

NOTE:HUGS AND DRUGS: RESEARCH ETHICS, CONFLICT OF INTEREST, AND WHY THE FDA'S ATTEMPT TO PREEMPT PHARMA FAILURE-TO-WARN CLAIMS IS A DANGEROUS PRESCRIPTION

Spring, 2008

Reporter

6 Ave Maria L. Rev. 587 *

Length: 34565 words

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Text

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Introduction

One of the most common claims brought by patients against drug manufacturers involves the failure to warn consumers of the risks associated with taking a drug. The Food and Drug Administration ("FDA") recently adopted labeling rules and issued an accompanying advisory opinion to preempt all failure-to-warn claims brought against compliant drug manufacturers. ¹ The actions taken by the FDA, however, ultimately jeopardize the rights of injured patients to recover damages when real injury has occurred.

The purpose of this Note is to discuss the effects that the conflicting interests in drug research should have in a court's deference to the recent FDA advisory opinion. Specifically, it exposes the faulty premises upon which the FDA opinion is based and argues that the opinion can and should be disregarded. Part I sets the scene and explains how the pharmaceutical industry ("pharma") influences the process that led to the adoption of the recent advisory opinion. Next, Part II discusses the doctrine of preemption, the FDA's most recent attempt to undermine failure-to-warn claims, and courts' varied reactions. Part III examines the serious ethical problems pervading pharmaceutical research and the detrimental effect these problems are having on the accuracy of research and, consequently, the safety of drugs and their warnings. Moving to the crux of the **[*588]** issue, Part IV argues that federal preemption of failure-to-warn claims is a dangerous policy and, in light of the problems pervading drug research, it would be unwise to give the FDA little, if any, deference in this regard.

I. Background

The pharmaceutical industry's influence reaches further than most people realize. Its influence is perhaps most apparent on television where prescription and over-the-counter drug advertisements occupy an estimated 8% of commercial airtime. ² The \$ 2.5 billion that pharma spends annually on direct-to-consumer advertising has

¹ See infra Part II.

undoubtedly purchased not only the interest of consumers, but also goodwill from the media who sell various forms of advertising.³ The advent of many innovative and life-saving drugs has also won pharma the admiration of the American public.⁴ Pharma exerts another more subtle influence by earmarking \$ 14 billion annually to promote drugs directly to physicians, amounting to about \$ 30,000 per physician.⁵ This expense typically manifests itself in the form of free seminars and educational funding that generate goodwill toward pharma and commonly "sell" doctors on the drug.⁶

[*589] Of course, pharma's influence extends far beyond the obvious realm of advertising; it reaches into government,⁷ politics,⁸ front groups,⁹ regulatory agencies like the FDA,¹⁰ advisory committees,¹¹ associations responsible for creating medical guidelines,¹² research labs and clinics,¹³ medical journals,¹⁴ and

² See Erica D. Brownfield et al., *Direct-to-Consumer Drug Advertisements on Network Television: An Exploration of Quantity, Frequency, and Placement*, 9 J. Health Comm. 491, 491-97 (2004). The average American may see as many as sixteen hours of prescription drug commercials per year. Dominick L. Frosch et al., *Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising*, 5 Annals Fam. Med. 6, 6 (2007). The average American may also view thirty hours of drug advertising in total per year. Brownfield et al., *supra*, at 496. Approximately 40% of spending on direct-to-consumer prescription drug advertising is consistently "on only 10 drugs, mainly new, expensive drugs for long term use by large population groups." Barbara Mintzes, *Direct to Consumer Advertising Is Medicalising Normal Human Experience*, 324 Brit. Med. J. 908, 908 (2002).

³ See Brownfield et al., *supra* note 2, at 492.

⁴ See Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* 114 (2004).

⁵ Michael S. Wilkes & Jerome R. Hoffman, *Book Review*, 293 J. Am. Med. Ass'n 3107, 3107 (2005).

⁶ See John Abramson & Barbara Starfield, *The Effect of Conflict of Interest on Biomedical Research and Clinical Practice Guidelines: Can We Trust the Evidence in Evidence-Based Medicine?*, 18 J. Am. Board Fam. Prac. 414, 416 (2005). About 70% of physicians' continued "medical education is now paid for by the drug and other medical industries." *Id.* Doctors who accept funding for travel or lodging for continued medical educational symposia are more likely to prescribe a sponsor's drug than those who do not. Anne Victoria Neale et al., *Editorial, Conflict of Interest: Can We Minimize Its Influence in the Biomedical Literature?*, 18 J. Am. Board Fam. Prac. 411, 411 (2005).

⁷ See Angell, *supra* note 4, at 198.

⁸ See *id.* at 200.

⁹ See *id.* at 201.

¹⁰ See *id.* at 210. As another author succinctly wrote: "Many members of very influential Food and Drug Administration (FDA) advisory panels and other governmental panels also have financial relations with industry." Trudo Lemmens, *Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene*, [32 J.L. Med. & Ethics 641, 644 \(2004\)](#); accord David Willman, *Ex-NIH Director Now Favors Limiting Drug-Company Ties*, L.A. Times, Mar. 13, 2004, at A21; David Willman, *Stealth Merger: Drug Companies and Government Medical Research*, L.A. Times, Dec. 7, 2003, at A1.

¹¹ Lemmens, *supra* note 10, at 644.

¹² Abramson & Starfield, *supra* note 6, at 416 (reporting that "59% of the experts participating in guideline creation" have financial ties that conflict with their interests as guideline makers). For example, in July 2004, the National Cholesterol Education Program updated its guidelines, recommending the use of statins to lower blood pressure. *Id.* Financial conflicts of interest were not disclosed with the issuing of the new guidelines, but later investigation revealed that eight out of the nine authors had financial ties to statin makers. *Id.* One of the authors was a fulltime employee of the National Heart, Lung, and Blood Institute and also received \$ 114,000 in consulting fees from statin makers between 2001 and 2003. *Id.*

¹³ See *id.* at 414.

¹⁴ *Id.* ("Approximately 75% of clinical trials published in The Lancet, the New England Journal of Medicine (NEJM), and the Journal of the American Medical Association (JAMA) are industry funded." (quoting Health Committee, *The Influence of the Pharmaceutical Industry, 2004-2005*, H.C. 42-I, at 53, available at <http://www.publications.parliament.uk/pa/>

even classrooms. ¹⁵ In 2004 alone, pharma's efforts generated the industry more than \$ 500 billion worldwide, \$ 248 billion of which came from the United States. ¹⁶ Furthermore, pharma's pervasive influence has significantly increased prescription drug use, even among the healthy. ¹⁷ Over the last ten years, "the number of prescriptions issued annually has increased approximately 67%." ¹⁸ Today, nearly half of Americans [***590**] take at least one prescription drug, ¹⁹ and in 2004 the average person had approximately twelve prescriptions each year. ²⁰

While drugs have saved the lives of many patients, increased drug use has demonstrated many harmful consequences. Independent research suggests that adverse reactions to even properly prescribed and administered medication is between the fourth and the sixth leading cause of death in the United States, killing more than 106,000 people annually. ²¹ Additionally, more than two million serious adverse reactions to properly taken prescription drugs occur annually. ²² This amounts to 6.7% of hospitalized patients sustaining drug-related injuries. ²³ Many researchers suggest that even these shocking figures are low, ²⁴ particularly since prescription drug use has significantly escalated since those estimates were made.

Despite such statistical research, most people do not realize the serious health risks that even over-the-counter and common prescription drugs pose. Drugs are often viewed as a safe and acceptable way to maintain a comfortable but unhealthy lifestyle. ²⁵ Regardless of whether there are apparent side effects, every drug has toxic effects. ²⁶ The United States has decided to weigh these toxic effects against potentially beneficial uses. ²⁷ Congress created the FDA in order to establish minimum safety requirements for products like prescription drugs. ²⁸ The FDA

cm200405/cmselect/cmhealth/42/42.pdf)); see also Neale et al., *supra* note 6, at 412 (explaining that medical journals ask authors to disclose conflicting interests, but do not have the resources, nor the responsibility, to personally investigate the conflicting interests of authors).

¹⁵ See David Blumenthal, Special Communication, Academic-Industry Relationships in the Life Sciences, 268 J. Am. Med. Ass'n 3344, 3344-49 (1992).

¹⁶ Jacky Law, Big Pharma: Exposing the Global Healthcare Agenda 10 (2006); Jonathan V. O'steen & Van O'steen, The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs, [48 Ariz. L. Rev. 67, 93 \(2006\)](#).

¹⁷ Cf. Mintzes, *supra* note 2, at 909.

¹⁸ O'steen & O'steen, *supra* note 16, at 93.

¹⁹ Nat'l Ctr. for Health Statistics, Centers for Disease Control and Prevention, Health, United States, 2004, with Chartbook on Trends in the Health of Americans 50-53 (2004).

²⁰ Greg Critser, Generation RX 2 (2005).

²¹ See Jason Lazarou et al., Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-Analysis of Prospective Studies, 279 J. Am. Med. Ass'n 1200, 1204 (1998).

²² See *id.* at 1200.

²³ See *id.*

²⁴ See, e.g., *id.* at 1204. The number of deaths supposedly caused by Vioxx alone suggest that the number may be higher than 106,000 per year: "A Food and Drug Administration ("FDA") study published after the recall estimated that Vioxx caused as many as 140,000 heart-related injuries and may have led to as many as 56,000 deaths in the United States alone in the five years the drug was on the market." O'steen & O'steen, *supra* note 16, at 67.

²⁵ See Law, *supra* note 16, at 23.

²⁶ Brian L. Strom, Commentary, Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: A Counterpoint, 292 J. Am. Med. Ass'n 2643, 2643 (2004).

²⁷ *Id.*

balances the reported benefits and risks associated with a drug and must find that the benefits appear to outweigh the risks in order for the drug to be legally sold in the [*591] United States. ²⁹ Additionally, the manufacturer must adequately warn consumers of potential risks and side effects associated with the drug. ³⁰

Unfortunately, the information that the FDA uses to approve drugs is frequently skewed by conflicting interests. Institutions, researchers, practicing physicians, and even FDA employees commonly have financial ties to pharma. ³¹ Even prestigious academic institutions such as Harvard Medical School are not immune from financial conflicts of interest. ³² The prevalence of these ties is a serious obstacle to the integrity of research and the practice of medicine, and has triggered a growing outcry. Medical journals commonly lament the serious problems created by these conflicting interests, and with good cause: such conflicts of interest undermine the objective study and evaluation of new medications. ³³ Accordingly, drugs frequently enter the market with exuberant approval, only to cause a rash of severe and unexpected side effects. ³⁴

In the meantime, alleged victims of adverse drug reactions are suing pharma en masse. The most prevalent claim is that the manufacturer failed to properly warn of the damaging side effects. ³⁵ For example, Merck, the manufacturer of Vioxx, faced more than 1357 product liability claims within the first year of the drug's withdrawal from the market. ³⁶ Since many claims result in multi-million dollar awards, they can pose a significant threat to pharma's financial [*592] viability. ³⁷ Consequently, some scholars support the creation of a fortress around pharma to protect it from allegedly frivolous claims that supposedly threaten to keep life-saving drugs from suffering patients. ³⁸

²⁸ Anne Erikson Haffner, Comment, The Increasing Necessity of the Tort System in Effective Drug Regulation in a Changing Regulatory Landscape, 9 J. Health Care & Pol'y, 365, 372-73 (2006).

²⁹ Howard L. Dorfman et al., Presumption of Innocence: FDA's Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate, *61 Food & Drug L.J.* 585, 590-91 (2006).

³⁰ Id. at 587-88.

³¹ See *infra* Part III.

³² See, e.g., Marcia Angell, Editorial, Is Academic Medicine for Sale?, 342 *New Eng. J. Med.* 1516, 1516 (2000) (noting that Harvard Medical School considered making the guidelines more lenient in 2000 with regard to permissible financial ties between faculty members and pharma).

³³ E.g., *id.*; Neale et al., *supra* note 6, at 411-13. But see Catherine D. DeAngelis, Editorial, The Influence of Money on the Medical Science, 296 *J. Am. Med. Ass'n* 996, 996 (2006) ("The influence of commercial interests on medical science is far-reaching but, to a great degree, essential.").

³⁴ Examples include Vioxx, Prozac, and a number of other selective serotonin reuptake inhibitors ("SSRIs"). See, e.g., Law, *supra* note 16, at 87-120 (explaining the rapid success of Vioxx, the health problems that resulted, and the long term success and use of SSRIs).

³⁵ O'steen & O'steen, *supra* note 16, at 82.

³⁶ Id. at 67 ("By March 9, 2005, Merck was already facing 1357 claims in connection with its defective drug.").

³⁷ See Ctr. for Legal Policy, Trial Lawyers Inc., Health Care 4, 6, 8, 9 (2005), <http://www.triallawyersinc.com/TLI-HealthCare.pdf>. For example, "in June 2005, the manufacturer [of the antipsychotic drug olanzapine] announced a \$ 690 million settlement of more than 8000 olanzapine lawsuits." Aaron S. Kesselheim & Jerry Avorn, Commentary, The Role of Litigation in Defining Drug Risks, 297 *J. Am. Med. Ass'n* 308, 309 (2007).

³⁸ Cf. O'steen & O'steen, *supra* note 16, at 93 ("The FDA contends that the threat of lawsuits harms the public by encouraging manufacturers to withdraw beneficial products or issue warnings that overemphasize risks, leading to underutilization of medical devices and prescription drugs." (footnote omitted)).

Naturally, pharma is not taking its litigation and settlement costs lightly. Pharma has made great strides to protect its interests by hiring more than 600 well-connected, full-time lobbyists (including many former members of Congress) and drawing in millions of dollars in campaign contributions.³⁹ A prime example of pharma's influence in Washington, D.C., is the rewritten Medicare drug law, which forbids the government from negotiating lower drug prices.⁴⁰ Shortly after the amended bill was passed, the congressman who promoted the bill was appointed as the President of the Pharmaceutical Research and Manufacturers of America (PhRMA), the industry's trade association.⁴¹ Most recently, in January 2006, pharma's efforts were rewarded by new FDA labeling rules and an influential advisory opinion that clearly attempts to block all failure-to-warn claims against the industry.⁴² This opinion specifically states that the FDA intends to preempt all failure-to-warn claims against drug manufacturers where the manufacturer complied with FDA regulations.⁴³

[*593] While some dismiss these developments as mere politics inside the Beltway, the FDA's latest actions in favor of pharma jeopardize the legal remedies of every American patient. If courts follow the FDA's recommendation to treat failure-to-warn claims as preempted, it would substantially hinder or even destroy a plaintiff's ability to recover against a manufacturer for inadequate and unsafe warnings.⁴⁴ It may also undermine other claims since "most civil actions brought against a pharmaceutical manufacturer for liability from a defective drug hinge on the company's failure to warn of a known risk."⁴⁵ Furthermore, the advisory opinion may be extended to protect pharma from a variety of other products liability claims since it states that FDA approval should preempt at least any failure-to-warn claims.⁴⁶

In addition to leaving plaintiffs uncompensated for corporate wrongs, the FDA's recommendation has a number of substantive flaws. It raises issues of federalism and arguably may interfere with constitutional rights. This Note does not address those issues since they have been amply commented on with relation to preemption.⁴⁷ Instead, this Note discusses the effect that the conflicting interests dominating drug research should have on the deference afforded to the FDA's advisory opinion. The conflicting interests haunting drug research destroy the premises on which the reasoning of the FDA's advisory opinion is based. Therefore, the FDA's opinion is outweighed by other factors and accordingly should not be followed.

II. Preemption

³⁹ Angell, *supra* note 4, at 198, 200 (stating that pharma employed 675 lobbyists in 2002, over twenty of whom were former congressmen, and in the 1999-2000 election cycle gave \$ 20 million in direct campaign contributions and an additional \$ 65 million in "soft" money).

⁴⁰ Law, *supra* note 16, at 169.

⁴¹ *Id.* (noting that former Congressman Billy Tauzin receives a salary that is rumored to be around \$ 2 million per year and that the Medicare bill passed in 2003 had an estimated cost of approximately \$ 400 billion over ten years).

⁴² See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, [71 Fed. Reg. 3922, 3933-36](#) (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) [hereinafter Labeling Requirements]. See generally Robert N. Weiner, Preemption and the FDA Preamble, 878 PLI/Pat 847 (2006) (explaining the ramifications of the FDA's 2006 advisory opinion and the prevalent arguments in relation to the rule).

⁴³ Labeling Requirements, *supra* note 42, at 3934.

⁴⁴ James T. O'Reilly, A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?, [58 Food & Drug L.J. 287, 288 \(2003\)](#).

⁴⁵ O'steen & O'steen, *supra* note 16, at 82.

⁴⁶ Labeling Requirements, *supra* note 42, at 3935-36.

⁴⁷ See, e.g., O'Reilly, *supra* note 44.

Proponents of greater protection for pharma have long argued that FDA approval should preempt failure-to-warn claims.⁴⁸ The doctrine of preemption is rooted in the Supremacy Clause of the U.S. Constitution, which states that federal law is the supreme law of the [*594] land.⁴⁹ Under the doctrine of preemption, "state law that conflicts with federal law is "without effect."⁵⁰

As a general rule, there is a presumption against the preemption of state law. Recognizing that states are "independent sovereigns," some courts have been wary of applying the preemption doctrine.⁵¹ For a federal statute to displace state law, congressional intent must be readily apparent in either the statute's language or its structure and purpose.⁵² Furthermore, a long history of tort litigation serves as evidence against preemption, since Congress would presumably express any intent to "deprive injured parties of a long available form of compensation."⁵³

There are three recognized forms of preemption: (1) express preemption, (2) implied field preemption, and (3) implied conflict preemption.⁵⁴ Express preemption occurs when Congress specifically states its intent to displace state law.⁵⁵ With the exception of a few state laws, courts agree that failure-to-warn claims against pharma do not present a question of express preemption.⁵⁶ Likewise, such claims do not [*595] involve implied field preemption, which is inferred where Congress has "implemented a comprehensive regulatory framework, thereby indicating its

⁴⁸ See, e.g., [Mich. Comp. Laws Ann. § 600.2946\(5\)](#) (West 2005) (a statute enacted to protect manufacturers from failure-to-warn claims where the drug complies with FDA regulations at the time of sale).

⁴⁹ [U.S. Const. art. VI, § 2.](#)

⁵⁰ [Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 \(1992\)](#) (quoting [Maryland v. Louisiana, 451 U.S. 725, 746 \(1981\)](#)).

⁵¹ See, e.g., [Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 \(1996\)](#) ("Because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.").

⁵² [Cipollone, 505 U.S. at 516](#) ("Congress' intent may be explicitly stated in the statute's language or implicitly contained in its structure and purpose. In the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." (internal quotation marks omitted) (citations omitted)).

⁵³ [Bates v. Dow Agrosciences L.L.C., 544 U.S. 431, 449 \(2005\)](#); [Levine v. Wyeth, 2006 VT 107U](#) P P 7-8, petition for cert. filed, **127 S. Ct. 2451 (2007)** (requesting the Solicitor General's view on granting certiorari), cert. granted, **128 S. Ct. 1118 (2008)**.

⁵⁴ [Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 \(2000\)](#); [English v. Gen. Elec. Co., 496 U.S. 72, 78-79 \(1990\)](#); [Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 95 \(1983\)](#).

⁵⁵ [Crosby, 530 U.S. at 372](#); [English, 496 U.S. at 78-79](#).

⁵⁶ See, e.g., [Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 684 \(E.D. Pa. 2006\)](#); [McNellis v. Pfizer, Inc., No. 05-1286, 2006 U.S. Dist. LEXIS 70844, at 14 \(D.N.J. Sept. 29, 2006\)](#); [Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964, 966 \(D. Neb. 2006\)](#); [Laisure-Radke v. Par Pharm., Inc., No. C03-3654RSM, 2006 U.S. Dist. LEXIS 78804, at 6 \(W.D. Wash. Apr. 3, 2006\)](#). Additionally, it is generally agreed that Congress has specifically precluded the use of express preemption with regards to defective drug claims. The Federal Food, Drug, and Cosmetic Act of 1962 states:

Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of State law.

Federal Food, Drug, and Cosmetic Act of 1962, [Pub. L. No. 87-781, 76 Stat. 780](#), 793 (1962).

intention to reserve that area solely for federal control." ⁵⁷ Accordingly, conflict preemption appears to be the only form of preemption that the FDA has the authority to exert in products liability cases against pharma.

Implied conflict preemption exists where "it is impossible for a private party to comply with both state and federal law, and where "under the circumstances of [a] particular case, [the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." ⁵⁸ Federal law will preempt state law only to the extent of the conflict between state and federal law. ⁵⁹ Until recently, defendants have generally been unsuccessful in claiming that FDA regulations conflict with state law and preempt failure-to-warn claims. ⁶⁰ Now, the FDA itself is formally claiming that its regulations should protect pharma from failure-to-warn claims. ⁶¹

A. The FDA's Preemption Preamble

A product is considered defective when it does not provide adequate warning of its dangers and "the foreseeable risks of harm posed by the product could have been reduced or avoided" by adequate warning. ⁶² Traditionally, a plaintiff can recover for a manufacturer's failure-to-warn by showing that the manufacturer knew or should have known of the risk, but did not warn consumers of it. ⁶³ For example, many plaintiffs have sued the manufacturer of the anti-depressant Zoloft for failing to warn consumers about an alleged increased risk of suicide linked to taking the drug. ⁶⁴ While the typical complaint against a drug manufacturer will include many [*596] claims, most recoveries against pharma rely on the defendant's failure to warn. ⁶⁵

The FDA, compelled by pharma's influence, is attempting to thwart failure-to-warn claims with new labeling requirements for prescription drugs announced in January 2006. ⁶⁶ In the preamble to these requirements ("Preamble"), the FDA announced that "under existing preemption principles ... FDA approval of labeling ... preempts conflicting or contrary State law." ⁶⁷ It further states that the "FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." ⁶⁸ If the FDA's current intention expressed in the Preamble is followed, it could effectively destroy

⁵⁷ [Verizon New Eng., Inc. v. R.I. Pub. Utils. Comm'n](#), 822 A.2d 187, 193 (R.I. 2003); see also [Crosby](#), 530 U.S. at 372; [English](#), 496 U.S. at 79.

⁵⁸ [Crosby](#), 530 U.S. at 372-73 (quoting [Hines v. Davidowitz](#), 312 U.S. 52, 67 (1941)) (alteration in original) (citation omitted).

⁵⁹ [Cipollone v. Liggett Group, Inc.](#), 505 U.S. 504, 516 (1992).

⁶⁰ O'Reilly, *supra* note 44, at 288 n.10.

⁶¹ Labeling Requirements, *supra* note 42, at 3935-36.

⁶² Restatement (Third) of Torts: Product Liability § 2 (1998).

⁶³ *Id.* at cmt. m.

⁶⁴ See, e.g., [Jackson v. Pfizer, Inc.](#), 432 F. Supp. 2d 964, 965 (D. Neb. 2006). For information discussing the link between suicide and certain kinds of anti-depressants known as SSRIs, see Law, *supra* note 16, at 104-20.

⁶⁵ O'steen & O'steen, *supra* note 16, at 82.

⁶⁶ See Labeling Requirements, *supra* note 42, at 3922; Dorfman et al., *supra* note 29, at 590.

⁶⁷ Labeling Requirements, *supra* note 42, at 3933.

⁶⁸ *Id.* at 3935.

all failure-to-warn claims against pharma that fail to prove outright fraud.⁶⁹ Further, it could usher in an era of federal preemption for other claims against pharma, such as design defect.⁷⁰

The FDA's strong stance against consumer lawsuits represents a complete reversal from its position only seven years ago.⁷¹ Historically, the FDA applauded failure-to-warn lawsuits and other products liability claims against pharmaceutical companies as a necessary component in protecting consumers.⁷² The FDA maintained that its regulations were merely the minimum safety requirement and that states could require better warnings.⁷³ In fact, when the new labeling requirements were part of a proposed amendment in 2000, the FDA clearly expressed its intent that they would have no preemptive effect on state law:

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Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule, if finalized, on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of Government. In addition, this proposed rule does not preempt State law.⁷⁴

What the FDA once intended to be a "minimum"⁷⁵ requirement is now intended to impose "both a floor and ceiling" on labeling requirements.⁷⁶

The FDA has forcefully argued its new position, submitting several amicus briefs in state and federal courts in defense of pharma.⁷⁷ The FDA points out that the misbranding of a drug is illegal.⁷⁸ Placing a false or misleading warning on a label constitutes misbranding of a drug.⁷⁹ The FDA considers any warning that is not scientifically substantiated to be false or misleading.⁸⁰ Additionally, the FDA is concerned that scientifically unsubstantiated warnings could frighten some people away from taking the drug, "thereby chilling the drug's otherwise beneficial

⁶⁹ See *id. at 3936* (describing the types of claims that are preempted, including where a company "breached an obligation to warn," but providing an exception where the FDA finds that "the sponsor withheld material information relating to the proposed warning").

⁷⁰ The Preamble stated that it intended to "at least" preempt failure to warn claims. Labeling Requirements, *supra* note 42, at 3935-36 (emphasis added). This leaves ample room for the Preamble to be invoked as support for preempting other products liability claims against pharmaceutical companies as well.

⁷¹ See *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 526 (E.D. Pa. 2006); O'Reilly, *supra* note 44, at 288.

⁷² Cf. O'steen & O'steen, *supra* note 16, at 69 (noting that historically the FDA was not "amenable" to the preemption argument).

⁷³ Cf. O'Reilly, *supra* note 44, at 288.

⁷⁴ Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Labels, *65 Fed. Reg. 81082, 81103* (proposed Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201) (emphasis added).

⁷⁵ *Id.*

⁷⁶ Labeling Requirements, *supra* note 42, at 3935 (internal quotation marks omitted).

⁷⁷ See, e.g., *Brief for the United States of America as Amici Curiae Supporting Respondents, Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597); Corrected Brief for the United States of America as Amici Curiae Supporting Respondents, *Kallas v. Pfizer, Inc.*, No. 2:04-00998 (D. Utah Sept. 29, 2005).

⁷⁸ *21 U.S.C. § 331(a)*, (b), (k) (2000).

⁷⁹ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 526 (1992).

⁸⁰ *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 527 (E.D. Pa. 2006) (indicating that "public policy requires that warnings be scientifically substantiated").

use." ⁸¹ Requiring warnings to be scientifically substantiated also helps prevent patients and doctors from becoming numbed to warnings and affording them little weight as a result of overexposure to trivial risks. ⁸² Likewise, more important warnings could lose meaning in a sea of other unsubstantiated [***598**] warnings. ⁸³ As it is, warnings accompanying drugs are long enough to confuse or lose the interest of many patients. ⁸⁴

Moreover, the FDA has asserted in an amicus brief that a "drug manufacturer is not permitted to add a warning or caution to the label without prior approval from the FDA." ⁸⁵ The Preamble explains that the "FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading." ⁸⁶ As the expert, it "carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use." ⁸⁷ Accordingly, the FDA argues that where a pharmaceutical manufacturer complies with FDA regulations, the manufacturer should not be blamed for a failure to warn since the FDA reviews proposed warnings and has authority to accept or reject them in accordance with the evidence. ⁸⁸

The most common retort to this assertion is that manufacturers have statutory authority to strengthen a warning label without prior FDA approval. Specifically, [21 C.F.R. § 314.70](#) states that a drug manufacturer with an approved drug may "add or strengthen a contraindication, warning, precaution, or adverse reaction" on a label, and distribute the drug with said changes "upon receipt by the [FDA] of a supplement for the change." ⁸⁹ But the FDA has contended in amicus briefs that this is not really an option - in practice, the industry simply does not use the rule. ⁹⁰ Rather, a pharmaceutical company that suspects that a warning should be added or strengthened submits the suggested change to the FDA, since the FDA ultimately must accept or reject the change. ⁹¹ While this argument seems weak on its face, it still carries weight with some courts. ⁹²

[*599] The question remains whether the Preamble will be accepted as the FDA has intended - as interpreting the regulation in such a way as to preempt state-law failure-to-warn claims. So far, courts' responses have varied.

B. Courts' Responses

⁸¹ Id.; see also Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, [11 Yale J. on Reg. 293, 385-91 \(1994\)](#) (explaining how warnings must be balanced in severity to sufficiently explain the risk associated with a product while not deterring individuals from using a useful product).

⁸² See Noah, *supra* note 81, at 382-83, 388-90. For the application of this concept to everyday household potentially hazardous substances, consider the discussion on labeling in H.R. Rep. No. 86-1861, at 2837 (1960), as reprinted in 1960 U.S.C.C.A.N. 2833, 2837.

⁸³ Noah, *supra* note 81, at 381-85.

⁸⁴ See *id.*

⁸⁵ [Colacicco, 432 F. Supp. 2d at 527](#) (citation omitted) (emphasis omitted) (internal quotation marks omitted).

⁸⁶ Labeling Requirements, *supra* note 42, at 3934.

⁸⁷ *Id.*

⁸⁸ See [id. at 3934-36](#).

⁸⁹ [21 C.F.R. § 314.70\(c\)\(6\)\(iii\)\(A\) \(2007\)](#).

⁹⁰ See [Colacicco, 432 F. Supp. 2d at 527](#).

⁹¹ Labeling Requirements, *supra* note 42, at 3934.

⁹² [Colacicco, 432 F. Supp. 2d at 527 n.11](#).

Supreme Court precedent directs courts to defer to an executive agency's interpretation of its organic statute and statutes it administers.⁹³ Deference should only be granted, however, to the degree that the agency acts within the authority granted by Congress.⁹⁴ Where an agency has been inconsistent in its interpretation of a statute, its position is sometimes afforded less deference.⁹⁵ Courts have varied in the degree of deference they give to the Preamble and the FDA's recent interpretation stated therein.

Some courts have deferred to the Preamble and precluded recovery against FDA-compliant drug companies for failure to warn.⁹⁶ In *Colacicco v. Apotex, Inc.*, a widower brought suit against the manufacturer of the anti-depressant Paxil as well as its generic brand equivalent, claiming that his wife's suicide resulted from the defendant's "failure to warn of the increased risk of suicidal behavior linked to the anti-depressant, Paxil and/or its generic equivalent."⁹⁷ Relying extensively on an amicus brief filed by the FDA, the U.S. District Court for the Eastern District of Pennsylvania dismissed the claim in deference to the FDA's Preamble.⁹⁸ The court noted the [*600] FDA's inconsistency in its preemption policy, but minimized the FDA's flip-flop by noting that, after 2000, it had been consistent in its construction of the preemption doctrine's applicability.⁹⁹

Other courts have not been so willing to defer to the FDA. In *Perry v. Novartis Pharmaceuticals Corp.*, a different district court judge in the Eastern District of Pennsylvania reached the opposite conclusion and minimized the impact of the Preamble.¹⁰⁰ In this case, an infant developed lymphoma six months after commencing use of Elidel, a prescription drug for eczema.¹⁰¹ The court refused to dismiss the failure-to-warn claim, reasoning that the Preamble had little, if any, authority - as defined in the Code of Federal Regulations, the Preamble is merely an advisory opinion and thus not entitled to any judicial deference.¹⁰² Moreover, the *Perry* court noted that inconsistencies in the FDA's interpretation of its own regulations further limited its influence.¹⁰³ In addressing the

⁹³ [*Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 \(1984\)](#) ("[The Court has] long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"); [*Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 \(1994\)](#).

⁹⁴ [*United States v. Mead Corp.*, 533 U.S. 218, 226-27 \(2001\)](#).

⁹⁵ See, e.g., [*Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 \(2000\)](#) (holding that deference to an agency is not appropriate when it "contradicts the agency's own previous construction that this Court adopted as authoritative").

⁹⁶ See, e.g., *Ackerman v. Wyeth Pharm.*, No. 4:05 CV84, [2006 U.S. Dist. LEXIS 64499, at 19 \(E.D. Tex. Sept. 8, 2006\)](#) ("Absent some evidence that a drug manufacturer has misled the FDA or failed to disclose critical information, preemption should apply in a failure to warn case."); [*Colacicco*, 432 F. Supp. 2d at 529](#) (dismissing failure-to-warn lawsuit because deference should be granted to the Preamble). But see [*Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 683 \(E.D. Pa. 2006\)](#) ("For a number of reasons, we find that the Preamble need not affect our analysis of the issues in this case."); [*Levine v. Wyeth*, 2006 VT 107U P 34](#), petition for cert. filed, **127 S. Ct. 2451 (2007)** (requesting the Solicitor General's view on granting certiorari), cert. granted, **128 S. Ct. 1118 (2008)** (effectively ignoring the Preamble).

⁹⁷ [*Colacicco*, 432 F. Supp. 2d at 518](#).

⁹⁸ [Id. at 526-28](#).

⁹⁹ [Id. at 531-32](#).

¹⁰⁰ [*Perry*, 456 F. Supp. 2d at 683](#).

¹⁰¹ [Id. at 681](#).

¹⁰² [Id. at 683](#).

issue of preemption, the court's most important consideration was that the Preamble "deals chiefly with "specific warnings that FDA had specifically considered and rejected as scientifically unsubstantiated." ¹⁰⁴ The court argued that, in order for preemption to even be considered, the proposed warning must have been considered and subsequently rejected by the FDA. ¹⁰⁵ That was not the case in Perry. ¹⁰⁶

The Supreme Court of Vermont discussed the Preamble's effect in *Levine v. Wyeth*. ¹⁰⁷ In *Levine*, a severe reaction caused by an improperly administered dose of the painkiller Phenergen forced doctors to amputate the plaintiff's arm. ¹⁰⁸ Rather than question the validity of the Preamble, the Vermont Supreme Court stated that the preemptive direction of the Preamble simply did not apply as either authoritative or persuasive since no "direct and positive conflict" [*601] between state and federal law existed. ¹⁰⁹ The court rested this judgment on a provision in [21 C.F.R. § 314.70](#) which "allows drug manufacturers to add or strengthen a warning "to increase the safe use of the drug product' without prior FDA approval." ¹¹⁰

On the other hand, the *Colacicco* court agreed with the FDA that this was an unreasonable interpretation. ¹¹¹ The FDA stated that, contrary to what decisions in cases such as *Levine* assert, a "drug manufacturer is not permitted to add a warning or caution to the label without prior approval from the FDA." ¹¹² The *Colacicco* court used [21 C.F.R. § 314.150](#) as evidence, noting that this regulation provides that the FDA will remove a generic drug's approval for sale if its label is different from that of the name brand drug. ¹¹³ In order to change the label, a generic drug maker must first receive approval from the FDA. ¹¹⁴ Further, the *Colacicco* court again stated that it would defer to the FDA - the congressionally-created expert for interpretation of all of its rules - including such rules that are clear on their face. ¹¹⁵

Colacicco, *Perry*, and *Levine* demonstrate an array of reactions to the Preamble. In *Perry* and *Levine*, the courts correctly did not defer to the FDA's Preamble. Nonetheless, this issue is still hotly contested. Considerations such as the FDA's authority, consistency, expertise, review of specific warning claims, and interpretation of the regulations themselves have influenced courts' decisions. ¹¹⁶ There are enough considerations that a judge's

¹⁰³ *Id.* ("To be sure, because of its expertise in the area, the FDA's construction of its own regulations is likely to carry great weight. But where an interpretation has changed frequently in significant respects, the persuasive force of the argument diminishes.").

¹⁰⁴ See [id. at 684](#) (quoting Labeling Requirements, *supra* note 42, at 3934).

¹⁰⁵ [Id. at 685](#).

¹⁰⁶ [Id. at 687](#).

¹⁰⁷ [Levine v. Wyeth, 2006 VT 107U P 34](#), petition for cert. filed, **127 S. Ct. 2451 (2007)** (requesting the Solicitor General's view on granting certiorari), cert. granted, **128 S. Ct. 1118 (2008)**.

¹⁰⁸ *Id.* P 2.

¹⁰⁹ *Id.* P 34.

¹¹⁰ *Id.* P 32 (quoting [21 C.F.R. § 314.70\(c\)\(6\)\(iii\)\(C\) \(2006\)](#)).

¹¹¹ See [Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 527 \(E.D. Pa. 2006\)](#).

¹¹² [Id. at 527](#) (emphasis omitted) (internal quotation marks omitted).

¹¹³ [Id. at 528](#).

¹¹⁴ *Id.* (relying on the FDA's interpretation of [21 C.F.R. § 314.150](#)).

¹¹⁵ *Id.*

personal view on the state of pharma is often likely to tip the scale.¹¹⁷ Accordingly, courts must consider the policy implications that FDA preemption would have on [*602] public health.¹¹⁸ Some would take the Preamble a step further and suggest that compliance with the FDA should also preempt defective design claims.¹¹⁹

These views are premised on the idea that the FDA rigorously evaluates each new drug application and can accurately weigh and balance the benefits and risks of a drug.¹²⁰ Inherent in this premise is the assumption that the FDA and the researchers who supply the FDA with data and interpretations of data are operating with objective and detached judgment.¹²¹ Unfortunately, the evidence is to the contrary.

III. Conflict of Interest in Research

Conflict of interest has been described in the medical community as "a set of conditions in which professional judgment concerning a primary interest ... tends to be unduly influenced by a secondary interest."¹²² Lawyers have long recognized that conflict of interest - particularly self-interest - often thwarts the pursuit of justice.¹²³ This knowledge has deeply affected the way that attorneys practice law. Attorneys have collectively decided to approach issues involving conflict of interest carefully.¹²⁴

[*603] Unfortunately, the medical community has not taken the same precautions, most likely because of self-perception: "The typical scientist finds it incredulous that any financial interest they might have connected to their research would affect the way they do science."¹²⁵ Such beliefs can possibly be attributed to the relatively recent appearance of financial interests in the medical community.¹²⁶ For instance, prior to the 1970s, drug companies

¹¹⁶ Cf. *supra* notes 93-96 and accompanying text.

¹¹⁷ Joseph J. Leghorn et al., *Defending an Emerging Threat: Consumer Fraud Class Action Suits in Pharmaceutical and Medical Device Products-Based Litigation*, [61 Food & Drug L.J. 519, 528 \(2006\)](#) (discussing that precedent demonstrates that "the amount of deference, if any, afforded to the Preamble will likely hinge upon the dispositive force of Chevron ... as well as the weight afforded to the consistency of FDA's position on preemption. Absent intervention by the Supreme Court, much will still depend upon whether a particular trial court judge holds strong convictions for or against implied preemption in the pharmaceutical context." (emphasis added)).

¹¹⁸ When considering whether to defer to the FDA, a court must consider "whether FDA's interpretation that labeling regulations preempt state law is a "reasonable accommodation of conflicting policies." Dorfman et al., *supra* note 29, at 611 (quoting [Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta, 458 U.S. 141, 154 \(1982\)](#)); cf. Leslie C. Kendrick, *FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption*, [62 Food & Drug L.J. 227, 227, 233-38 \(2007\)](#) (arguing that the Preamble should not be granted the high level of deference found in Chevron, but weighed on its own merits).

¹¹⁹ Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, [58 Okla. L. Rev. 135, 137 \(2005\)](#).

¹²⁰ See Dorfman et al., *supra* note 29, at 587, 591.

¹²¹ The FDA primarily relies on the data that a drug manufacturer submits to determine whether testing of a drug may move on to clinical trials. Accordingly, in order to accurately evaluate a drug, the data submitted must be accurate. See *id.* at 587.

¹²² Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 N. Eng. J. Med. 573, 573 (1993).

¹²³ Public mistrust of lawyers based on conflict of interest can be traced back earlier than the Industrial Revolution. Robert F. Cochran, Jr. & Teresa S. Collett, *Cases and Materials on the Legal Profession* 4-5 (2d ed. 2003). As a response to criticism and mistrust within the profession, states and the American Bar Association have adopted model codes and rules that forbid or regulate a variety of situations that involve conflicts of interest. See *id.* at 5.

¹²⁴ See Model Rules of Prof'l Conduct R. 1.7-1.9 (2003) (instructing lawyers to carefully handle conflicting interests by informing clients of any potential conflicts); see also Model Code of Judicial Conduct Canon 3E (2004) (addressing the disqualification of judges).

¹²⁵ Sheldon Krinsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* 129 (2003).

were rarely the sole sponsors of clinical studies; today it is a common practice. ¹²⁷ Today, however, it is often difficult to find an expert in any specialty involving "the heavy use of expensive drugs" who does not have financial ties to drug companies. ¹²⁸ Indeed, pharma's influence has reached deeper into the medical community than most realize.

As discussed above, pharma has invested billions in medical research, reaping substantial goodwill from the medical community. ¹²⁹ It poured over \$ 33 billion into research in 2003 alone, accounting for 70% of investment in clinical trials. ¹³⁰ Academia, the supposed voice of objectivity and independence, has accepted billions of dollars from pharma to conduct research. ¹³¹ In addition to funding studies of its drugs, pharma commonly hires influential experts as consultants. For example, a 1992 survey of 800 biotechnology faculty at universities and medical schools showed that 47% worked for pharma as [*604] consultants, 25% received pharma-supported grants, and 8% had investments in companies likely to be affected by their research. ¹³²

In many respects, this new relationship has been beneficial. ¹³³ Increased contacts between pharma and academia can allow for better communication and collaboration, and consequently, quicker dissemination of new products to the public. ¹³⁴ Furthermore, added financial incentive may keep highly qualified researchers working in public universities. ¹³⁵ In many cases, it also allows clinics to stay financially afloat. ¹³⁶ The flip-side of the coin is

¹²⁶ See [id. at 128](#) (explaining that "the association of conflict of interest with scientists and medical researchers is relatively new").

¹²⁷ Abramson & Starfield, *supra* note 6, at 414. There also used to be greater restrictions on academic scientists pursuing personal financial gain while serving in an academic position. The 1980s saw a massive breakdown between academic science and pharma. Krinsky, *supra* note 125, at 30-31. A series of laws, including the Bayh-Dole Act, encouraged academic institutions to further increase creating research situations wrought with conflict of interest by creating incentives for publicly funded researchers and employees to work with pharma. See *id.* at 30-33.

¹²⁸ Angell, *supra* note 32, at 1516.

¹²⁹ Wilkes & Hoffman, *supra* note 5, at 3107 (noting that \$ 14 billion is spent annually by pharma promoting drugs directly to physicians, which translates to approximately \$ 30,000 per physician).

¹³⁰ Gordon DuVal, Institutional Conflicts of Interest: Protecting Human Subjects, Scientific Integrity, and Institutional Accountability, [32 J.L. Med & Ethics 613, 613 \(2004\)](#) ("Between 1980 and 2003, overall research and development expenditures by US pharmaceutical companies increased from \$ 2 billion to \$ 33 billion ...").

¹³¹ See Hamilton Moses III et al., Financial Anatomy of Biomedical Research, 294 J. Am. Med. Ass'n 1333, 1337 (2005). Academic medical centers are now commonly dependent on money from pharma companies. See, e.g., Lemmens, *supra* note 10, at 645 (noting that 31% of Duke's research funding and 20% of MIT's research funding is from pharma).

¹³² Krinsky, *supra* note 125, at 111.

¹³³ See Angell, *supra* note 32, at 1516-17 (noting that rationales for the link between academic medicine and for-profit industry include helping to facilitate technology transfer and providing money for medical research in the academic setting); DeAngelis, *supra* note 33, at 996 ("The discovery of new medications, devices, and techniques is funded primarily by for-profit companies; testing new modalities of treatment is funded primarily by for-profit companies; and the manufacture and profitable marketing aspects of these modalities appropriately falls in the purview of this industry." (footnote omitted)).

¹³⁴ See Angell, *supra* note 32, at 1516.

¹³⁵ See *id.* at 1516.

¹³⁶ *Id.* at 1517. Medicare payment cuts in 1997 have made it particularly difficult for many medical centers to stay in business while still serving the poorest patients. *Id.* Increased commercialization of these nonprofit groups allows them to supplement their income. See *id.*

that such a connection creates a grave conflict of interest for researchers. ¹³⁷ Research is no longer simply an academic pursuit - it is now an industry. ¹³⁸

A. How Conflict of Interest Affects Research

Social scientists' research shows that a self-serving bias makes neutrality unlikely even for sincere sophisticated professionals. ¹³⁹ "Among even the highest quality clinical research ... the odds are 5.3 times greater that commercially funded studies will support their sponsors' products than noncommercially funded studies." ¹⁴⁰ This makes sense because researchers have a significant incentive to report **[*605]** findings that are favorable to their sponsor. ¹⁴¹ Favorable results mean that acquiring funding for another study will be easier. On the contrary, negative results may result in a loss of funding. ¹⁴² The New England Journal of Medicine reported one such example that involved a researcher who reported that a sponsor's drug caused adverse reactions. ¹⁴³ In response, the sponsoring pharmaceutical company vowed to never fund the researcher again. ¹⁴⁴

A closer look at the discretion required to conduct an accurate pharmaceutical study reveals the imperative need for objectivity. Every aspect of a study - the questions asked, the design of the study, the methods used, and the evaluation of data - is susceptible to at least some degree of bias. A poorly designed study can cause the results to falsely indicate differences between tested drugs, exaggerate benefits, or minimize risks. ¹⁴⁵ Pharmaceutical companies can influence research results by choosing studies that are likely to produce the most favorable results through design, approach, or subject matter. ¹⁴⁶

For example, because drug manufacturers are required to compare a drug with placebo to obtain Food and Drug Administration approval for that drug, industry-sponsored studies might be more likely than non-industry-sponsored studies to use placebo controls. A drug might be more likely to appear efficacious compared with a placebo rather than an alternative treatment. ¹⁴⁷

There are many examples of pharmaceutical companies sponsoring studies that use poor methodology. For instance, in clinical trials of a particular class of painkillers commonly prescribed to the elderly, only 2.1% of subjects were sixty-five years of age or older. ¹⁴⁸ This practice diminished the occurrence of side effects since this

¹³⁷ See, e.g., DeAngelis, supra note 33, at 996 (noting the influence of money on medical science, occasionally leading to research irregularities).

¹³⁸ Lemmens, supra note 10, at 644 ("Researchers have become part-time entrepreneurs. Since they themselves are increasingly being asked to be involved in patentable research endeavours within academia, requiring delays in offering access to data, it may have become harder for them to see problems with pharmaceutical sponsors doing the same.").

¹³⁹ Neale et al., supra note 6, at 411.

¹⁴⁰ Abramson & Starfield, supra note 6, at 414; see also Thomas Bodenheimer, Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry, 342 N. Eng. Med. J. 1539, 1541 (2000) (discussing industry-investor relationships and pharma's influence).

¹⁴¹ See generally Abramson & Starfield, supra note 6, at 414-18 (addressing the growth of pharma funding of research).

¹⁴² See Bodenheimer, supra note 140, at 1542.

¹⁴³ Id.

¹⁴⁴ Id.

¹⁴⁵ See id. at 1541.

¹⁴⁶ See id. at 1541-43.

¹⁴⁷ Mildred K. Cho & Lisa A. Bero, The Quality of Drug Studies Published in Symposium Proceedings, 124 Annals Internal Med. 485, 489 (1996).

drug, like most, has a higher incidence of side effects to the [*606] elderly.¹⁴⁹ In the end, the drug appeared to be safer than it truly was.¹⁵⁰ Likewise, almost half of these trials used proportionately smaller doses for competing drugs than for the sponsor's drug, creating the appearance that the sponsor's drug was more effective.¹⁵¹

Another problem with pharma sponsorship of trials lies in the contractual agreements between investigators and pharma. These agreements commonly limit investigators' access to trial data, restrict their right to prepare and publish manuscripts, and even limit where they can submit their manuscripts.¹⁵² Most clinical trial investigators are not allowed open access to the data they collect when pharmaceutical companies sponsor trials.¹⁵³ Without access to the collected data, peer reviewers and editors of the published results cannot evaluate the soundness of the analysis.¹⁵⁴ Controlling the data allows sponsors to evaluate it in a way that minimizes risks, exaggerates benefits, and "provides the spin on the data that favors them."¹⁵⁵

Publication rights are also crucial. It is common practice for a drug manufacturer who sponsors a study to require express approval before researchers may publish the results of a study.¹⁵⁶ By filtering out clinical studies with negative results, pharmaceutical companies can, and reportedly do, portray an improper balance of the benefits and risks of its drugs.¹⁵⁷ This practice is thought to be quite common.¹⁵⁸ While pharmaceutical companies are required to submit all data to the FDA, they can still create an unrealistically safe image of their drug to the doctors who write the prescriptions and the consumers who foot the bill.¹⁵⁹

The New England Journal of Medicine has reported many occurrences of commercially sponsored researchers running into [*607] trouble with their sponsors when they have wanted to publish unflattering clinical results.¹⁶⁰ For example, a 1987 study conducted by a University of California researcher showed that a particular thyroid drug was not more effective than competing drugs.¹⁶¹ The drug company refused to let the researcher publish the results or release any information relating to the study until ten years had passed.¹⁶²

¹⁴⁸ Bodenheimer, *supra* note 140, at 1541.

¹⁴⁹ *Id.*

¹⁵⁰ *See id.*

¹⁵¹ *Id.*

¹⁵² DeAngelis, *supra* note 33, at 996.

¹⁵³ Abramson & Starfield, *supra* note 6, at 414.

¹⁵⁴ *Id.*

¹⁵⁵ Bodenheimer, *supra* note 140, at 1541.

¹⁵⁶ *See id.* at 1541-42.

¹⁵⁷ *See id.*

¹⁵⁸ *Id.* at 1541 (noting that as many as half of all publishing contracts between companies and researchers have unacceptable publication clauses that must be renegotiated).

¹⁵⁹ *See id.* (discussing that while pharmaceutical firms have to submit data to the FDA for new-drug approval, "publication in prestigious journals is important, to persuade physicians to prescribe the company's products").

¹⁶⁰ *Id.* at 1541-42.

¹⁶¹ *Id.* at 1542.

¹⁶² *Id.*

Similarly, a researcher found that a particular drug, deferiprone, could worsen hepatic fibrosis, a liver problem.¹⁶³ The sponsoring company, Apotex, refused to let the researcher publish the findings and even threatened the researcher with a lawsuit if she disclosed them.¹⁶⁴ The contract required her to wait three years after completion of the study before she could publish the results.¹⁶⁵

Even admired academic institutions have had their scientific integrity called into question because of their participation with pharma.¹⁶⁶ Reportedly, medical schools routinely participate in studies that fail to meet adequate standards of accountability, access to data, and the right to publish their findings.¹⁶⁷ Nevertheless, for all of their questionable research practices, academic institutions have more independence and maintain a relatively safer distance than the primary organizations that perform research for pharma.¹⁶⁸

For-profit organizations, known as contract-research organizations ("CROs") and site management organizations ("SMOs"), are responsible for approximately two-thirds of clinical trials.¹⁶⁹ Trials conducted by CROs and SMOs are "heavily tipped toward industry interests, since [these organizations are] contracting with industry in a competitive market, [and] will fail if they offend their funding sources."¹⁷⁰ While pharma once relied on academia to conduct 80% of its clinical trials, it has responded eagerly to the subservient and cost- [*608] effective practices of the CROs and SMOs, increasingly diverting money from academic researchers to for-profit researchers.¹⁷¹

In addition to the collection and interpretation of research, commercial concerns have also influenced the type of research undertaken and the way in which it is reported. Scientists are more likely to pursue interests that coincide with strong commercial interests because it is easier to acquire funding.¹⁷² Accordingly, the medical research community as a whole continues to seek new palliatives and devices rather than emphasizing causes and mechanisms of disease and preventative treatment.¹⁷³

There is little clinical research to counterbalance the pharmaceutical companies' flawed research practices since pharma funds 70% of all clinical trials.¹⁷⁴ The problem is compounded once a drug has obtained FDA approval. Under the current system, pharmaceutical companies are expected to monitor and report suspected adverse reactions to drugs.¹⁷⁵ This presents an even greater challenge to objectivity: "When serious, even rare,

¹⁶³ Id. at 1541-42. See PDR Medical Dictionary 650, 784 (1995) (defining hepatic fibrosis as a formation of fibrous tissue relating to the liver).

¹⁶⁴ Bodenheimer, *supra* note 140, at 1542.

¹⁶⁵ Id.

¹⁶⁶ E.g., Angell, *supra* note 32, at 1516.

¹⁶⁷ Kevin A. Schulman et al., A National Survey of Provisions in Clinical-Trial Agreements Between Medical Schools and Industry Sponsors, 347 *New Eng. J. Med.* 1335, 1339 (2002).

¹⁶⁸ See Bodenheimer, *supra* note 140, at 1539-40.

¹⁶⁹ See id. at 1539; Abramson & Starfield, *supra* note 6, at 414.

¹⁷⁰ Bodenheimer, *supra* note 140, at 1543.

¹⁷¹ See id. at 1540; Angell, *supra* note 4, at 100-01. Academia's loss of importance to pharma may be related to the movement toward advertising prescription drugs directly to consumers, rather than exclusively through doctors.

¹⁷² See Lemmens, *supra* note 10, at 645; Law, *supra* note 16, at 37. Most importantly, a drug must have a significant market to be able to deliver sufficient profit. Id.

¹⁷³ See Lemmens, *supra* note 10, at 645; Law, *supra* note 16, at 37.

¹⁷⁴ Bodenheimer, *supra* note 140, at 1539.

¹⁷⁵ Bruce M. Psatsy et al., Potential for the Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: Use of Cerivastatin and Risk of Rhabdomyolysis, 292 *J. Am. Med. Ass'n* 2622, 2629 (2004).

[suspected adverse drug reactions] ... are detected, pharmaceutical companies have a complex and almost insurmountable conflict of interest in weighing and interpreting the risks and benefits of various courses of action."¹⁷⁶ After a drug has received approval, the pharmaceutical companies' marketing departments will often decide which clinical studies to fund and refuse funding for those studies whose results might damage sales.¹⁷⁷

[*609] Institutional Review Boards (also known as Research Ethics Boards) are expected to protect the welfare of human subjects involved in research investigations from unethical research practices.¹⁷⁸ Nevertheless, they are primarily "in-house organs," and, as such, their conflicts are inherent - particularly "when science and private industry collaborate in search of material gains."¹⁷⁹ While these committees consist of members who are independent from the investigators and sponsors,¹⁸⁰ many argue that they are not designed "to be sufficiently objective in the sense that they are as sufficiently concerned with the ethicality of the experiments they review as they are with the success of the experiments."¹⁸¹ A study of U.S. medical faculty members serving on Institutional Review Boards revealed that nearly half of those evaluated had worked as consultants for pharma.¹⁸² This raises the question of their ability to properly countervail the dangers presented by the researchers' conflicts of interest.¹⁸³

The inadequacy of Institutional Review Boards was demonstrated in *Grimes v. Kennedy Krieger Institute, Inc.*¹⁸⁴ In *Grimes*, the court found that an Institutional Review Board for Johns Hopkins University "encouraged the researchers to misrepresent the purpose of the research in order to bring the study under the label of 'therapeutic' and thus under a lower safety standard of regulation."¹⁸⁵ One can only hope that *Grimes* is the exception. But the evidence seems clear that, while these "ethics boards" may serve to protect test participants, they do not serve to protect the objectivity of the studies they oversee.

In short, pharma funds research that is unduly influenced by the financial interest of the drug being studied. There are few countervailing forces since pharma funds the vast majority of clinical research, hires researchers and other experts as consultants, and commonly exerts disturbing control over the trials, data, and **[*610]** interpretation. Ethics boards offer little protection because they have their own biases. This leaves a heavy burden on the FDA, particularly if courts are forbidden from helping fight the negative effects of bias.

¹⁷⁶ *Id.*

¹⁷⁷ Bodenheimer, *supra* note 140, at 1541. Bodenheimer notes:

Sometimes an investigator will propose a drug trial to the drug's manufacturer. Two investigators interviewed, including Steven Cummings, professor of medicine and epidemiology at the University of California at San Francisco, found that companies' marketing departments, which often rule on studies to be conducted after a drug has received FDA approval, declined to fund clinically important studies at least partly because the results might reduce sales of the drug.

Id.

¹⁷⁸ Lemmens, *supra* note 10, at 648.

¹⁷⁹ [Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 817 \(Md. 2001\)](#) ("The Institutional Review Boards, IRBs, are, primarily, in-house organs. In our view, they are not designed, generally, to be sufficiently objective in the sense that they are as sufficiently concerned with the ethicality of the experiments they review as they are with the success of the experiments.").

¹⁸⁰ Lemmens, *supra* note 10, at 648.

¹⁸¹ E.g., [Grimes, 782 A.2d at 817](#).

¹⁸² Lemmens, *supra* note 10, at 649.

¹⁸³ *Id.*

¹⁸⁴ [Grimes, 782 A.2d at 817](#).

¹⁸⁵ *Id.*

B. The FDA's Role

There should be little doubt that the FDA intends to serve consumers' best interests by protecting them from harmful substances while allowing helpful drugs to make timely entrances into the market. Unfortunately, given the FDA's limited resources and its own conflicting interests, it is simply incapable of providing consumers with sufficient protection.¹⁸⁶

The FDA has endured extensive criticism for its drug approval process. For years it was accused of proceeding too slowly and cautiously.¹⁸⁷ Congress responded with the introduction of the user-fee program, requiring pharmaceutical companies to pay a fee to get their drug reviewed by the FDA.¹⁸⁸ This program has helped change the FDA from the "slowest regulatory drug agency in the developed world to being the fastest."¹⁸⁹ The program increased approval speed, but it also increased pressure on FDA employees to meet time goals.¹⁹⁰ According to FDA employees, it undermined their ability to make "in-depth science-based reviews."¹⁹¹ In fact, in the decade after the user fee program was implemented, "a record thirteen prescription drugs have had to be withdrawn from the market - after they caused hundreds of deaths."¹⁹²

Speedier approvals increase the risk that dangerous drugs will enter the market.¹⁹³ Logically, pushing drugs on the market sooner should require greater post-approval monitoring of drug safety, adverse reactions, manufacturing standards, and advertising.¹⁹⁴ However, the FDA has been unable to meet this need since the bulk of **[*611]** the user fee is legislatively earmarked for the approval process alone.¹⁹⁵ As a result, "staffing and resources in other parts of the FDA have been relatively starved."¹⁹⁶

The user fee also casts doubt on whether the FDA can impartially evaluate drugs. Congress's generally friendly relationship with pharma is most likely due to the substantial campaign contributions pharma donates across party lines, and the over 600 lobbyists promoting pharma's cause.¹⁹⁷ Accordingly, the FDA "has a direct interest in satisfying the industry, because that is what Congress expects of it. If the FDA were to displease industry, the user fees might even be discontinued, and many agency employees would probably lose their jobs."¹⁹⁸ Furthermore,

¹⁸⁶ See Strom, *supra* note 26, at 2645.

¹⁸⁷ 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, 164 \(1998\)](#).

¹⁸⁸ Psatsy et al., *supra* note 175, at 2625.

¹⁸⁹ Angell, *supra* note 4, at 35.

¹⁹⁰ Psatsy et al., *supra* note 175, at 2629.

¹⁹¹ See Office of Inspector General, U.S. Dep't of Health and Human Services, FDA's Review Process for New Drug Applications: A Management Review, at iii (2003).

¹⁹² Angell, *supra* note 4, at 209.

¹⁹³ *Id.*

¹⁹⁴ Cf. *id.* at 209-10 (addressing that despite the expedited approval process, the FDA is still slow to remove products from the market).

¹⁹⁵ See [id. at 208, 210](#).

¹⁹⁶ [Id. at 209](#).

¹⁹⁷ See [id. at 198](#).

¹⁹⁸ [Id. at 210](#).

several of the FDA Commissioners appointed by President Bush were notoriously pharma-friendly. ¹⁹⁹ Such pressures have almost certainly affected the FDA's decisions. ²⁰⁰

In addition to these problems, pharma exerts influence on the FDA through the FDA's advisory committees. "These committees, which consist of outside experts in various specialties, are charged with reviewing new drug applications and making recommendations to the agency about approval. The FDA almost always takes their advice." ²⁰¹ Although FDA rules forbid individuals from serving on committees if they possess substantial conflicting financial interests, investigations show that these rules are regularly waived as "at 92 percent of the meetings, at least one member had a financial conflict **[*612]** of interest." ²⁰² Furthermore, "at 55 percent of meetings, half or more of the FDA advisers had conflicts of interest." ²⁰³ The condition of these advisory committees raises serious questions about the FDA's ability to adequately fulfill its duty.

Since 1998, the FDA has required drug manufacturers to disclose the financial interests of the researchers involved in acquiring the data submitted with an Investigational New Drug Application. ²⁰⁴ It is unclear whether this information has any significant effect on the drug approval process. ²⁰⁵ What is clear, however, is that the FDA relies considerably on pharma and its researchers' honesty and objectivity. ²⁰⁶ Further, the FDA has "little control over how research subjects are recruited, where they are recruited, where the research is taking place, who is involved in the conduct of the trials, and so on." ²⁰⁷ The FDA has even less control once a drug is approved for market use. ²⁰⁸ Substantial reform of the FDA would likely be insufficient to ferret out the conflicts of interest occurring on an individual basis that are tainting research. Despite these troubling truths, the FDA continues to push for preemption of failure-to-warn claims. This policy would not only protect these disturbing practices, it would reward them.

IV. Protecting the Public

¹⁹⁹ President Bush appointed both Lester Crawford (July 2005-Sept. 2005) and Mark McClellan (2002-2005) as FDA Commissioners. Angell, *supra* note 4, at 212; Sam Singer, Ending Long Delay, Senate Confirms Chief for FDA, *Chicago Tribune*, July 19, 2005, at 14. On October 17, 2006, Dr. Crawford pleaded guilty "to conflict of interest and false reporting of information about stocks he owned in food, beverage and medical device companies he was in charge of regulating." Andrew Bridges, Ex-FDA Chief Pleads Guilty in Stock Case, *Associated Press*, Oct. 17, 2006, 2006 WLNR 18118438. While confronting the disparity in drug prices between the United States and other advanced countries in his first international speech, Dr. McClellan criticized other wealthy countries for their low drug prices, and proposed that the answer to this disparity was for the other countries to raise their drug prices. Angell, *supra* note 4, at 212-13 ("Dr. Mark McClellan ... has consistently championed drug company causes.").

²⁰⁰ Angell, *supra* note 4, at 210 ("When added to the business-friendly pressure from its politically appointed leadership, and from an administration that is generally hostile to regulation, the Prescription Drug User Fee Act has undoubtedly constrained the FDA's independence and influenced its decisions.").

²⁰¹ *Id.*

²⁰² Dennis Cauchon, FDA Advisors Tied to Industry, *USA Today*, Sept. 25, 2000, at 1A (referring to advisory committee meetings from Jan. 1, 1998 to June 30, 2000).

²⁰³ *Id.* (emphasis added).

²⁰⁴ Lemmens, *supra* note 10, at 651.

²⁰⁵ *Id.*

²⁰⁶ *See id.*

²⁰⁷ *Id.*

²⁰⁸ *See* Angell, *supra* note 4, at 209-10.

Research tainted by conflicts of interest may strongly suggest that a pharmaceutical company knew or should have known that a certain warning should have been included with a drug.²⁰⁹ This knowledge would, under traditional product liability law, often render a manufacturer liable to injured parties.²¹⁰ In such situations, the FDA's Preamble would nonetheless attempt to shield such sordid behavior **[*613]** from lawsuits that would punish and deter bad research. Fortunately, the Preamble is not a legal requirement; rather, it is an advisory opinion that states the FDA's official interpretation of its labeling requirements.²¹¹ While it can carry significant weight, it is not binding.²¹² The FDA's inconsistent stance regarding products liability, the long history of tort litigation against pharma, and the absence of any evidence of congressional intent reveals that this advisory opinion carries even less weight. Accordingly, courts must use discretion and consider public policy arguments when deciding whether to defer to the FDA's interpretation stated in the Preamble. The state of pharma should play a significant role in policy considerations. Such unethical behavior should not be allowed to hide under the umbrella of the FDA. Rather, victims of manufacturer oversight should be given their day in court.

A. Pharma's Responsibility

The FDA asserts that the responsibility for the content of labeling warnings rests with the FDA, not pharma.²¹³ Accordingly, a drug company should not be held liable for inadequate warnings.²¹⁴ While this argument may sound compelling at first, it is sorely flawed. The FDA's reliance on the drug manufacturer places the responsibility to adequately warn squarely on the manufacturer's shoulders. As discussed above, the FDA relies on drug manufacturers to submit objective and accurate data.²¹⁵ Manufacturers may comply with the letter of the law and still miss its purpose by submitting skewed results inspired by inadequate studies.²¹⁶ As discussed in Part III, the data that the FDA receives is covered with the fingerprints of commercial interests.²¹⁷ The scientists who discover and evaluate the **[*614]** data are commonly motivated by conflicts of interest.²¹⁸ Pharma's interests all too often shape the questions posited, study design, methods, and interpretation of the results.²¹⁹ Accordingly, the FDA is evaluating data that has often been, at best, unintentionally skewed.²²⁰ At worst, pharma is intentionally creating situations that damage the integrity of the data, making it look best for its profit margin.²²¹

²⁰⁹ See, e.g., Margaret Z. Johns, Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest, [58 Hastings L.J. 967, 967-71 \(2007\)](#) (noting that upon the recommendation of pharmaceutical companies, doctors suggest uses for drugs that have not been approved by the FDA; therefore, no warning is listed or required for the use).

²¹⁰ See Restatement (Third) of Torts: Product Liability § 2 cmt. m (1998).

²¹¹ [21 C.F.R. § 10.85\(d\)\(1\) \(2005\)](#) (stating that a preamble to a rule will constitute an advisory opinion "unless subsequently repudiated by the agency or overruled by a court"); [21 C.F.R. § 10.85\(e\)](#) ("An advisory opinion represents the formal position of FDA on a matter and except [in unusual situations], obligates the agency to follow it until it is amended or revoked."); [21 C.F.R. § 10.85\(j\)](#) (an advisory opinion is not a legal requirement, but "may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards").

²¹² See supra Part I.

²¹³ Labeling Requirements, supra note 42, at 3934.

²¹⁴ See [id. at 3934-35](#).

²¹⁵ Lemmens, supra note 10, at 651.

²¹⁶ See supra Part III.

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.*

Even when a drug manufacturer proposes to add or strengthen label warnings and the FDA refuses, a drug manufacturer should still be liable to warn of the risks. Warning labels are only one method of alerting doctors and patients about the risks associated with a particular drug.²²² Most physicians gain medical knowledge about the risks and benefits of a drug through "publications of clinical trials or case reports, promotional materials or alert letters provided by pharmaceutical manufacturers, and formal documents such as the FDA-approved label."²²³ One would think that pharma has sufficient contact with the medical community through its \$ 14 billion investment to promote drugs to physicians.²²⁴

It is also a common practice for manufacturers to push uses of the drug that have not been approved by the FDA.²²⁵ While it is illegal for drug companies to market "off-label" uses, doctors may prescribe drugs for any use - FDA-approved or not. Drug companies seek to exploit this license by "informing" doctors about other unapproved uses for their drugs: "They sponsor make-believe education, and often buttress it by references to flimsy research studies they sponsor."²²⁶ With as many as half of all prescriptions written for off-label uses, the financial incentive to use such a technique is substantial.²²⁷

Since pharma is comfortable encouraging off label uses and promoting skewed articles, it should likewise be comfortable **[*615]** disseminating warnings that are still unsubstantiated by the FDA. Instead, pharma seems to drag its feet when it comes to confessing possible dangers to the FDA, let alone to the public.²²⁸ Since pharma is a main source of drug-related information for physicians, it has an obligation to give physicians and patients appropriate warnings through one of its means, even if the FDA refuses to accept the label change pharma proposes.

Presumably, the FDA does its best to protect and adequately warn citizens of the risks inherent in taking a particular drug. Nevertheless, it is improper for the FDA to suggest that, in its current conflict-ridden condition, it can provide sufficient protection to the American patient. Since the data that the FDA evaluates is typically corrupted by conflicting interests, it is difficult to imagine how, under the current system, the FDA could in good faith claim to serve as "the ceiling" for failure-to-warn claims. The premise that the FDA could sufficiently evaluate, at the time it approves a drug label, whether a drug manufacturer fulfilled its duty to warn the public is naive at best.

B. The Court's Competency

Proponents of federal preemption of failure-to-warn claims argue that the FDA is better suited to determine whether a drug manufacturer should include a particular warning than a post hoc evaluation by courts. The FDA has explicitly argued this in various amicus briefs and constructively asserted this claim in the Preamble, stating that it "makes approval decisions based not on an abstract estimation of [a product's] safety and effectiveness, but rather

²²² See Kesselheim & Avorn, *supra* note 37, at 308.

²²³ *Id.*

²²⁴ See Wilkes & Hoffman, *supra* note 5, at 3107.

²²⁵ See Angell, *supra* note 4, at 156-57.

²²⁶ [Id. at 137.](#)

²²⁷ [Id. at 204.](#) For example, Neurontin was approved by the FDA in 1994 for treatment of epilepsy. [Id. at 158.](#) This market was dissatisfyingly slim for Parke-Davis. *Id.* With time running out on the company's patent, they began to push off-label uses, rather than conduct clinical trials in hopes of gaining FDA approval for other uses. *Id.*

²²⁸ See, e.g., Kesselheim & Avorn, *supra* note 37, at 308-09 (noting that GlaxoKleinSmith only made data showing increased suicide risk in adolescents public after a government lawsuit).

on a comprehensive scientific evaluation of the product's risks and benefits." ²²⁹ This proclamation seems to echo a common complaint:

Prescription drug litigation requires judges and jurors to consider complicated legal, moral, and scientific topics in an emotionally charged courtroom without the time or training to wrestle with the issues. Some individuals in the legal decision-making process, therefore, **[*616]** may have an understandably difficult time viewing design and warning decisions as scientific calculations based on a careful balancing of risks and benefits. ²³⁰

Accordingly, many argue that the courts are unable to sufficiently handle failure-to-warn claims against pharma. This argument relies on two presumptions: (1) the FDA's approval process will catch and properly evaluate all dangers that are reasonably detectable at the time of approval, and (2) the courts cannot consistently analyze the relevant scientific issues and pharma's actions sufficiently to determine whether pharma could justly be held liable.

The first presumption stating that the FDA will serve as the ideal safety net against unreasonably dangerous drugs and inadequate warnings is incorrect. As already noted, the FDA simply cannot catch every reasonably detectable adverse reaction. ²³¹ It is stretched too thin and simply does not have the resources to fully analyze the data or the role that various conflicting interests play in coloring the results. ²³² The FDA must work with the data that manufacturers submit in a limited time period and, therefore, cannot evaluate it sufficiently to be solely responsible for protecting the public's health.

The second presumption, though reasonable on its face, is flawed. Courts and juries are regularly entrusted with interpreting extremely technical and difficult material. This is not unique to products liability. The American justice system rests upon a faith in judges and attorneys to understand and explain relevant evidence, and in juries to rightly find facts from that evidence. Although products liability suits may be emotionally charged, this is common in many other types of cases as well. Cases involving racial discrimination, sexual abuse, and murder are notoriously charged with emotion; nonetheless, they are unquestionably matters for the court and regularly entrusted to juries. Likewise, products liability claims must be entrusted to judges and juries.

Courts are not only competent, but have the benefit of information that was not available to the FDA because of the adversarial nature of litigation. Plaintiffs' attorneys, believing in the strength of the claim, often uncover many facts unavailable to the FDA. ²³³ An attorney can **[*617]** take the extra time and examine patterns of questionable research practices encouraged by a manufacturer to determine whether the manufacturer behaved appropriately. ²³⁴ Further, the discovery process allows attorneys to peruse and submit items such as internal company memoranda to the court. ²³⁵

The pro-pharma camp often points to litigation surrounding the drug Bendectin as the prime example of how juries cannot fairly evaluate scientific evidence. ²³⁶ A closer look reveals that Bendectin litigation may actually confirm the

²²⁹ Labeling Requirements, *supra* note 42, at 3934; accord [Brief for the United States of America as Amici Curiae Supporting Respondents, *Horn v. Thoratec*, 376 F.3d 163 \(3d Cir. 2004\)](#) (No. 02-4597); Corrected Brief for the United States of America as Amici Curiae Supporting Respondents, *Kallas v. Pfizer, Inc.*, No. 2:04-00998 (D. Utah Sept. 29, 2005).

²³⁰ Schwartz & Goldberg, *supra* note 119, at 164-65 (footnote omitted).

²³¹ See *supra* text accompanying notes 174 -85.

²³² See, e.g., Psatsy et al., *supra* note 175, at 2629 (arguing that pressure to meet time goals causes the FDA to limit its focus).

²³³ See Kesselheim & Avorn, *supra* note 37, at 308-10.

²³⁴ Cf. Charles L. Bennett et al., The Research on Adverse Drug Events and Reports (RADAR) Project, 293 J. Am. Med. Ass'n 2131, 2137-38 (2005) (noting that internal documents regarding drug safety, otherwise unavailable, have been obtained through the testimony of expert witnesses in trials).

²³⁵ See Kesselheim & Avorn, *supra* note 37, at 309.

²³⁶ Cf. *id.* at 310 (using Bendectin as an example of the downside of litigation involving drugs).

need for the courts to hold drug manufacturers liable. Since the late 1970s, a number of lawsuits have been filed against Merrell Dow Pharmaceuticals, alleging that its morning sickness drug Bendectin causes birth defects.²³⁷ In response, Merrell Dow has pointed to over thirty published articles, as well as the FDA's safety evaluation of the drug in the 1980s, that found no "statistically-significant association between Bendectin and limb defects."²³⁸ This body of "scientific research" has caused many courts to dismiss lawsuits and overturn jury awards to plaintiffs on the grounds that expert testimony to the contrary was scientifically unreliable and did not meet evidentiary standards.²³⁹

In *Blum v. Merrell Dow Pharmaceuticals, Inc.*, the trial court awarded the plaintiff damages, including \$ 15 million in punitive damages for crippling side effects allegedly caused by Bendectin.²⁴⁰ **[*618]** The Pennsylvania Supreme Court subsequently rejected the award, explaining that the plaintiff's expert testimony was inadmissible since it did not meet certain evidentiary standards of "general acceptance" or "evidentiary reliability."²⁴¹ The court attacked the plaintiff's main expert as a financially-driven professional plaintiff's witness.²⁴² Justice Castille wrote a thoughtful dissent, criticizing the majority's interpretation of the evidence as faulty and pointing out that Merrell Dow's expert testimony was equally questionable because of their expert witnesses' "own financial and litigation-driven biases."²⁴³

Justice Castille further demonstrated, through an extensive review of the evidence, how the trial court established that "Merrell Dow largely created the 'generally accepted orthodoxy' that would freeze out viewpoints contrary to their litigation interests."²⁴⁴ Merrell Dow's own witnesses testified to multiple instances of Merrell Dow directly influencing "scientific" studies.²⁴⁵ For example:

In the early 1980's, a Dr. Hendrickx performed an animal study that showed a significant increase in heart defects in monkeys from the use of Bendectin. Once again, Merrell Dow funded, with more than \$ 300,000 from the company's litigation defense budget, a second study that achieved much more positive results for the company. When Hendrickx wrote to the company regarding funding for the study, he indicated that he would be willing to discuss or modify his proposal to meet a common objective.²⁴⁶

²³⁷ See Gina Bari Kolata, *How Safe Is Bendectin?*, 210 *Science* 518, 518-19 (1980) (noting that even though the FDA saw little evidence that Bendectin caused birth defects as early as 1980, lawyers proceeded to sue the drug's manufacturer).

²³⁸ See *Blum v. Merrell Dow Pharm., Inc.*, 764 A.2d 1, 4 n.5 (Pa. 2000).

²³⁹ For example, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the plaintiffs, two minor children and their parents, sued Bendectin's manufacturer claiming that they suffered birth defects caused by the drug. [Daubert v. Merrell Dow Pharm., Inc.](#), 509 U.S. 579, 582 (1993). Defendant moved for summary judgment and presented expert testimony that there was no scientific evidence that Bendectin causes birth defects. [Id. at 582](#). Plaintiffs countered with expert testimony of their own, consisting of new tests and research not yet peer reviewed. [Id. at 583-84](#). The district court granted summary judgment for the defendant and held that the plaintiffs' expert testimony was not admissible because it did not meet the Frye general acceptance test. [Id. at 584](#). The Supreme Court overturned the district court's decision, holding that the Federal Rules of Evidence do not require scientific expert testimony to meet the "general acceptance" test. [Id. at 264](#).

²⁴⁰ *Blum*, 764 A.2d at 3.

²⁴¹ *Id. at 3-4*.

²⁴² *Id. at 4 n.5*.

²⁴³ *Id. at 11*.

²⁴⁴ *Id. at 16*.

²⁴⁵ *Id. at 12-15*.

²⁴⁶ *Id. at 13* (citations omitted) (emphasis added) (internal quotation marks omitted).

The plaintiffs offered compelling evidence demonstrating how conflict of interest pervaded studies, experts, the creation of a particular medical journal, and various publications in journals. ²⁴⁷ Justice Castille concluded that the trial court's ruling should not be overturned:

The trial court found, and the record amply demonstrates, that, with untold millions of dollars at its disposal, and untold millions more at stake, Merrell Dow was able to create and influence a scientific subdiscipline devoted to result-driven studies that Merrell Dow [*619] could then cite to defeat lawsuits brought by those who alleged that their birth defects were caused by Merrell Dow's Bendectin. ²⁴⁸

In light of such a powerful declaration, the Bendectin litigation should no longer serve as evidence that trial courts cannot justly rule in pharma products liability suits. Rather, in this case, it was the appellate court's distance from the evidence presented at trial that led to what Judge Castille characterized as an unjust resolution. While Bendectin might very well be safe, the conflicting interests that allegedly characterized Bendectin studies make it difficult to draw such a conclusion. Accordingly, Bendectin litigation should no longer serve as evidence of the court's inability to handle similar lawsuits.

C. The Effects of Litigation

The courts serve a much-needed role in drug safety. Although not perfect, they can adequately try cases and look at details that the FDA could not examine. Nevertheless, the FDA expressed concern in the Preamble that fear of litigation would drive manufacturers to make unfounded warnings as a preventative measure, thereby decreasing drug use. ²⁴⁹ While it is true that stronger warnings will ward off some doctors from prescribing and patients from taking particular drugs, it is wrong to suggest that the nation will underutilize drugs. Underutilization of drugs hardly appears to be a problem in the United States. In fact, there is a growing concern in the medical community and the public that this nation's heavy prescription drug use is a serious problem, contributing to the health woes of numerous Americans. ²⁵⁰ If litigation helps keep patients off drugs, then it is aiding in a fight against a far more serious problem than purported underutilization of prescription drugs.

[*620] Litigation promotes drug safety by shaping regulations and helping to pull unsafe drugs off the market. ²⁵¹ It serves as a watchdog, protecting the public from pharma, ready to pounce when the FDA fails to catch unreasonably dangerous drugs and inadequate warnings. For example, Merck eventually pulled Vioxx from the market after its link to heart problems was highly publicized. ²⁵² The FDA did not force this removal and later even suggested that it would not rescind approval for the drug. ²⁵³ Accordingly, one must conclude that public pressure - particularly a fear of lawsuits - caused Merck to officially recognize the risk it posed and to pull Vioxx off the market.

²⁴⁷ *Id.* at 11-17.

²⁴⁸ *Id.* at 14.

²⁴⁹ Labeling Requirements, *supra* note 42, at 3935.

²⁵⁰ See, e.g., Michael Misocky, The Epidemic of Antibiotic Resistance: A Legal Remedy to Eradicate the "Bugs" in the Treatment of Infectious Diseases, *30 Akron L. Rev.* 733, 734-41 (1997) (noting that overuse of prescription antibiotics has heightened the possibility of the "superbug" epidemic); see also World Health Organization, Promoting Rational Use of Medicines Saves Lives and Money, WHO Experts Say, Mar. 29, 2004, <http://www.who.int/mediacentre/news/notes/2004/np9/en/index.html> (2004) ("Irrational use of drugs due to inappropriate prescription can also lead to adverse drug events which cause illness or death. In the United States, adverse drug events represent one of the six leading causes of death.").

²⁵¹ See Kesselheim & Avorn, *supra* note 37, at 310.

²⁵² See O'steen & O'steen, *supra* note 16, at 95.

²⁵³ *Id.* at 68-69 (noting also that the FDA advisory panel's vote to permit the re-marketing of the drug was not designed to ever actually permit Vioxx sales to resume, but rather was used to undercut plaintiffs' claims that the benefits were outweighed by the dangerous side effects).

Litigation also advances knowledge about drug safety by helping "the medical community reassess drugs by bringing to light new information about adverse effects."²⁵⁴ For example, in the case of the anti-depressant Paxil, the State of New York filed suit against GlaxoSmithKline ("GSK"), alleging that GSK had failed to publicize clinical data that showed an increased risk of suicide in adolescents taking the drug.²⁵⁵ GSK claimed that because the FDA had not specifically approved the use of Paxil in adolescents, "GSK was under significant restraints imposed by federal law in communicating with physicians about those studies."²⁵⁶ GSK settled the suit with the state, and as a result, this information was released to the public, allowing doctors to assess that risk when monitoring a patient on the anti-depressant or considering whether to prescribe the anti-depressant to an adolescent.²⁵⁷

Drug litigation has also changed the FDA's official position regarding specific products, identified inadequate regulations and procedures, and "exposed important limitations in the FDA [***621**] information collection and dissemination procedures."²⁵⁸ In the case of Paxil, the FDA issued a health advisory shortly after the New York litigation warning doctors of the drug's link to increased suicidal tendencies.²⁵⁹ Additionally, as a result of another lawsuit that "challenged the manufacturers' promotion of [Paxil] as 'non-habit-forming' in television advertisements ... which had received FDA approval," the FDA recognized the drug's habit-forming nature and required the manufacturer to revise its label and warn of withdrawal symptoms that may result from discontinued use.²⁶⁰

These examples, among others, demonstrate that litigation comprises a necessary component of America's regulatory scheme. It educates doctors and the public about dangers that were previously buried. Likewise, it frequently brings dangers to the attention of the FDA itself and causes it to reevaluate the safety of a drug. It does not cause underutilization of drugs. Ideally, it limits the over-use of drugs, which remains a serious problem in the United States today. Litigation is not a threat to safe drug use; rather, it is a defense against dangerous drugs and drug use.

D. Economics

Pharma, as a conglomeration of private businesses, is first and foremost about profit: "The primary purpose of commercially funded clinical research is to maximize financial return on investment, not health."²⁶¹ Pharma must, therefore, consider a patient's health to be secondary to its bottom line.²⁶² This conflicts painfully with physicians and clinical researchers' professional responsibility to put the health of the patient first.²⁶³

²⁵⁴ Kesselheim & Avorn, *supra* note 37, at 308 ("Litigation brought by government agencies and individual patients can help uncover previously unavailable data on adverse effects, questionable practices by manufacturers, and flaws in drug regulatory systems.").

²⁵⁵ *People v. GlaxoSmithKline*, No. 04-CV-5304 MGC, slip op. at 4, 8 (S.D.N.Y. Aug. 26, 2004) (consent order); Kesselheim & Avorn, *supra* note 37, at 308 (revealing that what GSK specifically failed to disclose was the potential increased risk of suicide).

²⁵⁶ *GlaxoSmithKline*, No. 04-CV-5304 MGC, slip op. at 4.

²⁵⁷ *Id.* at 5-8 (stating that the agreement between New York and GSK represented a "full, complete settlement of the action ... concerning Paxil"); see also Kesselheim & Avorn, *supra* note 37, at 309.

²⁵⁸ Kesselheim & Avorn, *supra* note 37, at 310.

²⁵⁹ *Id.* at 309.

²⁶⁰ *Id.* at 310 (quoting [In re Paxil Litigation, 2002 U.S. Dist. LEXIS 16221 \(C.D. Cal. Aug. 16, 2002\)](#)).

²⁶¹ Abramson & Starfield, *supra* note 6, at 416; see also Mintzes, *supra* note 2, at 908 ("Companies are under intense pressure to garner and retain market share, leading to what the World Health Organization has called "an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way.").

²⁶² See Abramson & Starfield, *supra* note 6, at 416.

[*622] This perversion of medical research by a conflict of interest is a problem that would be difficult for the FDA to resolve. It would cost the FDA untold dollars (which they do not have) to institute a regulatory system that prevents scientists from being influenced by commercial interests.²⁶⁴ Further, it would work against congressionally implemented incentives for scientists to work with pharma.²⁶⁵ Commercial cooperation can benefit society and science. Such cooperation should not be altogether abolished, although added regulations limiting pharma's ability to influence entire fields would be helpful.

Although some FDA rules may provide useful guidance, pharma could easily minimize the effects of conflicting interests without the FDA holding its hand. Pharma will only make this change if it is spoken to in its native tongue: money. Lawsuits that hold drug manufacturers accountable for faulty warnings indirectly protect consumers from a certain degree of faulty research and unethical behavior.²⁶⁶ Although alone it is not enough, increased understanding of the nature of financially driven research may further assist plaintiffs in winning such lawsuits.²⁶⁷

Holding pharma to a higher standard than the baseline set by the FDA is extremely important for preventing severe adverse reactions to medications. These severe side-effects present more than a health concern; they also cost the United States, and a struggling medical system, a substantial amount of money.²⁶⁸ With over 100,000 deaths and over two million hospitalizations resulting from drug side-effects yearly, the cost to our economy is in the billions.²⁶⁹ On the other hand, protecting pharma from failure-to-warn lawsuits will only increase the production of flawed data, and consequently poor warnings and the approval of excessively dangerous drugs. Pharma will have no incentive (besides goodwill) to conduct their clinical trials more ethically and thereby minimize the occurrence of negative side effects.

[*623] In spite of the important role lawsuits play in protecting the public, many argue that pharma should, nonetheless, be sheltered from claims so that it can invest more into research.²⁷⁰ The fear that lawsuits are cutting into funds that would otherwise go into research and development stems, in part, from pharma's claim that it takes approximately \$ 800 million to bring a new drug into the market.²⁷¹ A closer look reveals that the \$ 800 million figure is grossly exaggerated and that fears of dwindling research and development funds are unfounded.²⁷² Using pharma's own figures, independent investigators have argued that the true cost of developing a drug and bringing it to market is limited to \$ 100 million or less.²⁷³ This price pales in comparison to the money pharma

²⁶³ See *id.*; see also Code of Med. Ethics § 10.015 (Am. Med. Ass'n 2005) ("[A] physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount.").

²⁶⁴ The FDA simply does not have the resources necessary to monitor issues of financial conflicts of interest. See Green, *supra* note 187, at 174; Angell, *supra* note 4, at 209-10.

²⁶⁵ See Angell, *supra* note 4, at 6-10.

²⁶⁶ See Kesselheim & Avorn, *supra* note 37, at 309-10.

²⁶⁷ See, e.g., *Blum v. Merrell Dow Pharm., Inc.*, 764 A.2d 1, 6-17 (Pa. 2000) (Castille, J., dissenting) (demonstrating how conflict of interest problems in the research field can strengthen an argument considerably).

²⁶⁸ See Lazarou et al., *supra* note 21, at 1204.

²⁶⁹ See *id.* (noting that an estimated 106,000 hospital patients died in 1994 from adverse drug reactions, and "an additional \$ 1.56 to \$ 4 billion in direct hospital costs per year" are attributable to adverse drug reactions).

²⁷⁰ See Schwartz & Goldberg, *supra* note 119, at 165.

²⁷¹ See Angell, *supra* note 4, at 37. See generally Joseph A. DiMasi et al., The Price of Innovation: New Estimates of Drug Development Costs, 22 J. Health & Econ. 151 (2003).

²⁷² See Angell, *supra* note 4, at 38-41.

²⁷³ *Id.* at 41. Marcia Angell explains how the data used to reach the \$ 800 million mark was faulty and deceptively evaluated. *Id.* at 41-46. The data was drawn from a handful of abnormally expensive drugs that were hand-picked by drug manufacturers. *Id.*

spends on marketing its drugs. In 2002, for example, the ten American drug companies on the Fortune 500 list spent "just over 14 percent of [sales] on R & D (about \$ 31 billion), they had a profit margin of 17 percent (\$ 36 billion)," and "they spent a walloping 31 percent of sales (about \$ 67 billion) on marketing and administration," the bulk of which goes into marketing. ²⁷⁴ Pharma's profit margin is huge (17%), particularly considering that the median profit margin for the other Fortune 500 corporations that year was 3.1%. ²⁷⁵ These figures are fairly typical, and while they vary from year to year, pharma has consistently kept profits high. ²⁷⁶

Regardless of overall high profits, pharma's camp points to the financial failures of some pharmaceutical companies and recent downward trends as evidence that pharma needs protection from lawsuits. ²⁷⁷ Blame for the financial failure of a company, however, cannot be pinned on a lack of governmental protection from excessive lawsuits. Blame must also fall on excessive advertising budgets, excessive administrative salaries and costs, and decreased production [*624] of innovative drugs. ²⁷⁸ The lack of new drugs in research distresses pharma and causes some to wonder whether efforts and funds are really being placed in the best direction. ²⁷⁹ In addition, drug manufacturers have paid considerable fines and settlement costs in cases alleging both criminal and civil misconduct, including rigging prices. ²⁸⁰ These problems are ultimately pharma's responsibility; no one can protect pharma from its own mismanagement.

Failure-to-warn lawsuits against drug manufacturers are the best mechanism available to hold pharma liable for biased and inadequate research. Holding pharma liable will help protect Americans from adverse reactions that impose substantial human and monetary costs. While many claim that pharma needs protection so that it can continue to make and develop new drugs, it is ignorant to suggest that lawsuits are cutting into research and development funds after looking at the drug companies' huge profits and excessive marketing budgets. First, pharma is still doing quite well as a whole, with global revenues of over \$ 500 billion per year. ²⁸¹ Secondly, pharma's primary objective is profit, as evidenced by its substantial profit margin and excessive marketing costs. Accordingly, it is foolish to suggest that money freed from lawsuits will necessarily be invested into research and development. While pharma will face some frivolous lawsuits, many are justified, and the real problem is unsafe drugs, faulty research, and improper marketing practices.

On the other hand, pharma influences every step of approval - from the creation and testing of a new drug, to the approval of that drug, and even the prescription process. ²⁸² Pharma distributes grants to fund research, creates patent and royalty deals with researchers, hires researchers as consultants, sends them on trips to promote drugs at symposia, asks them to serve on advisory boards, gives them free gifts, and even gives them equity interests in the company itself. ²⁸³ The FDA reviews the data these researchers provide to determine if the benefits of a drug outweigh the risks. ²⁸⁴ Unfortunately, the data is tainted with conflicting interests that frequently render the findings

at 42. The expense was then expanded from the out-of-pocket expense, to "the estimated revenue that might have been generated if the money spent on [research and development] had instead been invested in the equity market." **Id. at 44.** Further, there are a number of other problems with the evaluation, including a failure to consider tax breaks. **Id. at 45-46.**

²⁷⁴ **Id. at 48, 119-21.**

²⁷⁵ Marcia Angell, The Truth About the Drug Companies, [45 Jurimetrics J. 465, 467 \(2005\)](#).

²⁷⁶ See Law, *supra* note 16, at 34-36.

²⁷⁷ See O'steen & O'steen, *supra* note 16, at 95.

²⁷⁸ See Angell, *supra* note 4, at 48, 234-36.

²⁷⁹ See *id.*

²⁸⁰ [Id. at 229-34.](#)

²⁸¹ Law, *supra* note 16, at 10 (noting that revenue in 2004 was 25 times greater than the \$ 20 billion in global sales in 1972).

²⁸² See Critser, *supra* note 20, at 29-37.

²⁸³ Angell, *supra* note 32, at 1516.

[*625] dangerously inaccurate. ²⁸⁵ Accordingly, the FDA should not offer pharma more protection. Rather, the FDA should leave pharma liable for failure-to-warn claims to encourage it to pursue better practices.

Conclusion

Pharma, an assembly of corporations, has used its influence to help protect its profit margin and ensure its future viability. In 2006, the FDA seemed to bend under this influence when it adopted the preemption Preamble, which purports to bar failure-to-warn claims against pharmaceutical manufacturers who complied with FDA labeling requirements. Preemption by a federal agency is only appropriate when the agency is acting within its authority under the Constitution and congressional statutes. Thus far, courts have disagreed over the deference that should be afforded to the FDA's Preamble. In making such a determination, each judge's personal opinion of pharma is likely to alter the outcome of the case. Further, where a court determines that it should apply deference insofar as the Preamble has the "power to persuade," policy considerations will be particularly important.

The Preamble is premised upon the idea that the FDA is capable of sufficiently protecting consumers from unreasonably dangerous drugs. Nevertheless, the conflicting interests of the researchers involved have damaged the objectivity and accuracy of the data that the FDA uses to make its decisions. The FDA lacks the necessary resources to review these conflicting interests and to protect the public from unreasonably dangerous drugs. Likewise, considering the FDA's own conflicting interests, it cannot objectively monitor all drugs.

Litigation helps pull dangerous drugs off the market and has likely kept some from reaching pharmacies nationwide. While products liability claims may frequently present a jury with complex and emotional issues, courts are equipped to handle such matters and, given the state of pharma, they are left with no satisfactory alternative. Lawsuits may cost pharma money, but poor research costs our country lives. Leaving poor research unchecked, as the Preamble proposes, will only cost more lives. While the Preamble warrants consideration, it is unnecessary to apply it. Rather, courts should look **[*626]** past the FDA's advice and deny further protections to pharma. The nation's health, as well as justice, is at stake.

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²⁸⁴ Dorfman et al., *supra* note 29, at 591.

²⁸⁵ See *supra* Part III.