide the necessary safety and efficacy information to allow the FDA to make an overall risk-benefit


\textsuperscript{49} See 21 C.F.R. § 314.80. The FDA recently announced new initiatives to strengthen drug safety—the November 2004 Five-Step Plan and the February 2005 Drug Safety Announcement. See Drug Safety: Hearing Before the H. Comm. on Gov’t Reform, 109th Cong. (2005) (statement of Steven Galson, Acting Director of the Center for Drug Evaluation and Research), available at http://www.fda.gov/ola/2005/drugsafety0505.html [hereinafter Galson Testimony]. These plans were developed to better identify drugs with unacceptable risk profiles and to "promote a culture of transparency, openness, and enhanced oversight within the Agency." Id.

\textsuperscript{50} See PhRMA, Innovation, http://www.phrma.org/innovation (last visited Jan. 26, 2006) (stating that the average research and development time for a drug is fifteen years and costs the manufacturer over $800 million). But see Marcia Angell, The Truth About Drug Companies: How They Deceive Us and What to Do About It 40-41 (2004) (disputing the $800 million figure and claiming that the average after-tax cost for the research and development per drug is closer to $100 million to $300 million).

\textsuperscript{51} 21 C.F.R. § 312 (2005). The application generally should include the results of extensive animal toxicity studies. See id. § 312.23(a)(3)(iv)(f). On January 12, 2006, the FDA announced a plan to make clinical drug development more efficient by allowing earlier human studies before phase 1 begins. See Press Release, U.S. Food & Drug Admin., FDA Issues Advice to Make Earliest Stages of Clinical Drug Development More Efficient (Jan. 26, 2006), available at http://www.fda.gov/bbs/topics/news/2006/NEW01296.html. This will enable researchers to identify sooner which experimental drugs have a chance to be brought to the market. See id.

\textsuperscript{52} See 21 C.F.R. § 312.21.

\textsuperscript{53} Id. § 312.21(a).

\textsuperscript{54} Id.

\textsuperscript{55} Id. § 312.21(b).
determination. In addition, the results of the phase III trials are used to determine the essential information to appear on the drug package label.

Once the IND process is complete, the drug manufacturer analyzes the data and submits a new drug application ("NDA") to the FDA. As part of the NDA, the manufacturer must provide: (1) reports of investigations conducted to determine the drug's safety and efficacy; (2) a list of the drug's components; (3) a statement of the drug's composition; (4) a description of the drug's manufacturing, processing, and packing process; (5) samples of the drug and its components; and (6) the proposed labeling for the drug.

The FDA strictly regulates the content and format of all sections of a drug's label, informing the manufacturer of the specific labeling requirements in an "approvable" or "approval" letter. Approval of the NDA is "conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing."

After the FDA approves the NDA, the manufacturer has a continuing obligation to report to the FDA adverse drug experiences and additional safety-related information as they become available. In addition, the manufacturer is required to submit annual reports to the FDA that include all new safety and efficacy information obtained during the previous year, and describe actions taken in response to the newly acquired information.

During the post-marketing monitoring stage of a newly approved drug, the FDA continuously evaluates the frequency and seriousness of adverse events. The FDA's response to the information "depends on an

56. Id. § 312.21(c).
57. Id.
59. Id. § 355(b)(1). The term "labeling" includes the claims about the drug's risks and benefits, usage directions, and all of the written material printed on or accompanying the drug. See Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 55 (D.D.C. 1998).
61. 21 C.F.R. § 314.110(a) (2004). An "approvable" letter indicates that the new drug application ("NDA") is "basically approvable" pending the resolution of certain issues. Id.
62. Id. § 314.105. The FDA will send an "approval" letter only if there are minor deficiencies in the proposed labeling. Id. § 314.105(b).
63. Id. § 314.105(b).
64. See id. § 314.80(c).
65. Id. § 314.81(b)(2)(i).
evaluation of the aggregate public health benefit of the product compared to its evolving risk profile.\footnote{Id.} Based on this information, the FDA may withdraw its approval “upon finding imminent hazard to public health,” or require the manufacturer to make changes to the drug’s label.\footnote{See 21 U.S.C. § 355(e) (2000).} To quickly and easily provide safety information to patients and healthcare professionals, the FDA recently launched a new website devoted to drug safety.\footnote{See FDA’s New Drug Safety Initiative, http://www.fda.gov/cder/drugsafety.htm (last visited Jan. 25, 2006).} In addition, MedWatch, another FDA website, issues alerts to doctors and patients about emerging or potential safety risks associated with FDA-approved products.\footnote{See MedWatch, The FDA Safety Information and Adverse Event Reporting Program, http://www.fda.gov/medwatch/index.html (last visited Jan. 25, 2006).} These websites also allow consumers and healthcare professionals to report problems believed to be associated with FDA-approved drugs.\footnote{Id.} Violation of FDA regulations subjects manufacturers to criminal and civil penalties.\footnote{See 21 U.S.C. §§ 332-337 (2000).}

2. Ex Post Regulation by the Tort System

In addition to extensive FDA regulation, judicial decision makers co-regulate pharmaceuticals through case-by-case analysis under the products liability tort system. Focusing on a specific injury suffered by an individual plaintiff, lay judges and juries routinely impose liability on pharmaceutical manufacturers whose products comply with the FDA’s risk-benefit-based regulatory requirements.\footnote{See Richard B. Stewart, Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System, 88 Geo. L.J. 2167, 2173-75 (2000).} Pharmaceutical manufacturers and commentators argue that compliance with FDA regulations should preclude tort liability; the responses by Congress, state legislatures, and the courts vary.

a. Regulatory Compliance Defense

To fully appreciate the controversy surrounding the regulatory compliance defense, this section will provide an overview of the treatment of this defense both in general and specifically related to the FDA. This section will also compare the regulatory compliance defense to a similar, but fundamentally distinct tort law defense: federal preemption.

\footnote{Id.}
i. General Regulatory Compliance

Ever since a railroad grade-crossing collision case in 1892, it is fundamental law that compliance with relevant government safety statutes and regulations is admissible and relevant to a product’s defectiveness, but does not preclude manufacturer liability or a finding of a product’s defectiveness. In keeping with this traditional view, section 4(b) of the Restatement (Third) of Torts provides,

[A] product’s compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

Moreover, in a comment to section 4, the drafters of the Restatement (Third) reiterate the widely accepted rule that government safety statutes and regulations establish a minimum safety floor below which the product is deemed defective, and the manufacturer may be held liable. Although many commentators and the majority of courts espouse the traditional Restatement rule that compliance with safety regulations is not dispositive, commentators have recently focused on a qualifier within the commentary to Section 4 of the Restatement (Third) that would allow courts, in certain

74. See Grand Trunk Ry. Co. of Can. v. Ives, 144 U.S. 408 (1892) (holding that compliance with the railroad commissioner’s safety regulations does not preclude a jury finding of negligence).
75. See Restatement (Third) of Torts: Products Liability § 4(b) (1998); David G. Owen, Special Defenses in Modern Products Liability Law, 70 Mo. L. Rev. 1, 14-17 (2005); Rabin, supra note 2, at 2049-51.
76. Restatement (Third) of Torts: Products Liability § 4(b). However, noncompliance with product safety statutes or regulations is defectiveness per se. Id. § 4(a).
77. Comment e to section 4, in relevant part provides,
Subsection (b) reflects the traditional view that the standards set by most product safety statutes or regulations generally are only minimum standards. Thus, most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied. This is the general rule, applicable in most cases.
Id. § 4 comment e.
78. See, e.g., Vincent R. Johnson, Liberating Progress and the Free Market from the Specter of Tort Liability, 83 Nw. U. L. Rev. 1026, 1048-54 (1989) (book review) (stating that the regulations established by governmental regulatory agencies are not conclusive because these agencies are often underfunded, influenced by politics and special interest groups, and only establish minimum standards).
79. See, e.g., Feldman v. Lederle Labs., 625 A.2d 1066, 1070 (N.J. 1993) (holding that FDA regulations are merely minimum standards that “did not preclude Lederle from taking additional action”); Edwards v. Basel Pharmas., 933 P.2d 298, 303 (Okla. 1997) (finding that the FDA sets minimum safety standards as to drug warnings and design). But see Ramirez v. Plough, Inc., 863 P.2d 167 (Cal. 1993). In Ramirez, the court adopted the FDA’s determination that English-only drug labeling is adequate, stating, “[l]acking the procedure and the resources to conduct the relevant inquiries, we conclude that the prudent course is to adopt for tort purposes the existing legislative and administrative standard of care on this issue.” Id. at 176.
circumstances, to find that compliance with particular safety statutes or regulations precludes liability.\textsuperscript{80} This commentary states,

Occasionally, after reviewing relevant circumstances, a court may properly conclude that a particular product safety standard set by statute or regulation adequately serves the objectives of tort law and therefore that the product that complies with the standard is not defective as a matter of law. Such a conclusion may be appropriate when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise.\textsuperscript{81}

The FDA's regulation of pharmaceuticals, commentators argue, fits within this limited framework.\textsuperscript{82}

A similar, but principally distinct defense to state-law tort claims is federal preemption.\textsuperscript{83} Under the Supremacy Clause of Article VI of the United States Constitution, federal statutes, including administrative regulations,\textsuperscript{84} preempt conflicting state laws when: (1) Congress explicitly includes a provision in the federal statute stating the intent to preempt state law; (2) congressional intent to supersede state laws can be inferred from the existence of a pervasive federal regulatory scheme; or (3) state law actually conflicts with federal law to the extent that a party cannot comply with both state and federal requirements.\textsuperscript{85} Congressional intent, discerned

\textsuperscript{80} See Rabin, supra note 2, at 2051-52. In addition, Professor Rabin discusses a 1991 American Law Institute study that in limited circumstances supports a regulatory compliance defense to tort liability. \textit{Id.} at 2051 (citing ALI Study, supra note 45, at 83-110). Concerned about the over-deterrent effect of socially valuable activities, the study recommends that for particular products, such as pharmaceuticals, regulatory compliance, should at minimum, bar punitive damages. See ALI Study, supra note 45, at 95, 110. For a further discussion of the regulatory compliance defense recommended in the ALI Study, see Stewart, supra note 73, at 2167-71. Professor Stewart supports regulatory compliance preclusion to both compensatory and punitive damages. \textit{Id.} at 2167.

\textsuperscript{81} Restatement (Third) of Torts: Products Liability § 4 cmt. e.

\textsuperscript{82} See Rabin, supra note 2, at 2084 (cautiously supporting a regulatory compliance defense for pharmaceuticals); see also Lars Noah, \textit{Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability}, 88 Geo. L.J. 2147, 2157 (2000) ("less grudgingly" supporting a regulatory compliance defense for pharmaceuticals). \textit{But see} Owen, supra note 75, at 20-21 (arguing that because the FDA rarely fits a "perfect agency model," determinations of a drug's defectiveness should not generally be based on FDA safety regulations).

\textsuperscript{83} See Rabin, supra note 2, at 2053-54. Whereas the regulatory compliance defense is a state-law defense concerning a court's adoption of the safety standards of the relevant regulatory agency, preemption is a federal law defense where, when Congress intends, a federal regulation overrides a state law. See Owen, supra note 75, at 13.

\textsuperscript{84} See Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes.").

from the language, structure, and purpose of the federal statute, is the "'ultimate touchstone' in every pre-emption case." 86

Because the FDCA does not contain an express preemption provision for pharmaceuticals, 87 manufacturers typically argue solely for conflict preemption. 88 In analyzing conflict preemption of a state tort claim related to matters of health and safety, a field traditionally occupied by the states, courts begin their evaluation with the presumption against federal preemption. 89 Absent a "clear and manifest purpose of Congress" to supersede state regulations of health and safety matters, preemption will not be found. 90

ii. Legislative FDA Defense

Although not widespread, as part of the greater tort reform movement over the past twenty years, the FDA regulatory compliance defense has received moderate legislative support. Several states have enacted statutes concerning a manufacturer's compliance with FDA regulations and Congress has repeatedly considered the issue.

a. State Statutes

Concerned about the cost and availability of pharmaceuticals, a small minority of state legislatures have enacted tort reform statutes that recognize the FDA-compliance defense. 91 While a Michigan statute provides complete immunity from tort liability for manufacturers whose drug and drug labeling comply with FDA regulations, 92 this is not the norm. Instead, the few states that recognize the FDA regulatory compliance

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87. There is, however, an express preemption clause in the Medical Device Amendment to the FDCA. See 21 U.S.C. § 360k (2000). Importantly, in January 2006, the FDA included preemption language in the explanatory preamble of a new FDA drug-labeling rule. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601). The preamble states that the FDA "believes" that its approval of a drug's labeling "preempts conflicting or contrary State law." Id. Because the preemption language is located in the preamble and not within codified regulatory text, however, its future effect on judicial decisions is unclear. See Heather Won Tesoriero & Anna Wilde Mathews, Lawyers May Change Their Tactics in Drug Liability Cases, Wall St. J., Jan. 19, 2006, at D3.
89. See Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 723 (1985) (holding that local ordinances governing the collection of blood plasma were not preempted by federal regulations governing the collection of blood plasma).
90. Id. at 715 (citation omitted).
91. See, e.g., Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 967 (6th Cir. 2004) (discussing the Michigan Legislature's rationale for enacting a statute that immunizes drug manufacturers from liability if the drug and its labeling were approved by the FDA).
defense generally only provide a statutory safe harbor for punitive damages when a manufacturer complies with FDA regulations,\(^9\) or provide a rebuttable presumption that FDA-approved drug warnings are adequate.\(^4\)

Although these FDA-compliance statutes generally provide for an exception where a pharmaceutical manufacturer knowingly misrepresents to or withholds from the agency required information that is material and relevant to the alleged harm,\(^5\) the viability of a cause of action based on this exception is questionable after *Buckman Co. v. Plaintiffs’ Legal Committee.*\(^6\) In *Buckman*, plaintiffs alleged that a medical device manufacturer made fraudulent representations to the FDA while obtaining FDA approval, and that those representations played a substantial role in the plaintiffs' alleged injuries.\(^7\) Stating that “[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives,” the Supreme Court held that the plaintiffs' fraud-on-the-FDA claims were impliedly preempted by the FDCA, as amended by the Medical Device


\(^5\) The New Jersey statute is typical, and provides as follows:

Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the “Federal Food, Drug, and Cosmetic Act,” 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the “Public Health Service Act,” 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency’s regulations, which information was material and relevant to the harm in question, punitive damages may be awarded. For purposes of this subsection, the terms “drug”, “device”, “food”, and “food additive” have the meanings defined in the “Federal Food, Drug, and Cosmetic Act.”


\(^6\) 531 U.S. 341, 348 (2001) (holding that the plaintiffs' state-law fraud on the FDA claims were impliedly preempted by the FDCA, as amended by the Medical Device Amendments); see *Garcia*, 385 F.3d at 967 (holding that drug manufacturers enjoy immunity from product liability absent an FDA determination of fraud); Kobar v. Novartis Corp., 378 F. Supp. 2d 1166, 1177 (D. Ariz. 2005) (finding that a state statute immunizing drug manufacturers from punitive damages in products liability suits unless plaintiff proves fraud on the FDA was preempted by federal law).

\(^7\) *Buckman*, 531 U.S. at 343.
The Court observed that “complying with the FDA’s detailed regulatory regime in the shadow of 50 States’ tort regimes will dramatically increase the burdens facing potential applicants.” Moreover, the Court held that the FDA itself is statutorily empowered to deter and punish fraud—it regulates the approval process, can require additional information from the manufacturer, investigate fraud, seek injunctive relief and civil penalties, and pursue criminal prosecutions.

Lower courts have extended *Buckman’s* reasoning to pharmaceuticals, holding that state statutes immunizing manufacturers from liability unless plaintiffs can prove fraud on the FDA are similarly preempted by federal law. Without such preemption, “a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman.*” Punitive damages may still be obtained, however, if the FDA itself determines that it had been defrauded by the pharmaceutical manufacturer.

Unlike fraud-on-the-FDA claims, most lower courts reject the conflict preemption defense in state-law failure-to-warn claims against pharmaceutical manufacturers. Although the FDA has filed briefs urging for preemption in such cases, and at least three lower courts have obliged

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98. *Id.* at 350 (citation omitted). In addition, the Court found that because the relationship between the FDA and the manufacturer is “inherently federal in character” and the manufacturer’s statements were dictated by a federal statute, the usual presumption against preemption was absent from this case. *Id.* at 347-48. The Court in *Buckman* distinguished *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which similarly involved a medical device manufacturer, by stating that in *Medtronic*, the FDCA, as amended by the Medical Device Amendments, did not preempt the plaintiff’s state-law manufacturing, design, and warnings claims because the claims arose from the manufacturer’s failure to use reasonable care, and not from a violation of the FDCA. *Buckman*, 531 U.S. at 352.


100. *Id.* at 349 (citations omitted).


102. *Garcia*, 385 F.3d at 966.

103. *Kobar*, 378 F. Supp. 2d at 1175-76; see *Garcia*, 385 F.3d at 966 (citing *Buckman*, 531 U.S. at 351) (stating that under the Michigan statute, a manufacturer is not immunized from products liability if the FDA determines that it was defrauded).


105. See Brief for the United States, as Amicus Curiae Supporting Defendant-Appellee and Cross-Appellant, *Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2002) (Nos. 02-55372, 02-55498), available at 2002 WL 32303084, at *1-*2 (“The FDA . . . has a clear interest to ensure that state tort law does not undermine the agency’s authority to protect the public
(two of which filed unreported decisions),\textsuperscript{106} most lower courts reject the preemption defense because FDA regulations allow pharmaceutical manufacturers "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction," without prior FDA approval.\textsuperscript{107} Moreover, pharmaceutical manufacturers are required to provide a warning "as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."\textsuperscript{108} Because manufacturers are permitted, and sometimes even required, to make labeling changes without prior FDA approval, absent an express preemption clause for pharmaceuticals in the FDCA, courts are reluctant to find preemption of stricter state-law requirements.\textsuperscript{109}

\textbf{b. HEALTH Act of 2005}

At the same time as the states were enacting tort reform statutes, Congress began considering similar reforms in order to establish a uniform

health through enforcement of the FDCA’s prohibition against false or misleading labeling of drug products” and “federal law must prevail”). On the other hand, courts often find that state-law failure-to-warn claims are preempted in medical device cases because of an express preemption clause in the Medical Device Amendment to the FDCA. See 21 U.S.C. § 360k (2000); see, e.g., Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004); Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001). It is unclear how courts will consider the January 2006 FDA preemption language in the preamble of the new drug-labeling rule. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).


\textsuperscript{107} 21 C.F.R. § 314.70(c)(6)(iii)(A) (2005); see Cartwright, 369 F. Supp. 2d at 886 (finding that Texas products liability “law compliments and is parallel to the FDA’s regulations regarding safety warnings and, thus, does not interfere with the objectives of the FDA”).

\textsuperscript{108} 21 C.F.R. § 201.57(e) (2005). However, only “[k]nown hazards and not theoretical possibilities shall be listed” on the label. Id. § 201.57(d).

\textsuperscript{109} Although the FDCA permits manufacturers to add warnings without prior FDA approval, such warnings must not be false or misleading. See 21 U.S.C. § 355(e), (d) (2000). In addition, courts are hesitant to find conflict preemption between FDA regulations and state failure-to-warn law because courts often state that FDA warning requirements establish minimum standards that manufacturers must follow. See, e.g., Cartwright, 369 F. Supp. 2d at 882. While an express preemption is not necessary when conflict preemption exists, because Congress chose to include a preemption clause for medical devices in the FDCA but not for pharmaceuticals, courts generally find that “the absence of any such clause … demonstrates an implied intent not to preempt [pharmaceutical] cases.” Id. at 885. Further, when determining if implied conflict preemption exists, courts look to the language of the federal regulation with a strong presumption against preemption. Id. at 883 (citing Geier v. Am. Honda Motor Co., 529 U.S. 861, 886 (2000); Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 721 (1985)). For a further discussion of preemption in pharmaceutical products liability litigation, see Noah, supra note 82, at 2157-61; Rabin, supra note 2, at 2053-60.
law that would “reduce transaction costs, provide greater certainty as to the rights and responsibilities of all parties involved in product liability disputes, encourage innovation, increase the competitiveness of U.S. firms, reduce burdens on interstate commerce, and safeguard due process rights.”110 Most recently, the U.S. House of Representatives passed the HEALTH Act of 2005, which contains a safe harbor from punitive damages for manufacturers who comply with FDA regulations.111 This provision

111. Section 7 of the HEALTH Act, in relevant part provides as follows:
   (c) No Punitive Damages for Products That Comply With FDA Standards—
   (1) IN GENERAL—
   (A) No punitive damages may be awarded against the manufacturer or
distributor of a medical product, or a supplier of any component or raw
material of such medical product, based on a claim that such product caused
the claimant's harm where—
   (i)(I) such medical product was subject to premarket approval, clearance,
or licensure by the Food and Drug Administration with respect to the safety
of the formulation or performance of the aspect of such medical product
which caused the claimant's harm or the adequacy of the packaging or
labeling of such medical product; and (II) such medical product was so
approved, cleared, or licensed; or
   (ii) such medical product is generally recognized among qualified
experts as safe and effective pursuant to conditions established by the Food
and Drug Administration and applicable Food and Drug Administration
regulations, including without limitation those related to packaging and
labeling, unless the Food and Drug Administration has determined that such
medical product was not manufactured or distributed in substantial
compliance with applicable Food and Drug Administration statutes and
regulations.
   (B) RULE OF CONSTRUCTION.—Subparagraph (A) may not be
construed as establishing the obligation of the Food and Drug Administration
to demonstrate affirmatively that a manufacturer, distributor, or supplier
referred to in such subparagraph meets any of the conditions described in
such subparagraph . . .
   (3) PACKAGING.—In a health care lawsuit for harm which is alleged to
relate to the adequacy of the packaging or labeling of a drug which is required to
have tamper-resistant packaging under regulations of the Secretary of Health and
Human Services (including labeling regulations related to such packaging), the
manufacturer or product seller of the drug shall not be held liable for punitive
damages unless such packaging or labeling is found by the trier of fact by clear
and convincing evidence to be substantially out of compliance with such
regulations.
   (4) EXCEPTION.—Paragraph (1) shall not apply in any health care lawsuit in
which—
   (A) a person, before or after premarket approval, clearance, or licensure
of such medical product, knowingly misrepresented to or withheld from the
Food and Drug Administration information that is required to be submitted
under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or
section 351 of the Public Health Service Act (42 U.S.C. 262) that is material
and is causally related to the harm which the claimant allegedly suffered; or
   (B) a person made an illegal payment to an official of the Food and Drug
Administration for the purpose of either securing or maintaining approval,
clearance, or licensure of such medical product.
was included "[t]o help encourage new drug development and contain the costs of life-saving drugs."112 Citing the rigorous nature of the FDA approval process along with the continuing post-marketing requirements, supporters of the bill stated that absent fraud, the FDA’s determination that the medical product will aid the public health should be respected.113 While compensatory damages are permitted,114 punitive damages are reserved for cases where the manufacturer “knowingly misrepresented to or withheld from the [FDA] information that is required to be submitted under the [FDCA]... that is material and is causally related to the harm which the claimant allegedly suffered... or... made an illegal payment to an official of [the FDA]."115 Moreover, if punitive damages are awarded, they are limited to the greater of $250,000 or two times the economic damages awarded.116 The HEALTH Act does not preempt state laws that specify the amount of damages permitted in a health care lawsuit.117

Having briefly described the history of pharmaceutical products liability and its relationship to the tort reform movement, as well as the current dual track regulatory system of pharmaceuticals—the FDA and tort law—this Note now turns to the controversy surrounding the FDA regulatory compliance defense to punitive damages.

II. ARGUMENTS FOR AND AGAINST THE FDA-COMPLIANCE DEFENSE AS A SHIELD TO PUNITIVE DAMAGES IN PHARMACEUTICAL PRODUCTS LIABILITY

Although a number of states have enacted legislation barring punitive damages in lawsuits against drug manufacturers who have complied with FDA regulations, repeated efforts to enact similar federal legislation have passed in the House of Representatives, but have consistently failed to pass in the Senate.118 The HEALTH Act of 2005 is the most recent attempt. This part examines arguments surrounding the FDA-compliance defense in turn.

113. See id.
114. The HEALTH Act permits unlimited economic damages but limits noneconomic damages to $250,000. H.R. 5, § 4(a), (b). In addition, under the HEALTH Act, evidence of collateral source benefits may be introduced. Id. § 6.
115. Id. § 7(c)(4). This provision is questionable, however, because it is likely preempted by federal law. See supra notes 96-103 and accompanying text.
116. H.R. 5, § 7(b)(2).
117. Id. § 11(c).
A. Arguments for the FDA-Compliance Defense to Punitive Damages

1. Chilling Effect on Product Development and Availability

Proponents of the FDA-compliance defense to punitive damages for pharmaceutical manufacturers who comply with FDA regulations argue that the availability and unpredictability of punitive damages in medical products liability litigation discourages research and development of new drugs, drives existing therapies off the market, and increases the cost of drugs. They contend that the current dual track system, consisting of FDA regulation and tort litigation with punitive damage claims, over-deters both the FDA and manufacturers of beneficial products. Citing the overwhelming liability associated with Bendectin, vaccines, and contraception that led manufacturers to withdraw important drugs or leave the market altogether, FDA-defense proponents contend that such liability has an overall harmful effect on public health.

119. See Kobar v. Novartis Corp., 378 F. Supp. 2d 1166, 1175 (D. Ariz. 2005). The court in Kobar upheld an Arizona statute that immunizes drug manufacturers from punitive damage liability unless the FDA finds that the manufacturer committed fraud during the approval process. Id. at 1175. The court severed the subsection of the statute that would require a plaintiff to prove that the manufacturer defrauded the FDA, finding this requirement preempted by federal law. Id. at 1177.

120. See Marthaler, supra note 6, at 481. While punitive damages are meant to have a deterrent effect on wrongful conduct, in medical products liability litigation they often cause manufacturers to be overly cautious, either not developing new products or withholding new products from the market. Kuhlik & Kingham, supra note 3, at 699. For an in-depth discussion of the over-deterrent effect of FDA regulation and tort law, see Michael D. Green, Statutory Compliance and Tort Liability: Examining the Strongest Case, 30 U. Mich. J.L. Reform 461 (1997). Moreover, commentators claim that the FDA is becoming stricter—taking more time to review drugs, more closely scrutinizing side effects, and denying approval of drugs that would likely have been approved prior to the withdrawal of Vioxx. See Alex Berenson, Big Drug Makers See Sales Erode With Their Image: F.D.A. Grows More Strict, N.Y. Times, Nov. 14, 2005, at Al (discussing the FDA’s decision to deny approval of Pargluva, Bristol-Myers-Squibb’s new diabetes drug, until additional clinical trials are conducted, and the recent research budget cuts among the largest American drug manufacturers). Peter Huber, a fellow of the Manhattan Institute, contends that the FDA’s overly cautious regulation of thalidomide is an example of “a political layer of review of scientific research [that] has a corrosive effect on . . . science itself.” Peter Huber, FDA Caution Can be Deadly, Too, Wall St. J., July 24, 1998, at A1.

121. See Stewart, supra note 73, at 2171-77. The court in Grundberg v. Upjohn Co. explained that the costs associated with tort liability could result in the discontinuation of a prescription drug, which would lead to even more costly hospital procedures. 813 P.2d 89, 97 (Utah 1991) (citation and emphasis omitted). Citing a Utah statute that immunizes manufacturers of FDA-approved drugs from punitive damages, the Grundberg court “note[d] that the Utah Legislature has recognized the value of the FDA approval process and the public interest in the availability and affordability of prescription drugs by restricting the extent of liability for injuries resulting from the use of those drugs.” Id. at 97. The court agreed with the Legislature’s reasoning and held that under comment k, manufacturers of FDA-approved prescription drugs are immune from strict liability claims based on design defects. Id. at 90.
a. Bendectin’s Withdrawal Leaves a Therapeutic Gap

In 1980, at least one in ten pregnant women in America was taking Bendectin to treat the nausea and vomiting that often accompany pregnancy, commonly referred to as morning sickness. By 1983, however, Bendectin, the only drug approved for this condition, was driven off the market by hundreds of scientifically unsupported lawsuits costing manufacturer Merrell Dow Pharmaceuticals more than $100 million to defend. In Bendectin litigation, plaintiffs alleged that the morning sickness drug caused birth defects, an association that the FDA, doctors, and scientists failed to establish. Facing the possibility of defending and potentially losing hundreds of lawsuits which routinely included compensatory and punitive damages claims, despite the absence of scientific evidence of Bendectin’s human teratogenicity, Merrell Dow made a business decision to withdraw Bendectin from the American market. Because Bendectin was the only medication approved to treat this condition, pregnant women with morning sickness were left with no FDA-approved therapeutic alternative. Today, though a generic form is available in Canada, and despite its continued FDA approval, Bendectin is unavailable to pregnant American women. A recent study comparing morning sickness in American and Canadian women showed that American women are hospitalized more often, experience greater weight loss, and are absent more from work. Proponents of the FDA defense are quick to

122. Jane E. Brody, Shadow of Doubt Wipes Out Bendectin, N.Y. Times, June 19, 1983, at E7. Between 1956 and 1983, more than thirty-three million pregnant women took Bendectin to relieve morning sickness. See id. More than 300 lawsuits alleging birth defects in babies born to mothers who used Bendectin during their pregnancy were filed in the five years prior to the drug’s withdrawal from the market in 1983. See id.

123. See Marthaler, supra note 6, at 471; see also Brody, supra note 122.

124. See Gregory C. Jackson, Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation, 42 Am. U. L. Rev. 199, 207 (1992) (“The FDA and most courts were unequivocal in finding no increased risk of birth defects associated with Bendectin.”).

125. Brody, supra note 122. The director of professional communications for Merrell Dow stated, “We were forced for business reasons to take a safe and effective medication off the market.” Id. With an income of $13 million from sales of Bendectin, Merrell Dow’s insurance premium increased to $10 million. Id. Prior to its withdrawal, the cost of Bendectin rose over three hundred percent. See Brown v. Superior Court, 751 P.2d 470, 479 (Cal. 1988). Even though punitive damages were routinely awarded in Bendectin litigation, they were routinely reversed on appeal. See Kuhlik & Kingham, supra note 3, at 702, 703 & n.60; see, e.g., Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1163-64 (D.C. Cir. 1990) (overturning a jury’s award of $20 million in compensatory damages and $75 million in punitive damages because of the lack of a statistically significant association between Bendectin and the plaintiff’s type of limb defect).


127. Id. Neither Bendectin nor its generic form, Diclectin (a doxylamine/pyridoxine combination), is available in the United States. Id.

128. Id. at 363-64. The dehydration associated with nausea and vomiting of pregnancy can detrimentally affect the pregnant woman and fetus. Thus, medical experts are calling for
point out that the number of birth defects remains unchanged since Bendectin’s withdrawal. The therapeutic gap created by Bendectin’s withdrawal from the market is often used by proponents of the FDA-compliance defense as a striking example of the effect that tort liability has on safe and effective drugs.

b. Lack of Contraceptive Research

Proponents of the FDA defense argue that despite the tremendous number of reproductive age women, the fear of excessive tort liability has significantly contributed to the lack of contraceptive research and development. In support of this theory, one FDA-defense advocate points to Wooderson v. Ortho Pharmaceutical Corp., where a plaintiff was awarded $2.75 million in punitive damages after developing hemolytic uremic syndrome (“HUS”) allegedly caused by oral contraceptive use. There, the manufacturer was held liable for failing to warn of the risk of contraceptive-induced HUS even though the FDA expressly failed to concur with the manufacturer’s proposed drug labeling that included such warning. With punitive liability imposed for conduct specifically addressed by the FDA and consistent with its determination, proponents contend that the lack of contraceptive research is not surprising. Although new patents have been issued for contraceptive products, these are only incremental advances on existing therapies; the need for innovative, effective, safe, and user-friendly options is not being met. FDA-defense proponents argue that a compliance-based shield from

the reintroduction of Bendectin, which is still FDA approved to treat morning sickness. See Robert Brent, Medical, Social, and Legal Implications of Treating Nausea and Vomiting of Pregnancy, 186 Am. J. Obstetrics & Gynecology S262, S265 (2002). In addition, these experts are recommending that instead of blaming the Bendectin litigation crisis on trial lawyers, the medical community should focus its attention on the “junk scientists” who participate in nonmeritorious litigation. See id. at S263.

129. See Stewart, supra note 73, at 2171. Hospital admissions for pregnancy-associated nausea and vomiting have doubled since Merrell Dow withdrew Bendectin from the American market; the rate of birth defects remained unchanged. See James T. Rosenbaum, Lessons from Litigation over Silicone Breast Implants: A Call for Activism by Scientists, 276 Science 1524, 1524 (1997).

130. See Green, supra note 20, at 164-65 (“Peter Huber, who popularized the term ‘junk science,’ has repeatedly returned to the Bendectin litigation to demonstrate the ills of the tort system.” (citing Michael D. Green, Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation 21 (1996))). The FDA recently restated that Bendectin does not increase the risk of birth defects. Brent, supra note 128, at S266.

131. See Kuhlik & Kingham, supra note 3, at 701-02; see also Jerome F. Strauss III & Michael Kafriessen, Waiting for the Second Coming: Contraceptive Research Is Seriously in Need of Revitalization, 432 Nature 43 (2004) (arguing that tort liability hampers contraceptive research, depriving the 1.5 billion women of reproductive age of innovative products).


133. Kuhlik & Kingham, supra note 3, at 702.

134. Wooderson, 681 P.2d at 1057.

135. See Strauss & Kafriessen, supra note 131.

136. See Kuhlik & Kingham, supra note 3, at 702; Strauss & Kafriessen, supra note 131.
punitive damages would encourage much needed contraceptive development.  

c. Vaccine Liability

Similarly, advocates of the FDA defense argue that tort liability has driven manufacturers out of the vaccine business. In the 1980s, facing hundreds of suits involving punitive damages, vaccine manufacturers exited the industry because the business no longer made economic sense. Despite Congress’s efforts to ameliorate this situation, there are still relatively few manufacturers producing vaccines; this has resulted in recent shortages of five routinely recommended childhood vaccines, and the well-publicized annual shortages of the influenza vaccine. Moreover, commentators are concerned that the fear of unlimited tort liability is impeding the development of an AIDS vaccine, and more recently, a vaccine for the bird flu.

2. Complex Issues Regarding Inherently Hazardous Products

Because of the inherently hazardous nature of pharmaceutical drugs and the complex issues presented in medical products liability litigation, commentators argue that manufacturers who comply with FDA regulations should not be subject to punitive damages. The FDA, courts, and

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137. See Kuhlik & Kingham, supra note 3, at 702.
138. See id. at 699-701.
139. See id. at 700 (citations omitted).
140. See supra notes 41-42 and accompanying text.
141. There are currently only four manufacturers making vaccines, down from over twenty manufacturers in the 1970s and early 1980s. See Paul A. Offit, Opinion, Lawsuits Won’t Stop Pandemics, Wall St. J., Dec. 1, 2005, at A16. Dr. Offit, the Chief of Infectious Diseases at the Children’s Hospital of Philadelphia, describes the importance of vaccines and the unintended tragedies that they have caused. See id. He also explains that because of the inevitability of injuries, litigation does not make vaccines safer—it just increases their costs and decreases their availability. See id.
143. See Alan Murray, Roche Feels the Highs and Lows of Feverish Demand for Tamiflu, Wall St. J., Oct. 19, 2005, at A2 (discussing the current threat of a global bird flu pandemic). In response to the current threat of bird flu, President George W. Bush released a “National Strategy for Pandemic Influenza.” See Offit, supra note 141. To encourage the domestic development of a bird flu vaccine, the strategy contains liability protection from litigation. Id.
144. See Green, supra note 20, at 165 (citing Jon Cohen, Is Liability Slowing AIDS Vaccines?, 256 Science 168 (1992)).
145. See Offit, supra note 141.
146. See Kuhlik & Kingham, supra note 3, at 697 & nn. 19-20, 698.
commentators often point out that all pharmaceutical drugs pose some level of risk; drugs are physiologically active agents that have both significant health benefits and unintended side effects.\textsuperscript{147} Drug litigation typically involves the failure to warn about these adverse side effects, information about which may be present in the drug manufacturer's internal documents.\textsuperscript{148} FDA-defense supporters argue that jurors view this information as the requisite evidence of recklessness or malice to support a punitive damages claim against the manufacturer.\textsuperscript{149}

Moreover, FDA-defense supporters argue that pharmaceutical litigation involves complex scientific questions that are too difficult for "unsophisticated" jurors to understand.\textsuperscript{150} Because of the complicated nature of the issues surrounding the injury or death of a sympathetic plaintiff, FDA-defense supporters contend that jurors are particularly influenced by a plaintiff's experts.\textsuperscript{151} For instance, despite admittedly not understanding the medical evidence presented, the jury in the first Vioxx case to go to trial, \textit{Ernst v. Merck}, awarded the widow of a man who died of a heart arrhythmia, a condition Vioxx has not ever been found to cause, over $253 million, including $229 million in punitive damages.\textsuperscript{152}

3. The FDA Rigorously Regulates Pharmaceuticals

Supporters of the FDA defense argue that allowing punitive damages in cases where pharmaceutical manufacturers comply with FDA regulations ignores the stringency of the FDA regulatory process.\textsuperscript{153} They contend that the FDA is the most qualified agency to make the necessary scientific and public policy decisions surrounding the marketing of a particular drug. Besides the rigorous drug approval process, the FDA continues to regulate

\textsuperscript{147} Green, \textit{supra} note 20, at 168; see Grundberg v. Upjohn Co., 813 P.2d 89, 95 (Utah 1991) ("[P]rescription drugs . . . will almost always pose some risk . . . . Despite these risks, new drugs are continually approved by the FDA because of their social benefit in saving lives and alleviating human suffering."); Kweder Testimony, \textit{supra} note 66.

\textsuperscript{148} Kuhl\textsc{~}l & Kingham, \textit{supra} note 3, at 698.

\textsuperscript{149} Id.

\textsuperscript{150} Noah, \textit{supra} note 82, at 2150-51. Arguing for a complete regulatory compliance defense, Professor Lars Noah contends that jurors in medical products liability cases across the country make their own determinations about "appropriate prescription drug labeling, effectively second-guessing the FDA’s far more expert, accountable, and uniform determination." \textit{Id.} Supporters of the FDA defense to punitive damages state that the medical questions in medical products liability cases are too complex for lay jurors. See Kuhl\textsc{~}l & Kingham, \textit{supra} note 3, at 698.

\textsuperscript{151} Kuhl\textsc{~}l & Kingham, \textit{supra} note 3, at 698.

\textsuperscript{152} See Paul Davies & Heather Won Tesoriero, \textit{For Merck, Vioxx Venue Offers Shield}, Wall St. J., Oct. 24, 2005, at B3; Editorial, \textit{The Vioxx Hex}, Wash. Post, Sept. 16, 2005, at A30. An \textit{Ernst v. Merck} juror who thought that the medical evidence presented was confusing, stated that "‘[w]e didn’t know what the heck they were talking about.’" Editorial, \textit{The Vioxx Hex, supra}.

\textsuperscript{153} H.R. Rep. No. 108-32, pt. 1, at 56 (2003) ("The [FDA] requirements for [a new drug] are so extensive . . . that . . . punitive damages will not provide additional societal benefits beyond those achieved by the FDCA’s rules and regulations.").
the product throughout the drug’s life. These regulations, supporters and the FDA itself claim, are optimal standards, establishing both a "floor" and a "ceiling," not minimum standards open to reevaluation by unaccountable jurors.

Because pharmaceuticals are vital, nationally marketed products, the FDA with its scientific expertise, rather than the tort system, is far better suited to make accurate and uniform risk-benefit determinations in the overall interest of society. FDA-defense advocates contend that lay judges and jurors, on the other hand, evaluate the drug on a case-by-case basis, only after an alleged injury has occurred, and ignore the socially beneficial nature of the product.

4. Multiple Claims Subject to Differing Legal Standards Increases Settlement and Litigation Costs

Absent an FDA-compliance defense to punitive damages, proponents argue that pharmaceutical manufacturers are subject to multiple claims with differing legal standards. This inconsistency and uncertainty, they contend, increases settlement and litigation costs. Because drug

154. Id. at 54.
155. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934-35 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (stating that additional state-law requirements can expose a manufacturer to liability if additional risk disclosures are unsubstantiated or false and misleading, and undermine patient safety by overwarning about speculative risks, resulting in the underutilization of beneficial treatments); Noah, supra note 82, at 2151-52, 2158. Professor Noah contends that the FDA product safety standards meet the Restatement (Third), section 4, comment e, exception to the black-letter rule that regulatory compliance does not preclude liability. Id. Professors James Henderson and Aaron Twerski argue that FDA standards are not minimum standards and that compliance with FDA warning requirements "should practically foreclose liability." James A. Henderson, Jr. & Aaron D. Twerski, Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, 65 N.Y.U. L. Rev. 265, 321 (1990). They state that courts "should refuse to second-guess the judgments of agencies who possess not only expertise but also a capacity for knowledge and memory which the courts cannot match." Id.

156. See H.R. Rep. No. 108-32, pt. 1, at 56; Green, supra note 120, at 477 (discussing the inaccurate decisions of multiple Bendectin juries "despite a strong consensus in the medical, scientific, and FDA communities that Bendectin is not a teratogen.")

157. See Stewart, supra note 73, at 2174-75. Arguing for preemption of claims when manufacturers comply with FDA regulations, Professor David G. Owen states, "If the FDA fully and fairly evaluates all of the [clinical data, proposed warnings, and usage information], and approves for sale the drug and warnings, then it would seem to make little sense to let a jury reevaluate the same information and find the drug or warnings 'defective.'" Owen, supra note 75, at 20 (citation omitted).

158. See Kuhlik & Kingham, supra note 3, at 698; see also Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832, 839 (2d Cir. 1967) ("The legal difficulties engendered by claims for punitive damages on the part of hundreds of plaintiffs are staggering .... We have the gravest difficulty in perceiving how claims for punitive damages in such a multiplicity of actions throughout the nation can be so administered as to avoid overkill.").

159. Kuhlik & Kingham, supra note 3, at 697; see Nathan Koppel, Trial-less Lawyers, Wall St. J., Dec. 1, 2005, at B1 ("Scared off by huge jury verdicts, such as the $253 million awarded this year to the widow of a man who died after taking Merck & Co.'s Vioxx drug,
manufacturers potentially face thousands of catastrophic punitive damage claims for a single course of conduct, sometimes after losing just a couple of cases, they choose to settle the remaining cases rather than take that risk.\textsuperscript{160} Marcia Angell, the former editor-in-chief of The New England Journal of Medicine, stated that despite evidence showing that breast implants did not cause the injuries alleged in the “flood of lawsuits,” manufacturers, in effect, were forced to settle—“[a]ll it took was a couple of high stakes wins for [the manufacturers] to be brought to their knees essentially.”\textsuperscript{161} The House of Representatives stated that “[t]his effect alone warrants preclusion of punitive damages where there has been regulatory compliance.”\textsuperscript{162}

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\item See Hazardous to Our Health: Trial Lawyers, Inc. Hurts Consumer Health With its Full-Fledged Assault on the U.S. Medical System, Trial Lawyers Inc. Heath Care, The Lawsuit Industry’s Effect on American Health, 2005, http://www.triallawyersinc.com/healthcare/hc02.html (stating that a couple of multimillion-dollar verdicts can cause “cowed defendants [to] settle the thousands of weaker claims—often for billions of dollars.”). For instance, in the fen-phen lawsuits, Wyeth-Ayerst Laboratories, Inc. (formerly American Home Products Corp.) began to settle after losing two lawsuits totaling over $120 million. At this time, Wyeth has paid out over $14 billion of its estimated $21 billion fen-phen associated liability. Id. Despite its repeated statements that it would defend every Vioxx lawsuit, after losing the first Vioxx case, \textit{Ernst v. Merck}, which was almost universally considered a weak case on the issue of causation, Merck’s general counsel said that it would consider making individual settlements in cases where heart attack victims took Vioxx for a long period of time and lacked other risk factors. See Alex Berenson, \textit{Maker of Vioxx Says Some Suits May be Settled}, N.Y. Times, Aug. 26, 2005, at A1. After winning the second Vioxx case, \textit{Humeston v. Merck}, the Wall Street Journal reported that Merck was analyzing the litigation strategies of other mass pharmaceutical suits, including Wyeth’s fen-phen cases and Johnson & Johnson’s Propulsid cases, to determine the best approach to defending and settling the Vioxx lawsuits. See \textit{Barbara Martinez, Merck Faces Crossroads in Vioxx Cases}, Wall St. J., Nov. 7, 2005, at B1. The third Vioxx lawsuit to reach trial, in which a man died after taking Vioxx for less than a month, ended in a mistrial. See Alex Berenson, \textit{A Mistrial Is Declared in 3rd Suit Over Vioxx}, N.Y. Times, Dec. 13, 2005, at C1.
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5. Punitive Damages Are Unnecessary to Compensate Plaintiffs

Because plaintiffs would still be entitled to compensatory damages,\(^\text{163}\) FDA-compliance defense supporters argue that punitive damages are not necessary to compensate injured parties.\(^\text{164}\) If an injury occurs despite a pharmaceutical manufacturer’s good faith efforts to comply with FDA regulations, the injured party, such as the party in *Wooderson v. Ortho Pharmaceutical Corp.*,\(^\text{165}\) would be entitled to recover economic and noneconomic damages.\(^\text{166}\) Since punitive damages are meant to punish and deter wrongful conduct, FDA-defense advocates argue that punitive damages are unwarranted if the manufacturer diligently complied with the regulations promulgated by the agency charged with protecting public health.\(^\text{167}\) Furthermore, as Judge Friendly observed in 1967, “[m]any awards of compensatory damages doubtless contain something of a punitive element, and more would do so if a separate award for exemplary damages were eliminated.”\(^\text{168}\)

B. Arguments Against the FDA-Compliance Defense to Punitive Damages

1. The FDA Fails to Protect the Public Health and Safety

Opponents of the FDA-compliance defense to punitive damages for pharmaceutical manufacturers who comply with FDA regulations argue that the FDA fails to protect consumers from unacceptable risks associated with

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\(^{163}\) See HEALTH Act of 2005, H.R. 5, 109th Cong. § 4 (2005). The HEALTH Act of 2005 permits unlimited recovery for actual economic losses and up to $250,000 for noneconomic damages, defined as “damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, ... hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.” *Id.* §§ 4, 9. Moreover, up to $250,000 in punitive damages or twice the economic damages, whichever is greater, may be awarded if the manufacturer knowingly misrepresented or withheld material information from the FDA that is causally related to the plaintiff’s alleged harm, or made illegal payments to the FDA. *Id.* § 7(b)(2), (c)(4); see also supra Part I.B.2.a.i-b.

\(^{164}\) See Marthaler, *supra* note 6, at 485; see also Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832, 840-41 (2d Cir. 1967) (“A manufacturer distributing a drug to many thousands of users under government regulation scarcely requires this additional measure [of punitive damages] for manifesting social disapproval and assuring deterrence. Criminal penalties and heavy compensatory damages ... even without proof of negligence, should sufficiently meet these objectives ...”). Instead of tort liability with punitive damages, Professor Richard B. Stewart recommends an administrative no-fault compensation system to cover injuries sustained from FDA-approved products. See Stewart, *supra* note 73, at 2182.

\(^{165}\) 681 P.2d 1038 (Kan. 1984).


\(^{167}\) See Marthaler, *supra* note 6, at 485.

\(^{168}\) Roginsky, 378 F.2d at 841. More recently, Professor Catherine M. Sharkey noted that caps on noneconomic damages in medical malpractice cases will have an unintended “crossover effect,” thereby dampening the intended effect of the caps. See Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damage Caps*, 80 N.Y.U. L. Rev. 391, 391 (2005).
medical products. Critics often state that FDA regulations are "outdated, under-protective, or under-enforced." Concerned that injuries still occur despite FDA approval, critics contend that punitive damages are an important tool for motivating manufacturers to produce the safest drug possible.

Moreover, commentators claim that because much of the FDA approval process relies on self-reporting by the manufacturer, unconstrained tort liability plays an important role in educating consumers about serious health risks associated with medical products. In addition, commentators claim that the agency is heavily influenced by politics and the companies that they are regulating. Furthermore, they state that there is a conflict of interest—the agency responsible for approving a medical product is the same agency responsible for seeking and receiving post-marketing safety information, and ultimately for withdrawing the product from the market. The withdrawal of Vioxx and the Guidant heart device-defects are cited as examples of the FDA’s recent failures.

169. See H.R. Rep. No. 108-32, pt. 1, at 260 (2003); Bob Herbert, Op-Ed., A Gift for Drug Makers, N.Y. Times, Jan. 14, 2005, at A23 ("We know the F.D.A. has failed time and again to ensure that unsafe drugs are kept off the market. To provide blanket legal protection against punitive damages in such cases [where the drug or medical device had received FDA approval] is both unwarranted and dangerous."); see also Grundberg v. Upjohn Co., 813 P.2d 89, 102 (Utah 1991) (Stewart, J., dissenting) (stating that "the majority simply ignores FDA failures to protect the public against unnecessary and unacceptable risks").

170. H.R. Rep. No. 108-32, pt. 1, at 260. FDA-defense critics mention the Dalkon Shield and silicone breast implants as dangerous marketed products that caused injuries. Id. at 261. While the Dalkon Shield did cause injuries, it did not have FDA approval at the time it was sold because the FDCA did not require devices to have premarket approval. Id. at 56. The FDCA was amended in 1976 to require premarket approval of medical devices. Id. In addition, despite a multi-billion dollar settlement fund for alleged injuries caused by silicone breast implants, no association has been found between the implants and the injuries alleged (autoimmune and connective tissue diseases). See Rabin, supra note 2, at 2061-62.

171. See Marthaler, supra note 6, at 472.


173. Placitella & Klein, supra note 8, at 220; see Noah, supra note 82, at 2154 (discussing unsubstantiated claims of agency "capture" by opponents of the FDA-compliance defense). For an in-depth discussion of one commentator’s opinion on the pharmaceutical industry’s influence on the FDA, see Angell, supra note 50, at 193-216.


175. See Placitella & Klein, supra note 8, at 221.

176. See Barry Meier, F.D.A. Had Report of Short Circuit in Heart Devices: Confidentiality at Issue, N.Y. Times, Sept. 12, 2005, at A1. Guidant Corporation submitted annual reports to the FDA that included data about the malfunctioning of some of its heart defibrillators. Id. The FDA did not make the information public at the time because it treats the information in annual reports as confidential. Id. After the New York Times article was published, physicians, regulators, and industry officials gathered to discuss better ways to disclose safety information to physicians and patients. Barry Meier, Maker of Heart Devices
FDA-defense opponents claim that because the FDA fails to protect the public, tort law provides a “vital safety net” to ensure that manufacturers comply both with the “letter of the law” and “the unwritten laws of human morality and decency.”

2. FDA Regulations Establish Only Minimum Safety Standards

Opponents of the FDA defense contend that the FDA regulations only set a minimum standard of safety, ensuring “only a minimum level of protection for the public.” Critics argue that because FDA safety regulations establish merely a floor, state law and the tort system are necessary to ensure that products are designed as safely as possible and are accompanied by appropriate warnings. For instance, in Edwards v. Basel Pharmaceuticals, the Supreme Court of Oklahoma found that compliance with FDA regulations did not satisfy a nicotine patch manufacturer’s common-law duty to warn consumers. There, the court held that compliance with the FDA’s warning requirements is not conclusive; state products liability law must be applied to assess the adequacy of the warnings.

3. The FDA-Compliance Defense to Punitive Damages Is Unnecessary

Opponents contend that an FDA-compliance defense to punitive damages is not needed. They point out that punitive damage awards against pharmaceutical manufacturers who complied with FDA requirements are


177. See Placitella & Klein, supra note 8, at 234.
178. H.R. Rep. No. 108-32, pt. 1, at 260 (2003). This argument relies on the traditional rule that regulatory compliance is not a defense to liability—that governmental safety regulations generally establish a floor below which the product is deemed defective. See supra Part I.B.2.a.i.
179. See Edwards v. Basel Pharmas., 933 P.2d 298, 302 (Okla. 1997) (finding that the FDA sets minimum safety standards as to drug warnings and design); Rabin, supra note 2, at 2050 (citing Restatement (Third) of Torts: Products Liability § 4(b) (1997)).
181. Id.
182. See Eisenberg et al., supra note 24, at 745 (“Contrary to popular belief, juries rarely award such damages, and award them especially rarely in products liability and medical malpractice cases. Rather, juries tend to award punitive damages in intentional misconduct cases.” (citations omitted)); Michael Rustad, In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data, 78 Iowa L. Rev. 1, 23 (1992) (discussing that punitive damages are rarely awarded in products liability).
rare.\textsuperscript{183} Even if juries return large punitive damages awards, critics argue, they are often either reduced by state caps or on appeal.\textsuperscript{184} Moreover, opponents contend that the FDA defense is unnecessary because drug manufacturers are already protected by liability-restrictive devices, such as comment k, the learned intermediary doctrine, and the Federal Vaccine Act.

4. The Lack of Innovation Is Due to Manufacturers’ Choice to Profit from “Me-Too” Drugs

Marcia Angell, an outspoken critic of the pharmaceutical industry, blames the lack of innovative products on the manufacturers’ choice to profit at a low cost by marketing drugs that are similar to an already proven blockbuster drug, not on the fear of liability.\textsuperscript{185} She claims that these “me-too” drugs are currently pharmaceutical manufacturers’ major business, contributing to the manufacturers’ already high marketing costs.\textsuperscript{186} She states that instead of developing a cure for AIDS or cancer, or vaccines for Americans, manufacturers “would rather turn out another baldness drug.”\textsuperscript{187} In fact, true innovation, she contends, comes from National Institutes of Health (“NIH”) sponsored research.\textsuperscript{188}

5. Products Liability Law Is Best Reserved to the States

Opponents of an FDA-compliance defense argue that state legislatures, rather than Congress, are better situated to determine what is necessary to protect the health and safety of their citizens.\textsuperscript{189} Because tort-related safety regulation has traditionally been within states’ autonomy, opponents claim

\textsuperscript{183}. See H.R. Rep. No. 108-32, pt. 1, at 55 n.191; Eisenberg et al., \textit{supra} note 24, at 745.


\textsuperscript{185}. Frontline: The Other Drug War (PBS television broadcast Nov. 26, 2002), available at http://www.pbs.org/wgbh/pages/frontline/shows/other/interviews/angell.html (Interview with Marcia Angell) [hereinafter Frontline Interview with Angell]. Dr. Angell argues that manufacturers should be required to demonstrate to the FDA that the new drugs are improvements over the drugs already on the market, rather than merely better than a placebo. \textit{Id.} For further discussion of this theory, see Angell, \textit{supra} note 50, at 74-93.

\textsuperscript{186}. Frontline Interview with Angell, \textit{supra} note 185. Dr. Angell states that manufacturers spend, on average, fifteen to seventeen percent of their profits on research and development, and thirty-five percent on marketing and administration. \textit{Id.}

\textsuperscript{187}. \textit{Id.}

\textsuperscript{188}. \textit{Id.} The Wall Street Journal reports that Anthony S. Fauci, the director of the National Institute of Allergy and Infectious Disease within the NIH, spends $500 to $600 million per year providing NIH grants and contracts to private companies to develop drugs and vaccines needed to protect Americans against bioterrorism. See Bernard Wysocki, Jr., \textit{Agency Chief Spurs Bioterror Research—And Controversy}, Wall St. J., Dec. 6, 2005, at A1. Facing criticism, Dr. Fauci defends this government “bank-rolling [of] product development” by stating that “‘[t]he industry wasn’t going to make the investment when they had a choice between developing a new Viagra, a new Lipitor, versus the very risky procedure of doing advanced development in a product where there wasn’t going to be a guaranteed payback for them.’” \textit{Id.} (quoting Dr. Anthony Fauci). For a further discussion of Dr. Angell’s theory on pharmaceutical manufacturers’ innovation, see Angell, \textit{supra} note 50, at 52-73.

that absent clear evidence that interstate variations are impeding commerce among the states, federal legislation should not be enacted.\textsuperscript{190} Such evidence, opponents claim, has not been presented. Instead, opponents contend that juries rarely award punitive damages in products liability cases, and that the fear of tort liability does not deter the marketing of innovative drugs.\textsuperscript{191}

6. Disproportionate Impact on Seniors and Women

Finally, FDA-defense opponents argue that banning punitive damages in cases where manufacturers complied with FDA regulations will have a disproportionate impact on seniors and women.\textsuperscript{192} Citing the alleged injuries caused by the Dalkon Shield, oral contraceptives, and diethylstilbestrol, the opponents claim that women and seniors account for the largest class injured by medical products.\textsuperscript{193} Supporting this position, Professor Michael Rustad claims that the "Fen-Phen tragedy illustrates the potential problem of immunizing manufacturers who have complied with FDA standards but knowingly endanger the consuming public."\textsuperscript{194}

III. PUBLIC POLICY WEIGHS IN FAVOR OF THE FDA REGULATORY COMPLIANCE DEFENSES AS A SHIELD TO PUNITIVE DAMAGES IN PHARMACEUTICAL LITIGATION

This part contends that although there are strong arguments and valid concerns on both sides of the FDA regulatory compliance defense debate,\textsuperscript{195} it seems inherently unreasonable as a matter of public policy that the co-regulation of pharmaceuticals is left to punitive damages in tort law. Complex scientific and public health risk-benefit determinations are likely best left to the FDA, rather than lay fact finders.\textsuperscript{196} Because the FDA-compliance defense to punitive damages allows injured parties to be fairly compensated and maintains the punitive damages remedy for fraudulent conduct,\textsuperscript{197} the defense satisfies two of the key social goals of tort law, namely compensation for injury and deterrence of wrongful conduct. Absent an FDA determination of fraud, it is unclear who we are punishing

\textsuperscript{190} See Rabin, supra note 2, at 2059 (discussing federalism considerations surrounding preemption and the complete regulatory compliance defense to products liability claims).

\textsuperscript{191} S. Rep. No. 105-32, at 74, 88-89; see Grundberg v. Upjohn Co., 813 P.2d 89, 102-03 (Utah 1991) (Stewart, J., dissenting) ("[N]ot a shred of evidence has been presented to this Court that indicates that liability under the tort system has deterred pharmaceutical companies from introducing new drugs.").


\textsuperscript{193} Id. at 260-61.

\textsuperscript{194} Rustad, supra note 25, at 1356 (discussing the "unanticipated negative impact" of the FDA defense on women—the majority of the three hundred thousand fen-phen plaintiffs were women).

\textsuperscript{195} See supra Part II.A-B (explaining the arguments for and against the FDA regulatory compliance defense).

\textsuperscript{196} See supra Part II.A.2-3.

and what we are attempting to deter by imposing punitive damage awards against FDA-compliant pharmaceutical manufacturers.

Congress should resolve the long-standing debate by passing the HEALTH Act, which includes an FDA regulatory compliance defense to punitive damages provision. Along with the enactment of the FDA defense, however, FDA regulations should be reevaluated to ensure that the agency provides the most effective pre- and post-marketing safety regulation of pharmaceuticals. Finally, this part discusses possible consequences of the FDA regulatory compliance defense.

A. FDA Compliance Should Preclude Punitive Damage Awards

In the majority of jurisdictions, a pharmaceutical manufacturer can spend years and hundreds of millions of dollars researching and developing a new drug, fully comply with the FDA's rigorous pre- and post-marketing safety regulatory requirements, and then, when an inevitable injury occurs, be subject to tort liability, including punitive damage claims. The availability of punitive damages in such litigation has caused long-standing disagreement among legal commentators and the issue is routinely considered by Congress.

1. The Regulation of Pharmaceuticals Is Far Too Important to Entrust to Lay Fact Finders

Controversy surrounding the effect that tort liability has on the pharmaceutical industry is extensive. Concerned that the availability of punitive damages has a chilling effect on product development and availability, and increases settlement and litigation costs, commentators argue that compliant pharmaceutical manufacturers, who are already extensively regulated by a specialized agency, should be shielded from punitive damage awards. Moreover, these commentators are concerned about the nonscientific co-regulation of complex, inherently hazardous products by fact finders who lack expertise.

On the other hand, critics of the pharmaceutical industry contend that the lack of innovative therapies is caused by manufacturers' greed for profits

198. See id. § 7(c).
199. See infra Part III.B.
200. See supra Part II.A-B (explaining the arguments for and against the FDA regulatory compliance defense).
202. See supra Part II.A-B (explaining the arguments for and against the FDA regulatory compliance defense).
203. See supra Part II.A.1 (discussing the effect of liability on drugs and vaccines).
204. See supra Part II.A.4 (describing the argument that liability increases settlement and litigation costs).
205. See supra Part II.A.3 (explaining the argument that drugs are already rigorously regulated by the FDA).
206. See supra Part II.A.2 (noting that all drugs pose some level of risk).
evidenced by "me-too" drugs,\textsuperscript{207} and that punitive damage awards are rare in pharmaceutical litigation where there has been FDA compliance.\textsuperscript{208} Furthermore, these critics claim that FDA regulations establish merely minimum safety standards,\textsuperscript{209} and that punitive damages are necessary because the FDA fails to adequately protect the public from unacceptable risks.\textsuperscript{210}

Unfortunately, because of the lack of reliable supporting evidence, this important controversy remains unsettled.\textsuperscript{211} What is clear, however, is that after being mired by tort litigation with punitive damages claims, safe and beneficial drugs have been voluntarily withdrawn from the market\textsuperscript{212} and only few manufacturers continue to make vital vaccines.\textsuperscript{213} In addition, juries have been known to award punitive damages even absent a clear causal connection between the defendant's drug and the claimant's alleged injury.\textsuperscript{214} Finally, drug manufacturers have settled an unknown number of weak cases rather than risk devastating punitive damage awards imposed by lay jurors.\textsuperscript{215}

If a pharmaceutical manufacturer has fully complied with FDA regulatory requirements and disclosed all material information that is causally related to the claimant's alleged injury, there is no valid justification for a punitive damage award.\textsuperscript{216} Because claimants are often adequately compensated in pharmaceutical litigation, using punitive damages as a regulatory device for deterrence when there has been FDA compliance is irrational. The regulation of both a drug's design and warnings is an inherently complex and multifaceted process that requires experience, scientific expertise, and open access to a manufacturer's data in order to render a responsible judgment in the interest of all users of drugs. This ultimate judgment can only be responsibly and consistently made by a group with the essential expertise. Allowing inexpert fact finders to

\textsuperscript{207} See supra Part II.B.4 (describing Marcia Angell's claim that the lack of pharmaceutical innovation is due to drug manufacturers' choice to market drugs that are similar to existing drugs).

\textsuperscript{208} See supra Part II.B.3 (noting that punitive damages are rarely awarded in pharmaceutical litigation).

\textsuperscript{209} See supra Part II.B.2 (describing the argument that FDA regulations establish only minimum standards and that tort liability provides the necessary additional protection for consumers).

\textsuperscript{210} See supra Part II.B.1 (discussing FDA regulatory compliance defense opponent's argument that the FDA fails to adequately protect the public).

\textsuperscript{211} See supra Part II.A-B (explaining the arguments for and against the FDA regulatory compliance defense).

\textsuperscript{212} See supra Part II.A.1.a (discussing Bendectin's withdrawal from the market).

\textsuperscript{213} See supra Part II.A.1.c (describing the argument that tort liability has driven vaccine manufacturers from the market).

\textsuperscript{214} See supra notes 124-25 and accompanying text (describing jury awards in Bendectin litigation, despite the lack of association between the drug and the alleged injuries).

\textsuperscript{215} See supra Part II.A.4 (discussing settlements in the breast implant and fen-phen litigation).

\textsuperscript{216} See ALI Study, supra note 45, at 101 (explaining that the case for a regulatory compliance defense is strongest when there is a claim for punitive damages).
second-guess the decisions of the extensive regulatory system of the FDA can and has decreased the availability of essential drugs, leaving potential users with no adequate therapy.

While commentators disagree about the appropriateness and necessity of the FDA-compliance defense to punitive damages, they do not dispute the broader public interest in the development and availability of pharmaceuticals. Pharmaceuticals are a vital part of modern medical care. It is the unique importance of pharmaceuticals, combined with their comprehensive regulation by the FDA that justifies departure from the traditional doctrine that regulatory compliance is not legally dispositive.

2. Reevaluating FDA Regulations

While this Note argues that Congress should establish a uniform standard that bars punitive damages in pharmaceutical litigation where manufacturers have complied with FDA regulations, it also suggests that the FDA’s pre- and post-marketing safety regulations should be reevaluated and reworked. Though identifying the necessary and best method to revise FDA regulations is beyond the scope of this Note, it seems that the FDA itself is aware of the need to strengthen drug safety, as evidenced by the recent initiatives. Furthermore, the FDA needs to be adequately funded in order to ensure that the agency is able to perform its critical regulatory activities.

B. Consequences of the FDA Regulatory Compliance Defense to Punitive Damages

As with any new legislation, Congress’s enactment of the FDA regulatory compliance defense to punitive damages would likely have both intended and unintended consequences.

1. Impact on the Pharmaceutical Industry

The ideal effect of the FDA regulatory compliance defense to punitive damages would be to encourage manufacturers to develop innovative life-enhancing and life-sustaining therapies and to maintain the availability of

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217. As Harvard Medical School Professor Thomas P. Stossel recently wrote, doctors are not very useful to patients without drugs developed by drug companies, companies who are often erroneously vilified by the media as greedy sinners. Thomas P. Stossel, Opinion, Mere Magazines, Wall. St. J., Dec. 30, 2005, at A16.

218. This departure is especially appropriate now that the FDA itself has explicitly established that it does not consider FDA approved drug labeling to be a minimum standard. See supra note 155 and accompanying text.

219. For a discussion of ways to strengthen drug safety regulation, see Angell, supra note 50, at 242-47.

220. See supra notes 60, 69-71 and accompanying text (discussing the FDA’s new drug labeling rule, New Drug Safety Initiative, and MedWatch, an FDA website dedicated to providing drug safety information).

221. Galson Testimony, supra note 49.
vital drugs with unavoidable side effects. Research has yet to be conducted to determine whether such legislation would have this desired effect.222

In addition, critics’ concerns that because the FDA approval and post-marketing reporting process is largely based on self-reporting, manufacturers will have no incentive to reveal unfavorable data are likely unfounded.223 Safety incentives will not be removed because the HEALTH Act of 2005 and most state statutes that provide a regulatory compliance defense do not bar punitive damages when manufacturers fail to comply with FDA regulations.224

2. The Crossover Effect

Pursuant to the HEALTH Act of 2005 as passed by the U.S. House of Representatives on July 28, 2005, punitive damages awards against pharmaceutical manufacturers are barred absent fraud.225 Aware of this shield, plaintiffs’ attorneys will likely restructure their arguments in an effort to characterize damages as economic damages,226 which are not limited by legislation, thereby dampening the shield’s effect.227 Because pharmaceutical litigation often involves sympathetic plaintiffs, jurors may want to punish and “send a message” to the pharmaceutical manufacturer, even after the FDA has determined that the manufacturer did not withhold material information that was causally related to the claimant’s alleged injury. This “crossover effect” seems most likely to occur when questionable business conduct that is not causally related to the plaintiff’s injury is presented to the jury.228

3. Changes in Safety Regulation by the FDA

Perhaps the greatest impact of FDA regulatory compliance defense legislation will be on the FDA itself. Without the potential regulatory role of punitive damages in tort litigation, the FDA might become more conservative during the pre-market drug approval process and more

222. See Green, supra note 120, at 509-10.
223. See supra note 172 and accompanying text (describing critic’s concerns about the self-reporting nature of the FDA regulatory process and tort liability’s role in educating the consumer about drug safety risks).
224. See supra Part I.B.2.a.ii (examining provisions of state statutes and the HEALTH Act that bar punitive damage when there has been FDA regulatory compliance).
225. See supra Part I.B.2.a.ii-b.
226. See Sharkey, supra note 168, at 493-95 (arguing that caps on noneconomic damages in medical malpractice cases will have an unintended “crossover effect,” thereby dampening the intended effect of the caps); see also Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832, 841 (2d Cir. 1967) (“Many awards of compensatory damages doubtless contain something of a punitive element, and more would do so if a separate award for exemplary damages were eliminated.”).
228. See Rabin, supra note 2, at 2068-69 (quoting Angell, supra note 162, at 60) (discussing Dow Corning’s “dubious business ethics” in the development and marketing of breast implants).
aggressive in its labeling requirements.\textsuperscript{229} The trick will be for these effects to strengthen drug safety without stifling innovation or decreasing drug availability.

CONCLUSION

Despite detailed and comprehensive regulation by the FDA, pharmaceuticals are co-regulated by lay fact finders who second-guess the FDA's complex public health decisions. Even if a pharmaceutical manufacturer fully complied with the FDA's requirements and disclosed material information related to the plaintiff's alleged injury, jurors are free to award punitive damages. Although regulatory compliance does not generally preclude liability, the public's interest in the availability of pharmaceuticals and the FDA's rigorous regulation, justify departure from this general rule. Because the FDA regulatory compliance defense to punitive damages allows injured claimants to be adequately compensated, and pharmaceuticals are extensively regulated by the FDA, Congress should pass the HEALTH Act, which contains a provision that precludes the award of punitive damages absent fraud. Without such a defense to punitive damages, it is likely the public, in addition to the manufacturer, that is being punished.

\textsuperscript{229} See Green, \textit{supra} note 20, at 190 n.147.