
Prescription Drug Liability and Postmarketing Surveillance: A Modest Proposal

Sean M. Basquill *

I. INTRODUCTION

Pharmaceutical manufacturers and their prescription drugs occupy unique territory in the product liability landscape. While historically one of the most profitable sectors of the economy,¹ and vilified as a result,² the industry's innovation and corresponding benefit to public health has offered a limited defense.³ Although prescription drugs have caused substantial harm such as injury, incapacitation, and death, even when used as intended,⁴ pharmaceuticals have greatly contributed to the

* J.D. expected May 2007, Temple University Beasley School of Law. Profound thanks to Richard Collier for his invaluable guidance in narrowing down a topic which would otherwise have wandered aimlessly, Richard Bauer, Ph.D. for his editorial suggestions, and my wife Rosemary for her inspiration, support, and remedial English lessons.

¹ *E.g.*, William M. Sage, *Drug Product Liability and Health Care Delivery Systems*, 40 STAN. L. REV. 989, 1016 (1988). *See also* MARCIA ANGELL, M.D., *THE TRUTH ABOUT THE DRUG COMPANIES* 3 (Random House 2004) (indicating that since the early 1980s the pharmaceutical industry has consistently ranked as the most profitable in the United States).

² *See* Gardiner Harris, *Drug Makers Seek to Mend Their Fractured Image*, N.Y. TIMES, July 8, 2004, at C1 (indicating the public approval of pharmaceutical companies is similar to that enjoyed by the oil, managed care, and tobacco industries). *See generally* ANGELL, *supra* note 1.

³ *C.f.* Sage, *supra* note 1, at 1016 (stating that “few would begrudge the industry [profits]” because “[d]rug therapy has contributed greatly to the public welfare”).

⁴ Examples include incidents of severe birth defects related to the use of the drug Accutane, and liver toxicity and death associated with Rezulin. *See, e.g.*, Gardiner Harris, *Man in the News*, N.Y. TIMES,

enviable standard of health and longevity enjoyed by today's Americans.⁵ Government and industry, therefore, struggle to balance the need to compensate injury suffered by individuals with the need to ensure the benefit to society brought by continued pharmaceutical innovation and development.

The state of public health in America today has benefited in large part from the pharmaceutical industry's efforts to develop innovative therapies.⁶ To ensure society continues to receive that benefit, pharmaceutical companies should be encouraged to develop innovative therapies. This contribution notwithstanding, pharmaceutical companies expose themselves to extraordinary liability, both compensatory and punitive, by developing and selling prescription drugs.⁷ Despite the fact that the very nature of punitive damages is to punish some form of wrongdoing,⁸ often punitive damages are assessed where no misconduct deserving of such punishment has occurred.⁹ These liability concerns have at times led manufacturers to abandon further research and development,¹⁰ or even withdraw products from the market,¹¹ thereby reducing the availability of innovative products or drastically increasing costs for those treatments which remain available.¹²

Nov. 20, 2004, at A16 (describing the career of an agency employee). Still other injuries have resulted from off-label or other unauthorized, unadvertised, non-recommended uses. The liability laid at the foot of the pharmaceutical industry as the result of non-promoted use of their products is an area of law deserving of its own treatise; therefore it will not be reached here. See Donald C. Arbitlit & Wendy Fleishman, *The Risky Business of Off-Label Use*, 41-MAR. TRIAL 46, 51 (2005) (discussing liability placed on Upjohn Co. for promotion of Depo-Medrol for off-label uses).

⁵ Vaccines, in particular, exemplify this change. Vaccines created by the pharmaceutical industry have nearly eliminated deaths resulting from pertussis, polio, measles, rubella, and meningitis. Paul A. Offit, *Lawsuits Won't Stop Pandemics*, WALL ST. J., Dec. 1, 2005, at A16. See generally CTR. FOR DRUG EVALUATION AND RES., FROM TEST TUBE TO PATIENT: IMPROVING HEALTH THROUGH HUMAN DRUGS 4 (2006), available at <http://www.fda.gov/cder/about/whatwedo/testtube-full.pdf>.

⁶ Sage, *supra* note 1, at 1. See generally PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH, 331 (Alfred A. Knopf ed., publisher 2003) ("[United States has] the safest food supply and the safest medical products in the world.").

⁷ E.g., Brenda Shapiro Jeffreys, *Record-Setting \$1 Billion Verdict Returned in Fen-Phen Suit*, 20 TEX. LAW. 1, 1 (May 3, 2004); Diedtra Henderson & Sascha Pfeiffer, *Merck Told to Pay \$253M in Vioxx Suit*, BOSTON GLOBE, Aug. 20, 2005, at A1 (Merck's estimated liability in Vioxx exposure cases may run as high as \$18 Billion).

⁸ Note, *'Common Sense' Legislation: the Birth of Neoclassical Tort Reform*, 109 HARV. L. REV. 1765, 1771-72 (1996).

⁹ Rachel F. Ochs, *Pharmaceuticals: The Battle for Control in the 21st Century*, 10 J.L. & HEALTH 297, 316 (1996) (stating that courts have not only granted large [damages] awards, but at times assign punitive damages while holding manufacturers to strict liability standards even though "[p]unitive damages ordinarily do not apply to strict liability since punitive damages are supposed to alter behavior"). The widespread modification of punitive damages on appeal or through remittitur supports the idea that often juries award far more in punitive damages than is justified by the harm suffered by the plaintiff. See Michael Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data*, 78 IOWA L. REV. 1, 51-59 (1992) (explaining the various processes in place to ensure jury verdicts are appropriate, helping prevent a "miscarriage of justice").

¹⁰ See, e.g., Sheldon Segal, *Introduction*, 23 N.Y.U. REV. L. & SOC. CHANGE 329, 330-31 (1997) (indicating liability concerns have dissuaded many companies from continuing innovative contraceptive research).

¹¹ *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349, 1356 (6th Cir. 1992). Bendectin, a drug approved to treat morning sickness, was voluntarily removed from the US market by Merrell Dow in 1983, despite continuing FDA approval, owing to the cost of litigation.

¹² See *Brown v. Abbott Labs.*, 751 P.2d 470, 479 (Cal. 1988) (indicating that, following an onslaught of litigation, the cost of a DPT vaccine dose increased from \$0.11 to over \$11.00 in approximately four

Pharmaceutical companies, like other manufacturers, are subject to liability for injuries caused by their products.¹³ However, unlike other manufacturers, pharmaceutical companies are most often found liable for failing to warn of risks associated with using their products, rather than alternate theories of design or manufacturing defects.¹⁴ Drug manufacturers generally become aware of these risks in the course of conducting clinical trials of their drugs in order to receive Food and Drug Administration (FDA) approval.¹⁵ The limited size, scope, and duration of those clinical trials means that rare side effects, or risks not clearly identifiable as related to a drug's use, are generally neither discovered nor effectively described by the drug's manufacturer.¹⁶ The FDA rarely requires additional research following its approval of new drugs, and often the research that is performed is subject to publication bias or even nondisclosure.¹⁷ As a result, the true extent of risks associated with the use of prescription drugs is neither known nor communicated to doctors or patients. If these risks were better known, the incidence of injury caused by prescription drug use may be greatly reduced.¹⁸ Incentives in the form of protection from liability could encourage a more thorough evaluation of prescription drugs and their inherent risks.

There is no question prescription drugs are of great value to society.¹⁹ Thus, to encourage continuing research and development a balance must be struck between compensating those injured by the use of prescription drugs and limiting the liability borne by manufacturers for those injuries. Providing prescription drug manufacturers with limited immunity from tort liability in exchange for improved prescription drug monitoring and increased reporting of safety data should reduce the number of injuries that result from prescription drug use. In addition, this could ensure the continued availability of safe and effective drug therapies, and perhaps encourage development in areas abandoned or underserved due to liability concerns. To implement such an exchange of liability for monitoring and reporting, legislatures would need to pass laws providing protection from liability under certain circumstances, and both drug manufacturers and the FDA would need to adjust to

years).

¹³ This exposure to liability has had a chilling effect on the industry. For example, lawsuits based on adverse effects tangentially or unrelated to the use of vaccines effectively disincentivizes innovation in vaccine development, making it unlikely that a vaccine to protect against even a "bird flu" pandemic will be developed without governmental protection. *Id.* In addition, simple negative public perceptions or disinformation campaigns have resulted in vaccines established as safe and effective being withdrawn from the market. See Editorial, *When a Vaccine is Safe*, 439 NATURE 7076, 509 (2006) (reporting a lyme disease vaccine was forced from the market following a public relations campaign attributing nonexistent side effects to the vaccine).

¹⁴ LARS NOAH & BARBARA NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 523 (2002).

¹⁵ Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 587, 587 (2005).

¹⁶ *Id.*

¹⁷ See Justin E. Beckelman, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JAMA 454, 456-59 (2003) (analyzing the impact publication of negative publications on funding availability). See generally ANGELL, *supra* note 1.

¹⁸ This is not to suggest blame for injury is strictly the fault of the patient or the physician, but to recognize that the lack of a thorough and complete understanding of the risks associated with a prescription drug's use leads to it being administered inappropriately.

¹⁹ Sage, *supra* note 1, at 1016.

provide and evaluate the resulting increase in the flow of drug safety data.

Part II of this article describes the current status of product liability as it relates to prescription drugs. Part III discusses the current roles and responsibilities of both the FDA and the pharmaceutical industry in approving and monitoring prescription drugs. Part IV describes and evaluates the Michigan legislature's approach to addressing the prescription drug liability issue. Part V proposes a means by which incentives may encourage the continuing and increased evaluation of the safety of prescription drugs. Part VI addresses some of the issues that may impede implementation of that proposal.

II. THE LANDSCAPE OF LIABILITY

The law places on all manufacturers a duty to ensure their products are safe for use by consumers.²⁰ Certain products, specifically those that pose an unavoidable risk to users or consumers, are considered unavoidably unsafe.²¹ If a product, such as a prescription drug is unavoidably unsafe,²² the manufacturer bears a duty to both adequately instruct the consumer in the safe use of the product, and warn the consumer of the risks inherently associated with its use.²³ Prescription drugs are granted special treatment, owing to both the benefit they provide to the public as well as their unavoidably unsafe nature.²⁴ Because new drugs are unavailable to consumers without a prescription, this duty to warn extends primarily to the prescribing physician rather than the consumers themselves.²⁵ So long as the physician responsible for prescribing the drug has received adequate warning of the associated risks, the manufacturer will not bear liability.²⁶

²⁰ RESTATEMENT (SECOND) OF TORTS § 402A (1965). The majority of actions taken against pharmaceutical companies are based on a failure to warn. Although pharmaceutical manufacturers may also be held liable under design or manufacturing defect theories, those issues are beyond the scope of this paper.

²¹ Liability for harm resulting from an unavoidably unsafe product is held through a failure to adequately warn of the risks associated with use. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

²² *Id.*

²³ "The actor is required to exercise reasonable care to give an effective warning to those likely to be affected by his act...but he is not required to do more than a reasonable man would regard as sufficient." RESTATEMENT (SECOND) OF TORTS § 301 cmt. e (1965).

²⁴ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 (1998). This liability shield does not apply to manufacturing defects, defects in design, or inadequate warnings provided to physicians. *Id.* The majority of tort claims against pharmaceutical manufacturers proceed under "failure to warn" theories of liability, rather than design or manufacturing defect theories. NOAH, *supra* note 14, at 523. Courts generally have rejected the application of strict liability to prescription drug claims. *E.g.*, *Brown v. Superior Court*, 751 P.2d 470, 481-83 (Cal. 1988).

²⁵ Known as the "learned intermediary" doctrine, this rule provides that a manufacturer of a prescription drug has no legal duty to warn a consumer directly of the risks associated with the use of a prescription drug, so long as adequate warnings are provided to the prescribing physician. Diane Schumer Kane, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5TH 1, 1 (1998).

²⁶ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. §6 (1998). The advent of widespread direct-to-consumer advertising calls into question the continuing validity of the learned intermediary doctrine as a defense to failure to warn claims. *See generally* Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where it Belongs*, 25 CARDOZO L. REV. 2241, 2250-53 (2004) (arguing that direct to consumer advertising has upset the traditional physician-patient relationship); *see* Sage, *supra* note 1, at 1018 (indicating that courts have on occasion held that promotional efforts by manufacturers may negate the protection afforded by FDA-required warnings).

Despite this protection, drug manufacturers are nevertheless exposed to an extraordinary degree of potential liability through the products they develop and sell.²⁷ While compensating those individuals harmed by the drug in question, this exposure to liability has further chilled the development and availability, in addition to increasing the cost, of prescription drugs.²⁸ Studies show that liability concerns decrease both the development of new products²⁹ and the availability of existing therapies,³⁰ while raising costs for remaining manufacturers who then pass cost increases on to the consumers.³¹

Holding manufacturers liable for both the cost of injuries caused by their products as well as the threat of punitive damages raises the possibility that awards may grossly exceed the degree of the actual harm suffered.³² For example, a Texas jury recently awarded \$229 million in punitive damages as part of a \$253 million wrongful death verdict against Merck & Co.³³ While likely to be reduced on appeal or through other means,³⁴ this verdict represents the high water mark of extraordinary punitive jury awards in the prescription drug context.³⁵ In addition,

²⁷ Data available from between 1989 and 1995 indicate the median drug product liability award was \$3.75 million, with awards ranging from between \$50,000 and nearly \$78 million. Gail M. Richmond, *Current Trends in Product Liability Verdicts and Settlements*, in CURRENT TRENDS IN PRODUCTS LIABILITY II, 68-71 (LRP Publications 1996).

²⁸ Ochs, *supra* note 9, at 319.

²⁹ Fear of potential liability has decreased research investment possibly leading to the development of an AIDS vaccine. See Robert M. McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943, 943-44 (1988) (predicting that the liability issues concerning other vaccines and their manufacturers will not impede the development of an HIV vaccine, which should be available by the mid 1990s). More than seventeen years have passed since that optimistic prediction, with neither a vaccine available, nor one on the horizon. The persistence of personal injury claims against manufacturers for harms varying from Sudden Infant Death Syndrome to the current crop of autism claims, despite epidemiologic studies showing no causal link between the vaccines and the injuries complained of, Offit, *supra* note 5, at A16, substantially undermine claims that liability concerns play little if any role in impeding innovation.

³⁰ The infamous Bendectin litigation forced E.R. Squibb to remove the product from the U.S. market for economic reasons, Ochs, *supra* note 9, at 319, despite a preponderance of evidence demonstrating no causal link between use of the drug and the rate of birth defects in newborns. See, e.g., *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349, 1353 (referring to 35 epidemiological studies clearly demonstrating no causal relation between birth defects and the use of Bendectin). As a result, there is currently no FDA approved drug available in the U.S. to combat nausea in pregnancy. See also Ochs, *supra* note 9, at 319 (while still FDA approved and available outside of the United States, Bendectin is no longer available for purchase within the United States).

³¹ DPT vaccine increased in cost more than a hundred-fold following a rash of litigation forcing all but two manufacturers to cease production and distribution. See *Brown v. Abbott Labs.*, 751 P.2d 470, 479 (Cal. 1988) (indicating the cost of a DPT vaccine dose increased from \$0.11 to over \$11.00 in approximately four years). Vaccine research in general has declined, and the cost of procuring those available vaccines has skyrocketed. See Robert M. McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943, 955 (1988) (indicating that lawsuits, which vaccine manufacturers consistently lose, have had two major effects: an exodus of companies from vaccine production and dramatic increases in vaccine prices).

³² By “grossly exceed” I refer to situations where punitive damages total many multiples of compensatory damages awarded or exceed compensatory damages by hundreds of millions of dollars.

³³ Henderson & Pfeiffer, *supra* note 7, at A1.

³⁴ See *id.* (reporting a Texas punitive damages cap “could drastically reduce the amount of the award”).

³⁵ The dubious honor having previously belonged to American Home Products (now Wyeth-Ayerst Laboratories) and their products Pondimin and Redux, otherwise known as “Fen-Phen.” See Alison Frankel, *Still Ticking*, 27 AM. LAW. 92 (2005) (indicating “there’s never been anything quite like” the

this was merely the first result from more than 1,800 suits filed claiming damages from Vioxx.³⁶ There has been speculation that this could drive Merck, a company long respected for their contributions to pharmaceutical science, into bankruptcy.³⁷ Even if bankruptcy represents merely a doomsday scenario, the Vioxx litigation appears to have effected the company already.³⁸ To be sure, those suffering injury are entitled to recover damages commensurate with their injury. However, the damages awarded may not justify the elimination of the benefit brought and promised to society by forcing pharmaceutical companies to either cease operations or drastically reduce their ability to innovate and develop new therapies.

III. THE FDA'S ROLE AND THE PHARMACEUTICAL INDUSTRY STATUS QUO

A. Understanding the FDA's Regulatory Authority:

To understand the purpose of exchanging immunity for ongoing studies of the safety of approved prescription drugs requires an understanding of what FDA approval represents, in addition to what is required to receive it. Before a pharmaceutical company can legally sell a prescription drug in the United States, they must receive FDA approval to do so.³⁹ Among its many other responsibilities, the FDA evaluates a "New Drug Application"⁴⁰ (hereinafter "NDA") for the sale of any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man."⁴¹ The agency maintains a complex review and approval process by which research data related to the safety and efficacy⁴² of

Fen-Phen litigation, expected to cost nearly \$21 Billion).

³⁶ Henderson & Pfeiffer, *supra* note 7, at A1. See also Merck & Co., Inc., Annual Report (Form 10-K), at 16 (Mar. 11, 2005) (indicating approximately 850 lawsuits, representing more than 2,425 plaintiffs' groups, had been filed or were pending as of January 31, 2005). Recently, Merck has received relatively good news in the form of two defense verdicts in the last two Vioxx cases to go to trial. *Federal Jury Clears Merck in Death of Vioxx Patient*, N.Y. TIMES, Feb. 18, 2006, at C4; Alex Berenson, *Merck is Winner in Vioxx Lawsuit on Heart Attack*, N.Y. TIMES, Nov. 4, 2005, at A1.

³⁷ Henderson & Pfeiffer, *supra* note 7, at A1.

³⁸ See Alex Berenson, *Revamping at Merck to Cut Costs*, N.Y. TIMES, Nov. 29, 2005, at C1 (announcing layoffs of approximately 7,000 employees, comprising eleven percent of Merck's global workforce).

³⁹ Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 355 (2000). The FDA possesses the power to remove unapproved products from the market through issuing warnings to the manufacturer of impending action including seizure, injunction, or even criminal proceedings. *U.S. v. Alcon Labs.*, 636 F.2d 876, 879 (1st Cir. 1981). However, the FDA may not issue a recall of a prescription drug; drug recalls are voluntary actions taken by manufacturers to avoid the public exposure of one of the other means of enforcement. See Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873, 887-88 (1997) (indicating that the FDA lacks the statutory authority to order a recall, and has resisted attempts to include such powers within the scope of their granted authority).

⁴⁰ 21 U.S.C. § 355(a) (2000).

⁴¹ Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 321(g)(1)(b) (2000) (originally enacted as Federal Food and Drugs Act of 1906).

⁴² Almost as important as an outline of what the FDA evaluates is an understanding of the limits of that review. The FDA, in evaluating the safety and efficacy of proposed new drugs, does not engage in an evaluation of either safety or efficacy as related to currently available therapies. See Struve, *supra* note 15, at 658 n.328 ("The FDA's premarketing review does not generally require a comparison of the product's safety and efficacy with those of competitor products."). So long as the drug under consideration passes a "safe and effective" threshold, it will be approved. See 21 C.F.R. § 314.126 ("[r]eports of adequate and well-controlled investigations provide the primary basis for determining

proposed new drugs are to be submitted and evaluated.⁴³ Companies wishing to submit an article to the FDA for approval as a new drug must first file a statement indicating the purpose of the research to be conducted, along with a description of the means that will be used to assess the drug's safety and efficacy.⁴⁴ The FDA retains the authority to withdraw approval for drugs when data demonstrate that the drug is no longer safe for use.⁴⁵ Courts have continually upheld as constitutional the power of regulatory agencies to mandate such rigorous compliance.⁴⁶ Prescription drugs, therefore, may only be sold following a determination that the agency standards of both safety and efficacy have been met.⁴⁷ Stringent labeling requirements complement this sanctioning with an explicit declaration of, among other information, side effects and warnings applicable to those for whom the article is intended.⁴⁸ These requirements act to ensure that articles introduced into commerce are safe, effective, and accompanied by warnings appropriate to the risks associated with their use.⁴⁹

whether there is 'substantial evidence' to support the claims of effectiveness for new drugs.”).

⁴³ 21 U.S.C. §§ 355, 356. The Food, Drug, and Cosmetics Act in its original 1906 form provided sanctions only for those foods and drugs found to be “adulterated” or “mislabelled” within the meaning of the statute. HILTS, *supra* note 6, at 329-331. Later events, including the elixir sulfanilamide and thalidomide tragedies of 1938 and the 1960's, led to amendments incorporating safety standards and finally mandating pre-marketing approval for all prescription drugs sold in the United States. *See id.* (outlining the history of the interaction between the FDA and pharmaceutical industry).

⁴⁴ 21 U.S.C. § 355(b); *see also* 21 C.F.R. § 312.23 (2005) (providing regulatory details supplementing the broad, general provisions of the U.S. Code). Commonly referred to as an “Investigational New Drug Application,” or IND, this permits companies to ship unapproved new drugs in interstate commerce for the express purpose of conducting research intended to lead to the filing of an NDA. 21 C.F.R. §§ 312.1, 312.2(a). The IND establishes parameters for safety and efficacy which the clinical trial data must meet or exceed for the FDA to grant NDA approval. *Id.* at § 312.22. To receive an IND the applicant must provide detailed information concerning, among others, the plan for human investigations including the actual clinical trial protocols, information concerning the drug under study including chemical, pharmacologic, toxicology, and animal testing data, any data related to safety and efficacy in humans, as well as information related to the drugs' manufacturing. *Id.* at § 312.23.

⁴⁵ 21 U.S.C. § 355(e). In addition to having the power to withdraw approval for a new drug, the FDA retains their traditional enforcement methods of seizure, injunction, criminal prosecution, and issuing public health advisories. 21 U.S.C. §§ 332, 333, 334, 335, 337.

⁴⁶ *See, e.g.,* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984) (courts grant considerable weight to agency construction of statutes they are entrusted to administer); *see also* U.S. v. Rutherford, 442 U.S. 544, 553-54 (1979) (“construction of a statute by those charged with its administration is entitled to substantial deference” (citing Board of Governors of FRS v. First Lincolnwood Corp., 439 U.S. 234, 248 (1978))).

⁴⁷ *See* New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452 (Feb. 22, 1985) (codified in scattered sections of 21 U.S.C.) (ensuring prescription drugs are safe and effective, and that benefits outweigh the risks associated with taking the drug).

⁴⁸ 21 C.F.R. § 314.50(c)(2)(i) (requiring submission of proposed text of labeling in accordance with other regulatory provisions); *see also* 21 C.F.R. § 314.50(d)(5) (requiring submission of all known clinical trial data).

⁴⁹ 21 C.F.R. § 314.50(c)(2)(i). On January 24, 2006, the FDA issued revised rules relating to the labeling of prescription drugs. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. §§ 201, 314, 601) [hereinafter “Labeling”] (label revisions designed to make it easier to access, read and use important drug information, enhancing the safe and effective use of prescription drugs and reducing the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information). These revised requirements make it clear that it is the federal government, rather than the governments of the individual states, which regulates the content and format of prescription drug labels. *Id.* In addition, this regulation effectively debunks the “myth” that changes to

While the FDA requires submission of data sufficient to establish the safety and efficacy of the drug under consideration,⁵⁰ the agency cannot guarantee that all available clinical data will be submitted during either the approval or ongoing evaluation processes.⁵¹ For example, clinical trials conducted under certain circumstances are exempt from the reporting requirements applicable to most studies.⁵² Still, despite the best efforts of industry and physicians, not all information pertaining to the safety of a drug will be obtained and assessed before the manufacturer makes the product available to the public.⁵³ Adverse events that may be too rare to have been detected during a clinical trial may manifest themselves quickly when a population hundreds of times larger is exposed to the drug.⁵⁴ By virtue of the size and demography of the population used to evaluate the drugs' safety and efficacy certain rare conditions, or conditions endemic to only a subset of the population perhaps not included in pre-marketing trials, inevitably will be missed.⁵⁵ To help compensate for this inevitability, the FDA has established elaborate requirements for the reporting of safety data following the approval of a new drug.⁵⁶ To be sure, mandating increased sample size and patient diversity in pre-approval clinical trials could result in a more thorough evaluation of potential risks. However, this increased burden of pre-marketing evaluation would delay or

product labeling may be made without FDA approval. *See id.* at 3934 ("Under FDA regulations, to change labeling (except for editorial and other minor revisions), the sponsor *must* submit a supplemental application fully explaining the basis for the change.") (emphasis added).

⁵⁰ 21 U.S.C. § 355(b).

⁵¹ This is one of the more controversial issues surrounding the conduct and dissemination of clinical trial data. Articles claim that so-called "publication bias" prevents academic physicians from publishing results unfavorable to those who funded the studies. *See infra* note 68; Jerome M. Stern & R. John Simes, *Publication Bias: Evidence of Delayed Publication in a Cohort Study of Clinical Research Projects*, 315 BRIT. MED. J. 640, 640 (Sep. 13, 1997), available at <http://bmj.bmjournals.com> (showing that studies with positive outcomes were more than twice as likely to be published than those with negative outcomes). In addition, data submitted for supplemental indication approvals which are denied are not generally released into the public domain. Jeanne Lenzer, *Drug Secrets: What the FDA Isn't Telling*, SLATE, Sept. 27, 2005, <http://www.slate.com/id/2126918/>.

⁵² 21 C.F.R. § 312.2(b)(1) (2005) (providing the most substantial of the exemptions). Safety data need not be reported to the FDA for any trial conducted which (a) is not intended to be reported to the FDA as part of an NDA or Supplemental New Drug Application ("SNDA"); (b) is not intended to support a significant change in advertising; (c) does not involve a route of administration or dose level in humans which would significantly increase the risks associated with the use of the product; and (d) is conducted in compliance with the established requirements for both institutional review and informed consent. *Id.*

⁵³ Struve, *supra* note 15, at 598-99.

⁵⁴ *Id.* at 598-606; *see also* JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS 109 (Vintage Books 2005) (2004) (indicating that it is impossible to learn enough about risks from trials conducted before a prescription drug is marketed).

⁵⁵ Struve, *supra* note 15, at 598-99. The limited size of the population exposed to the drug during any clinical trial pales in comparison to the extent of exposure once the drug is approved and marketed. Ochs, *supra* note 9, at 326 (antibiotic Omniflox, tested in 400 patients prior to receiving FDA approval, was prescribed to more than 200,000 patients in the first three months of marketing); *see also* AVORN, *supra* note 54, at 109 ("It is simply not possible for any pre-marketing study of a new drug to include enough people of sufficient clinical diversity, and follow them long enough to provide a clear picture of all the important side effects the drug may cause once it is in widespread, lifelong use in typical patients.").

⁵⁶ *See* 21 C.F.R. §§ 314.80, 314.81 (2005) (detailing post-marketing safety surveillance required to supplement each approved NDA). This is separate from the additional safety evaluation required under a "fast track" drug approval, regulated by 21 C.F.R. § 314.500 (2005).

deny access to potentially life-changing treatments,⁵⁷ while still leaving undiscovered potential risks.⁵⁸

B. Understanding the Impact on the Pharmaceutical Industry:

From the perspective of the pharmaceutical industry, current estimates place the cost to bring a single drug to market well into the millions of dollars.⁵⁹ In addition to this staggering financial burden, the time required to shepherd a product through the development process is estimated to take an average of fifteen years.⁶⁰ Patent law only grants a right to exclude others from making, selling, or using a patented product for a period of twenty years from the date a patent is filed.⁶¹ Because of the delays inherent in testing and regulatory evaluation, pharmaceutical companies receive market exclusivity for a considerably shorter time than the original term of the patent in which to recoup their multimillion dollar investment.⁶² In addition to the costs required simply to bring a new drug to market, pharmaceutical companies must continue to collect, compile, and report safety data to the FDA following the approval of their new drug.⁶³ Failure to timely report safety information could result in administrative action anywhere along the spectrum of that authorized by Congress: warning letters, injunctions, seizure, or even a withdrawal of approval for the product in question.⁶⁴

The FDA reviews data submitted in an NDA, required by federal law before a prescription drug may be sold in the United States,⁶⁵ to determine the safety and effectiveness of the proposed new drug.⁶⁶ So long as the data submitted satisfies the requirements of substantial evidence of safety and efficacy, no questions are asked as

⁵⁷ AVORN, *supra* note 54, at 381.

⁵⁸ *Id.* at 108-109.

⁵⁹ The amount spent by the industry to develop and bring a new drug to market is a highly controversial and debated figure. Estimates vary greatly, but the consensus holds that the development and approval of a new drug runs well into the millions of dollars. Compare Michael A. Friedman, M.D., *What is the Value of an FDA Approval in a Judicial Matter?*, 12 J.L. & POL'Y 559, 560-62 (2004) (estimating the average cost to bring a drug to market at approximately \$900 million), with ANGELL, *Supra* note 1, at 40-41 (indicating actual development costs per drug were likely under \$100 million). See generally U.S. DEP'T. OF COMMERCE INT'L. TRADE ADMIN., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES, 29-31 (Dec. 2004), available at <http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf>.

⁶⁰ In addition, approximately one chemical compound in 25,000 makes it through clinical trials, and perhaps one in three of those compounds are approved by the FDA. Friedman, *supra* note 59, at 560-62.

⁶¹ 35 U.S.C. § 154(a)(2) (2000).

⁶² Statutory provisions allow certain limited extensions of patent life and market exclusivity; most prominently the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as "Hatch-Waxman"), and "pediatric exclusivity" amendments to the US Code. 35 U.S.C. §§ 155, 155A, 156 (2000). See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-73 (1990), *rehearing denied*, 497 U.S. 1047 (1990) (indicating the Drug Price Competition and Patent Term Restoration Act of 1984 was designed to address patent term distortion resulting from regulatory delays).

⁶³ Reporting requirements vary based primarily on the severity of the event reported. Serious, unexpected events, as defined in CFR, must be transmitted to the FDA within 15 days of the manufacturer's having received notice of the event. All other safety data must be compiled and periodically transmitted annually, at least for the first few years following approval. 21 C.F.R. §§ 314.80, 314.81 (2005).

⁶⁴ *Id.* at § 314.150(b)(1).

⁶⁵ *Id.* at § 314.2.

⁶⁶ *Id.*

to what data may have been omitted. Although all clinical trial protocols conducted under what is known as an Investigational New Drug Application (Hereinafter “IND”) must be submitted to the FDA for their review,⁶⁷ pharmaceutical companies are obligated to neither register nor thereafter publish data collected from the clinical trials they conduct.⁶⁸ Because of this lack of accountability, pharmaceutical companies may exclude from their NDA data that may be adverse to the success of their application.⁶⁹

Following the approval of their NDA, pharmaceutical manufacturers must report all adverse event information received through any means, such as ongoing trials or spontaneous physician or consumer reports.⁷⁰ Manufacturers and the FDA use this ongoing collection of clinical data, particularly regarding adverse events, to continually evaluate the safety of their approved drugs.⁷¹ Trends identified in side effects that justify a change to the approved labeling of a new drug may be effected immediately, so long as the proper notice is provided to the FDA.⁷² The FDA permitted this change in procedure to recognize the need to quickly inform

⁶⁷ While obligated to submit detailed trial protocols for review, the FDA does not “approve” individual clinical trials under an approved IND. The agency will only notify a study sponsor if they do not approve of some part of a proposed clinical trial. If within thirty days of submitting a proposed clinical trial protocol, the sponsor has not received notice from the FDA, they are permitted to begin recruiting patients. *See id.* at § 312.20(c) (establishing a 30 day approval timeframe for initial IND); *id.* at § 312.23(6) (inclusion of trial protocols required as part of initial IND application); *id.* at § 312.30 (detailing requirements for submission of new trial protocols and protocol amendments); *id.* at § 312.40(b) (providing effective dates for IND and amendments).

⁶⁸ Literature abounds detailing the incidences of publication bias in medical research, particularly those studies funded all or in part by interested pharmaceutical companies. *See, e.g.,* Beckelman, *supra* note 17, at 456-59 (analyzing the impact on published study results of industry financing of medical research); Thomas Bodenheimer, *Uneasy Alliance – Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENG. J. MED. 1539, 1539 (2000) (describing how current reliance on industry funding, and the conditions industry places on acceptance of that funding, introduces the likelihood of bias in publication of results). Entire books have been written describing the length to which pharmaceutical companies go to ensure positive results, both in terms of clinical trials and return on investment. *See generally* ANGELL, *supra* note 1.

⁶⁹ While provisions of the CFR require drug companies to submit within a particular timeframe information related to all serious adverse events of which they have been notified, 21 C.F.R. §§ 314.80, 314.81, and a summary of all clinical trial data must be included in an NDA, 21 C.F.R. § 314.50, submission of either the analyses or results of particular clinical trials are not required independent of an NDA.

⁷⁰ AVORN, *supra* note 54, at 109.

⁷¹ *But see* Food & Drug Admin., *Report on Performance of Drugs and Biologics Firms in Conducting Postmarketing Commitment Studies*, 68 FED. REG. 27822-23 (May 21, 2003) (indicating that 61% of the required post-marketing commitments have not yet even begun to accrue the required safety data, while over twenty percent of the open post-marketing commitments had reports due which were not yet received).

⁷² *See* 21 C.F.R. § 314.70(c) (2005) (describing the circumstances under which a change to the labeling of an approved drug may be made without prior FDA approval, specifically to strengthen warnings, improve safe use, or to delete false, misleading, or unsupported indications for use or claims for effectiveness). Ordinarily, proposed changes in labeling must be approved by the FDA. *Compare* Feldman v. Lederle Labs., 479 A.2d 374, 390-91 (N.J. 1984) (noting that FDA regulations do not prevent manufacturers from adding warnings to drug labels once aware of their necessity, further indicating such a requirement would run contrary to the agency’s primary purpose of protecting the public), *with* LABELING, *supra* note 49 (suggesting pre-approval changes to prescription drug labels, if ultimately rejected by the FDA, may be subject to FDA enforcement actions for misbranding).

prescribing physicians of new safety concerns.⁷³ This is currently a “passive” reporting requirement; there is no affirmative duty placed on manufacturers to solicit safety data, they must only report within the applicable timeframe any information that they receive.⁷⁴ As a result, medical researchers believe that a mere ten percent of all adverse drug experiences are actually reported, with some studies indicating the actual rate of reporting is far lower.⁷⁵

IV. MICHIGAN SPEAKS: SHOULD WE LISTEN?

Seeking to strike a balance between compensating injury and encouraging innovation in drug development, a handful of states have enacted legislation exchanging FDA approval of a drug for either total or partial immunity in product liability suits.⁷⁶ Perhaps acknowledging the tension between compensating injured consumers and maintaining the benefit provided by innovative new drugs, the Michigan legislature chose to immunize pharmaceutical manufacturers who comply with FDA regulations in receiving approval for and labeling their drugs.⁷⁷ Michigan’s statute confers on drug manufacturers or sellers absolute immunity in product liability actions.⁷⁸ This immunity applies where the drug is FDA approved and the product labeling, when it left the control of the manufacturer, was in compliance with that approval.⁷⁹ This veil of immunity may be pierced by showing either that the manufacturer withheld from or misrepresented to the FDA data that would have resulted in either a refusal to approve or a withdrawal of approval for the product in question, or evidence of bribery in connection with the approval.⁸⁰

⁷³ See 21 C.F.R. § 314.70(c) (2005) (detailing the changes to labeling which require submission to the FDA at least 30 days prior to distribution).

⁷⁴ *Id.*

⁷⁵ Friedman, *supra* note 59, at 570-71.

⁷⁶ For laws indicating that compliance with federal regulations or safety guidelines provides a rebuttable presumption of non-defective nature of prescription drugs, see MICH. COMP. LAWS ANN. § 600.2946(4) (West 2000); COLO. REV. STAT. § 13-21-403(1)(b) (2004); IND. CODE ANN. § 34-20-5-1(2) (West 1999); N.D. CENT. CODE § 28-01.3-09 (Supp. 2005); TENN. CODE ANN. § 29-28-104 (2000); UTAH CODE ANN. § 78-15-6(3) (2002). One state requires that, for products that conform to government standards, an additional showing that a reasonably prudent seller would have provided additional warnings is required to establish a breach of the duty to warn. KAN. STAT. ANN. § 60-3304(a) (Supp. 2005). Other statutes merely restate the common law rule of compliance as a fact to be considered by the jury. ARK. CODE ANN. § 16-116-105(a) (2006); OHIO REV. CODE ANN. § 2307.75(B)(4) (LexisNexis 2005); WASH. REV. CODE ANN. § 7.72.050(1) (West 1992). Others raise a rebuttable presumption that warnings that comply with federal regulations are adequate. N.J. STAT. ANN. § 2A:58C-4 (West 2000). Additional statutes provide protection from punitive damages so long as the manufacturer does not knowingly withhold or misrepresent relevant information. ARIZ. REV. STAT. ANN. § 12-701 (2003); N.J. STAT. ANN. 2A:58C-5(c); OHIO REV. CODE ANN. § 2307.80(C); OR. REV. STAT. § 30.927 (LexisNexis Supp. 1998); UTAH CODE ANN. § 78-18-2.

⁷⁷ MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000). “In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration’s approval at the time the drug left the control of the manufacturer or seller.” *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ MICH. COMP. LAWS ANN. §§ 600.2946(5)(a)-(b).

This statute was challenged as representing an unconstitutional delegation of the state's legislative authority.⁸¹ People injured by prescription drugs argued that by granting the FDA the power to determine whether a drug could form the basis of a liability suit in Michigan, the statute unconstitutionally delegated a portion of legislative authority to a federal agency.⁸² The Michigan Supreme Court, holding that no impermissible delegation of authority occurred, indicated that the fact-finding deference contained in the statute constituted nothing more than a "referral" to the authority of the federal agency.⁸³ Such allegations of improper delegation "to the power of federal regulatory agencies have been uniformly unsuccessful" since the explosion of breadth and depth of regulatory agencies under the "New Deal" of the 1930s.⁸⁴ While withstanding a challenge under state law, the statute had yet to see its day in federal court.

In *Garcia v. Wyeth-Ayerst Labs.*,⁸⁵ that federal challenge came as the Sixth Circuit subjected Michigan's statute to federal constitutional scrutiny.⁸⁶ This challenge focused on whether the Michigan statute was preempted by provisions of the Federal Food, Drug, and Cosmetic Act.⁸⁷ Federal preemption doctrine applies when a federal statute either expressly or implicitly preempts a state law, or when the federal or state laws are in conflict.⁸⁸ Identifying no express preemption or conflict, the court decided that under certain circumstances, the Michigan statute would be held unconstitutional.⁸⁹ Specifically, where a state court must prove fraud it would require that those courts act in an area reserved to the powers and resources of a federal agency, in this case the FDA.⁹⁰ If, however, the FDA itself found instances of fraud during the regulatory approval process, the exception to immunity embodied in the Michigan statute would not run afoul of the preemption doctrine.⁹¹

Those interested in using the Michigan statute as a template for widespread liability change can extract valuable lessons from this litigation. The sixth circuit's holding may indicate the Michigan approach could be held unconstitutional as an

⁸¹ Taylor v. SmithKline Beecham Corp., 658 N.W.2d 127, 129 (Mich. 2003).

⁸² *Id.* at 129-30.

⁸³ *Id.* at 133.

⁸⁴ *Id.* at 132.

⁸⁵ 385 F.3d 961 (6th Cir. 2004).

⁸⁶ *Id.* at 964.

⁸⁷ *Id.* at 965.

⁸⁸ *Id.* Federal preemption doctrine indicates that, among others, state law tort claims specifically based on "fraud on the FDA" inevitably conflict with the FDA's policing responsibilities. *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001). State activities attempting to police federal agencies are therefore preempted by federal law. *Id.* at 347-48. In *Buckman*, a medical device company was accused of making fraudulent representations to the FDA which resulted in the approval of devices which caused injuries. *Id.* at 343. The Court held that state law "fraud on the FDA" claims conflicted with the express powers of the FDA to punish and deter fraud against the administration. *Id.* at 348. Because the state law purported to intrude on an area which Congress had empowered the federal government to regulate, even though the federal law did not expressly preempt state action, state law was impliedly preempted by virtue of the scope of the federal law. *Id.*

⁸⁹ *Garcia*, 385 F.3d at 966.

⁹⁰ *Id.* at 965-66, citing *Buckman*, 531 U.S. at 350 ("[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives").

⁹¹ *Garcia*, 385 F.3d at 966.

infringement on the FDA's ability to police itself. To be sure, a state law that permitted a "fraud on the FDA" claim would necessarily be void,⁹² therefore, any legislation relying on FDA approval should avoid such a provision. However, the Michigan Supreme Court's holding that it was constitutionally permissible to rely on the independent fact-finding role of the FDA could be employed to justify an exception to immunity.⁹³ Legislation which did not create a cause of action based on fraud on the FDA, and which did not place on each state the burden of demonstrating fraud on the agency, would not interfere with the supremacy of the federal government in this area.⁹⁴ Instead, a determination of fraud or misrepresentation *by the FDA itself* could serve to pierce the veil of immunity granted by state law, and permit actions otherwise barred by immunity.⁹⁵ Such legislation is analogous to state law sovereign immunity statutes, with many states requiring a common law cause of action falling within specific enumerated exceptions to immunity as described by the legislation.⁹⁶ Legislation which uses nothing more than the FDA's independent role as a fact-finder could, therefore, justify reliance on FDA actions as the basis of either permitting or denying suit in tort against prescription drug manufacturers.

V. A MODEST PROPOSAL

Under the existing scheme, the FDA analyzes a limited amount of clinical trial data to determine the risks and benefits of a particular new drug, as well as what information will be included in the product's labeling.⁹⁷ Pharmaceutical companies and the FDA will be better positioned to determine risks associated with new drugs by evaluating a larger pool of data created by monitoring new drugs in actual medical practice, rather than relying on the limited opportunity provided by the clinical trial atmosphere. Moreover, manufacturers can analyze and use this additional data, in cooperation with the FDA, to improve both instructions for and risks inherent in the use of those particular drugs. Physicians would receive more robust information on which to base their treatment decisions. It follows that physicians could then more carefully prescribe drugs, reducing incidences of drug-

⁹² *Id.*

⁹³ Both the U.S. and Michigan Supreme Courts "recognize 'that the separation of powers principle, and the nondelegation doctrine in particular, do not prevent Congress [or our Legislature] from obtaining the assistance of the coordinate Branches,'" *Taylor*, 658 N.W.2d at 132, citing *Mistretta v. U.S.*, 488 U.S. 361, 371. "There is no improper delegation where the agency or outside body making the finding . . . is doing it for purposes independent of the particular statute to which it makes reference." *Taylor*, 658 N.W.2d at 133.

⁹⁴ See *Buckman*, 531 U.S. at 354 (Stevens, J., concurring) (indicating a claim proceeding after an agency determination of fraud may not contradict preemption doctrine).

⁹⁵ Concurring in *Buckman*, Justice Stevens anticipates precisely these circumstances: "[i]f, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during [the approval process] . . . a plaintiff would be able to establish causation without second-guessing the FDA's decisionmaking [sic] or overburdening its personnel." *Buckman*, 531 U.S. at 354 (Stevens, J., concurring).

⁹⁶ See *e.g.*, 42 PA. CONS. STAT. ANN. § 8522 (1998) (codifying specific, narrowly construed exceptions to state sovereign immunity which must be coupled with a cause of action ordinarily available at common law).

⁹⁷ AVORN, *supra* note 54, at 109.

related injury, and saving both consumers from harm and pharmaceutical companies from liability.

The pharmaceutical industry responds predictably to certain types of behavior modification. Providing financial incentives as a means of encouraging certain behaviors has met with past success in the FDA, with the so-called “pediatric exclusivity” provisions of the Food and Drug Modernization Act (FDAMA) offering an excellent example.⁹⁸ Prior to the enactment of FDAMA, physicians had available little information concerning the safety and effectiveness of prescription drugs in children.⁹⁹ Strictly voluntary efforts did not result in appreciably greater availability of data for these age groups.¹⁰⁰ The FDA decided that providing economic incentives, specifically a six-month extension of market exclusivity in exchange for clinical trials conducted on pediatric populations, could provide necessary safety and efficacy data.¹⁰¹ In the years immediately following the implementation of this incentive program, the number of pediatric studies of prescription drugs increased dramatically,¹⁰² in sum, incentives work.

Therefore, in exchange for an ongoing and increased investment in safety data monitoring and reporting, pharmaceutical manufacturers should be provided either full immunity, as in Michigan, or at a minimum immunity from punitive damages in product liability suits. This optional protocol would grant companies interested in marketing safe drugs and reducing their liability exposure the ability to monitor safety data constantly and to report to the FDA any changes requiring an alteration of the drug’s label. This increased safety monitoring would provide additional information based on real world use of their drug that would improve the ability of manufacturers to warn consumers of the risks associated with their products. This, in turn, would better enable consumers and physicians to make decisions effecting the health and treatment of disease in their patients, and ideally reduce the number and severity of any resulting injuries. Similar to the pediatric exclusivity incentives, pharmaceutical companies would exchange an initial, predictable capital investment for future financial benefit.¹⁰³ In my safety data monitoring proposal, companies would receive not the additional revenue resulting from an extension of market exclusivity, but either expense avoidance or greater predictability through total or partial immunity from liability.

While complete elimination of risk is not possible, pharmaceutical companies may discharge their legal obligations by completely cooperating with and disclosing

⁹⁸ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355a (b) (2000).

⁹⁹ See 21 C.F.R. §§ 201, 312, 314, 601 (2005) (indicating that safety and effectiveness information for some pediatric age groups is difficult to find, which poses significant risks for children receiving those medicines).

¹⁰⁰ 21 C.F.R. §§ 201.

¹⁰¹ 63 Fed. Reg. 66632, 66633 (Dec. 2, 1998) (codified at 21 C.F.R. §§ 201, 312, 314, 601) (“FDA expects the exclusivity offered by FDAMA to provide a substantial incentive for sponsors to conduct some pediatric studies...increas[ing] the number of drug and biological products that have adequate labeling.”).

¹⁰² Christopher-Paul Milne, *Exploring the Frontiers of Law and Science: FDAMA’s Pediatric Studies Incentive*, 57 FOOD & DRUG L. J. 491, 492 (2002).

¹⁰³ In this case, the additional cost of conducting the required safety monitoring trials would be offset by the protection from liability granted.

to the FDA all relevant information related to the safety of their products. To be sure, manufacturers may be put at a temporary economic disadvantage by disclosing negative aspects of their products.¹⁰⁴ This temporary dip in revenue would be balanced by the decreased probability of being held liable in tort for injuries resulting from the use of their prescription drugs. Complete, accurate disclosure of this ongoing clinical trial safety data, primarily to the prescribing physician but also to the consumer themselves, would discharge the legal obligation to warn imposed on the manufacturer.

In light of recent developments in drug product liability,¹⁰⁵ also considering the prevailing perceptions of the pharmaceutical industry,¹⁰⁶ it may not be practical to advocate an absolute bar to immunity. Granting only partial immunity by eliminating punitive damages would retain the consumer's ability to recover for injuries suffered through the use of pharmaceuticals while also limiting the liability exposure of the drugs' manufacturer. By compensating injury in this limited way, injured consumers are "made whole," and manufacturers can better quantify, assess, and calculate exposure from future injuries. As an added benefit to the public, this immunity may encourage innovation and investment in important therapeutic areas previously abandoned or currently underserved due to liability concerns.

VI. A "SWIFT" REVIEW OF REMAINING ISSUES

As controversial as this "immunity for safety" exchange may be, a number of hurdles must be overcome before this or a substantially similar idea may be practically applied. First, government must take action to legitimize the incentive program: laws must be passed that outline and encode the grant of immunity, in addition to detailing the requirements for sustaining that immunity through a continuing evaluation of compliance. Second, the industry must commit to generating the data needed to engage in the continuing analyses. Third, the FDA must prepare for the additional workload these ongoing analyses would create. Each issue as outlined above walks hand in hand with the others, combining to provide both incentive and immunity only when all are implemented.

Government action may be the most difficult burden to overcome, requiring a coordinated effort among the states as well as acquiescence of the federal government in order to succeed. For example, should this be a single federal law, or an amalgamation of state laws? Either option presents problems: a federal law may impermissibly regulate the ability of states to regulate themselves and their workings, a situation famously cast as an unconstitutional violation of the principles of federalism;¹⁰⁷ a patchwork of state laws may lead to constitutional challenges like

¹⁰⁴ Struve, *supra* note 15, at 598-99.

¹⁰⁵ Recent revelations of corporate misconduct and nondisclosure, such as with Merck and Vioxx, Jeffreys, *supra* note 7, at 1, Wyeth and Fen-Phen, Henderson, Pfeiffer, *supra* note 7, at A1, and the extraordinary side effects or fatalities experienced with drugs such as Rezulin, Harris, *supra* note 4, at A16, make it clear that the current environment would not tolerate a complete bar to recovery when persons are injured by prescription drugs.

¹⁰⁶ Harris, *supra* note 2, at C1.

¹⁰⁷ See *Printz v. U.S.*, 521 U.S. 898, 925 (1997) ("[T]he Federal Government may not compel the States to implement, by legislation or executive action, federal regulatory programs.").

that in *Garcia*,¹⁰⁸ or possibly both inconsistent legislation and inconsistent adoption or application, with a forum shopping nightmare following soon thereafter.¹⁰⁹

Luckily, the second and third issues are considerably less problematic: the infrastructure for meeting those challenges already exists,¹¹⁰ and would simply need a fine-tuning to address the increased collection, reporting, and evaluation requirements. To provide the raw data for analysis, the pharmaceutical industry need only expand the scope of its existing Phase IV trial infrastructure and apply it to all currently marketed products. Knowledge and the network of investigators developed during the NDA approval process could be “rolled over” into further safety evaluation of the drug. Physicians reluctant to devote time to safety reporting, time which could be spent seeing patients and billing their insurance companies, would be financially compensated by the pharmaceutical companies themselves in the context of a clinical trial. To be sure, pharmaceutical companies face potential downsides in disclosing adverse event data. Negative public perception of their product could drive down sales, or a sufficient accumulation of adverse event data could force the FDA to withdraw approval for their product. These potential downsides are ameliorated by the immunity from suit such disclosure would provide.¹¹¹

To handle the increased influx of data would require only a slight expansion of FDA staff, because the agency already mandates similar ongoing studies for drugs approved on the so-called “fast-track” designation.¹¹² By simply expanding the resources available for the evaluation of the ongoing safety studies, the FDA would help fulfill their agency mandate of ensuring approved drugs are safe and effective. This may represent a significant hurdle unless approached properly, because for all their responsibility,¹¹³ the FDA is woefully understaffed and under-funded. While

¹⁰⁸ 385 F.3d at 964.

¹⁰⁹ See Scott Rosenberg, Jeffrey Lipman, *Developing a Consistent Standard For Evaluating a Retaliation Case Under Federal and State Civil Rights Statutes and State Common Law Claims: An Iowa Model for the Nation*, 53 *DRAKE L. REV.* 359, 418 (2005) (explaining how “contrast[ing] approaches among the states and various circuits to a single fact pattern can be played out in endless scenarios. Such inconsistency has and will continue to encourage forum shopping”). While completely unrelated to tort claims, the principle holds true when applied to all manner of jurisdictional variations of law.

¹¹⁰ The pharmaceutical industry already has in place the means of collecting and analyzing additional safety information. This proposal amounts to requiring little more than extending to all approved drugs the Phase IV safety evaluation trials currently required of only those new drugs approved under the so-called “fast-track.” 21 C.F.R. § 314.500 (2005). Similarly, the FDA need only provide additional staff wholly dedicated to the review and evaluation of ongoing safety studies. This amounts to a mere augmentation and expansion of the services they currently provide.

¹¹¹ Given what we know now, considered in the context of this proposal, does anyone believe that if Merck had a “do over,” they would have hidden their Vioxx data? Certainly revenue would have been lost because of decreased sales, but the \$253 million in punitive damages, with over a thousand other cases pending, may have been avoided. See generally *supra* note 7.

¹¹² See 21 C.F.R. § 314.510 (2005) (“Approval under this section [accelerated approval of New Drugs] will be subject to the requirement that the applicant study the drug further, to verify and describe its clinical benefit”).

¹¹³ In addition to the review, approval, and ongoing monitoring of pharmaceuticals, the FDA is also responsible for monitoring and inspecting the food, dietary supplement, cosmetic, and medical device industries. See 21 U.S.C. § 331 (2000) (outlining the scope of acts prohibited by the Food, Drug, and Cosmetic Act falling within the FDA’s authority to regulate); see also U.S. Food & Drug Admin. Homepage, <http://www.fda.gov/default.htm> (last visited Nov. 22, 2005) (providing links to explanations of the areas of FDA regulation).

bearing responsibility for the regulation of a staggering 25% of the US economy,¹¹⁴ the agency employs fewer than 10,000 employees and receives a relative dearth of funding, given their role in the US economy.¹¹⁵ The additional cost required for such an expansion could be borne by the pharmaceutical companies, rather than shouldered by the taxpayers, under a system of “user fees” similar to those charged by the FDA currently.¹¹⁶ This would provide the third leg of incentive to pharmaceutical companies: ongoing assurance that their marketed drugs are “safe,” and insulating them from liability for their ongoing investigation.

VII. CONCLUSION

The pharmaceutical industry operates in a high-risk, high-reward environment that provides to society tools necessary to prolong and improve our quality of life. The status quo of industry, regulatory, and legal interaction leaves an information gulf which can be exploited to improve both the quality of medical care provided to society, as well as the financial circumstances facing pharmaceutical manufacturers. By providing incentives to further develop, discover, disclose, and disseminate the risks associated with prescription drug use in the form of protection from legal liability, we can reduce the frequency with which patients are avoidably injured by unavoidably unsafe products. While an ambitious goal, requiring a coordinated effort of industry, legislators, and regulators, in addition to the widespread support of the public at large, the hurdles to overcome are not insurmountable. The infrastructure and administration required currently exist on all levels, industry as well as agency, to handle the work the additional influx of information will create. This requires merely the will to provide additional staffing and funding to become reality. Fulfilling an objective as noble and as basic as protecting the American people surely justifies an increase in the operating budget of the FDA, which the pharmaceutical companies themselves may supply in the form of fees, similar to those already collected to expedite drug approval.

¹¹⁴ FDA Overview, <http://www.fda.gov/oc/opacom/fda101/sld002.html>. (last visited Mar. 13, 2006) (Noting FDA regulated products account for 25% of every consumer dollar spent. The agency employs approximately 9000 people in the conduct its business of inspection and regulation, as well as administrative staff. F.D.A., *FDA: The Nation's Premier Consumer Protection And Health Agency*, <http://www.fda.gov/oc/opacom/brochure/fdahealthbro.html> (last visited Mar. 25, 2006).

¹¹⁵ See FDA Talk Paper, <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01135.html> (Feb 4, 2002) (indicating the FDA proposed budget for FY 2003 consisted of \$1.727 billion). For comparison, the proposed operating budget for NASA in the same year was approximately \$15 billion. NASA, Fiscal Year 2004 Budget Estimates, available at http://www.nasa.gov/pdf/1967main_2004_full_budget.pdf.

¹¹⁶ These fees are paid by companies along with their drug applications or supplements thereto, in addition to annually during the review of their applications. Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (codified as amended in scattered sections of 21 U.S.C.). This money is used in part to fund the drug review process. TUFTS CTR. FOR THE STUDY OF DRUG DEV., *Recent News 11/1/2005: New Drugs are Taking Longer to Bring to Market in the U.S.*, <http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=58> (last visited Nov. 19, 2005).